Abstracts*

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Blood sampling

ID: 12321

BD BARRICOR® LH PLASMA TUBES FOR COPPER (CU) AND ZINC (ZN) DETERMINATION

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BACKGROUND-AIM: In 2016 Becton Dickinson launched BarricorTM Lithium Heparin plasma blood collection tubes with mechanical separator. Especially for trace analyses the following BD tubes are in use: K2 EDTA Trace Element and Serum Trace Element (TE). Contamination is a major problem in trace analyses. So, standardization of preanalytical phase requires testing of each kind of tubes in the labs, even for particular LOT. The main goal of the study is comparison between BD BarricorTM LH tubes and the other specialized TE BD tubes for Cu and Zn. METHODS: Blood was drawn simultaneously from 32 patients into 3 types BD tubes: BarricorTM LH Plasma (REF 365032), K2EDTA 10.8 mg TE (REF 368381) and Serum TE (REF 368380). All vacutainers were further processed in similar manner. Standards, controls and patient samples were measured for Cu and Zn by flame atomic absorption (FAAS) - AAnalyst 400, Perkin Elmer, USA.

RESULTS: Results (mean ± SD in µmol/L) for Cu: BarricorTM LH Plasma - 20.1 ± 4.0; K2EDTA 10.8 mg TE - 19.8 ± 3.9 and Serum TE - 20.5 ± 4.4, and for Zn: BarricorTM LH Plasma – 10.4 ± 2.2; K2EDTA 10.8 mg TE – 10.5 ± 2.1 and Serum TE – 10.6 ± 2.3. Zn concentration in heparin plasma tubes did not differ significantly from that in the other two TE types: p>0.05. Also no statistical difference was observed between serum (TE) and plasma (LH, K2EDTA) zinc. Significant statistical difference between copper in 3 tested tube types were established with the highest levels measured in BD Serum TE Tubes. Significant difference between plasma Cu in LH and K2EDTA tubes was found (p < 0.001) and also between Cu in LH plasma and TE serum (p = 0.006). The difference between Cu in all 3 tested tube types as absolute concentration was less

CONCLUSION: It could be recommended for each laboratory to test the preferred vacutainers for determination of Cu and Zn especially when low concentrations in plasma or serum have been suspected.

ID: 12324

IS PLASMA THE ANSWER? AN EVALUATION OF BD BARRICOR TO MEET ED TURNAROUND TIME REQUIREMENTS

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BACKGROUND-AIM: Providing rapid turnaround times for Clinical Biochemistry tests for the ED has been a key target for labs in the UK following the RCPath guide in 2013. The initial aim was to provide 90% of results within 1 hour of receipt with a further target of 1 hour from needle to authorisation. In Derby we get 95% within an hour but even that is not adequate for patients. Most UK Labs use serum but this requires 30 mins clotting before a 10 minute centrifugation. We evaluated a new Lithium Heparin blood tube from BD, with an innovative separation device, which requires no clotting time and only a 3 minute spin time.

METHODS: 497 BD Barricor tubes were collected in the same draw as BD SST II tubes were analysed on Roche cobas 8000s for the tests requested by ED only. Samples were processed in tandem with ED samples but did not get authorised with the same priority, with results

RESULTS: Plasma results were comparable across the range of tests measured. Sample quality was very good with only one sample reported as clotted and, unexpectedly, the rate of haemolysis was half of that of the SST II tubes taken in the same draw. The average improvement in turnaround time of Barricor over SST II for 125 requests was 23 minutes, ranging from 0 minutes to 76 minutes.

CONCLUSION: Barricor, has a smaller blood draw than SST II (4.5 mL vs 6 mL), which is a significant improvement for patients, without compromising the ability of labs to assay samples. The innovative barrier removes the potential problems of sample probe blockages with gel. Barricor provides a faster time from receipt to analysis as it removes to clotting time and spin times are 7 minutes faster. Barricor reduces the problems of microfibrils and samples clotting on the analysers with serum samples, reduces the incidence of pseudohyperkalaemia and potentially provides a reduced rate of sample haemolysis.

THE EFFECT OF USING BD PUSH BUTTON ULTRATOUCH™ WING SETS ON POTASSIUM VALUES

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BACKGROUND-AIM: In the past decade there has been an increase in our laboratory of the use of push button wing set collection devices from 11% to 33% of all collections. An increase in the number of potassium results greater than 5.0 mmol/L was noted in the same time period and an investigation to determine if using a new push button wing set could decrease the number of potassium values greater than 5.0 mmol/l was performed.

METHODS: For 4 consecutive weeks the BD UltraTouch™ push button wing set collection devices were used on Sunday at all collection sites but on other days regular BD push button wing sets were used. Phlebotomists were asked to follow their normal collection practice regarding the method of blood collection (wing set or regular). The percentage of potassium results greater than 5.0 mmol/l was calculated for each day of the 4 weeks and for 2 weeks prior to the study.

RESULTS: On the Sundays of the 4 weeks of the study the percentage of potassium results greater than 5 mmol/L averaged 5.4% (range 4.3 to 6.2%) and the average for Monday through Friday was 7.2% (range 6.1 to 9.9%). The 2 tailed P value for the percentage of potassium values greater than 5.0 mmol/L on Sunday versus the mean for Monday through Friday was 0.0162 and was considered statistically significant. The difference in means between Sunday and Monday through Friday means was -1.775 (95% confidence interval from -3.087 to -0.463).

CONCLUSION: There was a significant reduction in the number of potassium results greater than 5.0 mmol/L when BD UltraTouch™ push button wing set devices were used.

ID: 12386

IMPACT OF AN ORGANIZATIONAL CHANGE ON PRE-ANALYTICAL QUALITY INDICATORS

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BACKGROUND-AIM: In 2015 our laboratory experienced a generational shift in the nursing staff in charge of blood collection. Such members of the staff were replaced by technical staff, but a blood collection team was organized and managed by the laboratory.

METHODS: The impact on the pre-analytical quality indicators and the possible relationship between the composition of the blood collection team and the pre-analytical errors were studied. The perception of users regarding these changes was assessed. The statistics results of the preanalytical errors quality indicators were taken from the laboratory system. The user's perception was assessed based on satisfaction surveys. RESULTS: The placement of the staff was carried out in stages, preceded by a two-weeks training program. The main percentage of eventuality (38.9%) took place in Oct and Nov 2015 and in Jan 2016. The peak periods were in Mar 2015 and Feb 2016. The maximum percentage of hemolysis samples rejection (0.35%) was registered in Mar 2015, coinciding with the second peak period and the placement of eventual staff, and in Nov 2015, coinciding with the highest eventuality peak. 36.4% of hemolyzed samples corresponded to the polyclinic module and 63.6% to the hospitalization module. The highest percentage of not received samples was 0.35% in Oct 2015. The highest hemolytic rates were observed in Nov 2015, decreased until Feb 2016 and increased again due to the placement of trainees. The lowest rate took place in Aug 2015. The overall level of user satisfaction was of 8.5 and 7.9 out of 10 in 2015 and 2014 respectively.

CONCLUSION: The highest number of errors coincided with the eventuality and the activity peaks, and with the complexity of patients. Once the process of staff placement ended, the errors were similar to the period before the change. The renewal of the team had a positive impact on the user's satisfaction.

ID: 12391

USE OF PLASMA FOR THE EMERGENCY TESTS IN CLINICAL CHEMISTRY LABORATORY

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BACKGROUND-AIM: Medical laboratories need fast and accurate test results for emergency testing and for this reason plasma samples can be used rather than serum samples. The aim of this study is to compare the emergency test results of serum and plasma samples.

METHODS: Venous blood samples of 78 patients from the emergency service and intensive care units of Bakirkoy Dr. Sadi Konuk Training and Research Hospital were collected into BD Vacutainer® SST™ II Advance serum gel tubes and BD Vacutainer® Barricor™ (Becton Dickinson-USA) plasma tubes. Blood samples were analyzed for albumin, ALT, amylase, AST, direct bilirubin, total bilirubin, BUN, calcium, chloride, creatinine, glucose, potassium, magnesium, sodium, phosphorus, total protein, CK, CRP, BNP, troponin T, D-Dimer and β -hCG. Hemolyzed samples were not included in the study. The Number Cruncher Statistical System 2007 (Utah, USA) software was used for the statistical analysis. ICC test was performed in the evaluation of concordance between the plasma and serum tubes, whereas Cohen Kappa concordance levels were used in the evaluation of concordance between the decisions. (< 0.40: Weak; 0.40 - 0.59: Medium; 0.60 - 0.74: Good; 0.75 - 1.00: Strong). Wilcoxon Signed Rank test was used for evaluating the biases between variants from two separate tubes. The results were within 95% of confidence interval and the statistical significance was p < 0.05.

RESULTS: When the results of plasma and serum were compared, it was determined that chloride and sodium tests had a good concordance and the remaining tests had a strong level of concordance.

CONCLUSION: Clotting occur in 15 to 30 minutes, and serum obtaining is time consuming in comparison to plasma. Also fibrin formation is not a problem for plasma samples. Our results are promising that plasma samples can be used routinely instead of serum for emergency testing.

ID: 12394

QUANTIFICATION OF PLASMA OR SERUM SHORT-CHAIN FATTY ACIDS: CHOOSING THE CORRECT BLOOD TUBE

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BACKGROUND-AIM: Short-chain fatty acids (SCFA; acetate, propionate and butyrate) are more and more recognised as mediators of local gut and systemic health. Quantification of SCFA in plasma and serum is challenging due to their low concentrations in human blood and the ubiquitous nature of acetate, requiring careful standardisation of the sample preparation procedure. Also the choice of the blood tube might affect the resulting concentrations. We investigated the influence of different blood collection tubes on plasma and serum SCFA concentrations. METHODS: SCFA concentrations were measured in blood samples, collected from 10 healthy subjects in 6 different blood tubes i.e. an ethylenediaminetetraacetic acid (EDTA) K2 tube, a lithium-heparin tube, a plasma separator tube (PST), a red top glass serum tube, a red top glass serum tube to which 100 µL of heparin was added and a serum separator tube (SST). Control samples included milliQ (MQ) water and standard SCFA solutions. After preconcentration and clean-up of the samples using a hollow fibre liquid membrane extraction, SCFA concentrations were measured using gas chromatography coupled to flame ionisation detection.

RESULTS: The analytical procedure did not induce contamination as evidenced from the analysis of control MQ water. Acetate concentrations were significantly higher (ANOVA, p < 0.01) when blood was collected in an EDTA K2 tube, whereas propionate and butyrate levels were significantly higher in plasma and serum prepared in a PST tube and SST tube, respectively, both containing a polyacrylamide gel (ANOVA, p < 0.01 for both). Similar profiles of contamination were observed when analysing standard SCFA solutions that had been centrifuged in the different blood tubes. Lowest levels of contamination were observed when using red top glass serum tubes.

CONCLUSION: Red top glass serum tubes induce no contamination and are the preferred tubes for the quantification of SCFA. When plasma is preferred over serum, a lithium-heparin tube is the most appropriate test tube.

ID: 12396

TRANSITIONING FROM SERUM TO LITHIUM-HEPARIN PLASMA: EVALUATION OF BD BARRICORTM, A NEW BLOOD **COLLECTION TUBE WITH A "MECHANICAL" SEPARATOR**

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BACKGROUND-AIM: There are several blood collection tubes available with and without separator gels. Recently, BD launched a new lithium heparin tube: the BD Barricor plasma blood collection tube, containing a mechanical separator rather than the conventional gel separator. The aim of this study was to evaluate the transition from a predominant serum workflow to a lithium-heparin plasma workflow using the new BD Barricor tube for our routine 24/7 chemistry and immunochemistry tests.

METHODS: After informed consent, two additional blood specimens were collected from 40 patients visiting the outpatient clinic of our internal medicine department. Tubes were processed according to the manufacturers specifications. The lithium-heparinized plasma (BD Barricor) and serum (BD SSTII) samples were assayed simultaneously for 66 clinical chemistry and immunochemistry tests using Roche Cobas analyzers, and results were statistically analyzed using Passing-Bablok (PB) regression analysis.

RESULTS: Overall, the serum vs. plasma comparison was good. The minimum and maximum relative bias observed was 0,94 (myoglobin) and 1,05 (estradiol) respectively. Of the 66 analytes, 54 were within the relative bias of the PB 95% confidence interval (95% CI). The remaining 12 analytes fell outside the 95% CI range. However, the observed relative bias was well within the total allowable error margin of those analytes. For all 66 analytes, no significant differences were found for the absolute bias.

CONCLUSION: The results of the new BD Barricor tube showed good comparison with serum from the BD SSTII. Importantly, when compared to the BD SSTII, the reference range remained the same for all the analytes in the BD Barricor tube. We conclude that when transitioning from a predominantly serum to a lithium-heparin plasma workflow for routine 24/7 chemistry and immunochemistry tests, the Barricor tubes can be used.

ID: 12402

EVALUATION OF BD BARRICOR™ TEST TUBES FOR SELECTED ANALYTES IN ROUTINE BIOCHEMISTRY

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BACKGROUND-AIM: Obtaining quality specimen (serum or plasma) and reducing the delays in turn-around time (TAT) are major demands in clinical laboratory practice. In an effort to avoid latent clotting, no clotting, fibrin threads formation and to shorten TAT the use of heparin plasma tubes is encouraged. We evaluated novel BD BarricorTM lithium heparin plasma tubes for testing selected analytes in comparison to BD Clot Activator Tubes (CAT) and BD Rapid Serum Tubes (RST).

METHODS: Blood samples were drawn by routine venipuncture from 60 participants (40 outpatients, 10 ER patients and 10 hemodialyzed patients). Routine clinical chemistry testing for glucose, AST, electrolytes and serum indices were performed on Roche Cobas C501 analyzer. Colected data were analyzed by ANOVA with MedCalc 10.4.0. statistical software.

RESULTS: Most results from the BD Barricor™ tubes were comparable with those from BD CAT and BD RST tubes. Significant difference was observed in potassium measurements (P = 0.029) and in determination of Lipemic index (P < 0.001).

CONCLUSION: BD Barricor™ test tube is plastic evacuated tube with a mechanical separator that ensure fast specimen collection and equivalent results for the vaste majority of routine clinical chemistry tests. Measurement of the potassium encounters established difference between serum and plasma concentration. Turbidity of specimen is different between serum and plasma probably because of the content of various protein species.

ID: 12405

COMPARISON OF BD VACUTAINER® BARRICOR™ PLASMA BLOOD COLLECTION TUBE AND BD VACUTAINER® SST™ TUBE IN BECKMAN COULTER POWER PROCESSOR CENTRIFUGATION CONDITIONS

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BACKGROUND-AIM: Comparison and validation of the blood collection tubes is an important topic of clinical laboratories for preanalytical improvements. In this study, we aimed to compare the performance of two different tube brands: namely, BD Vacutainer® Barricor™ Plasma Blood Collection Tube (BD Barricor™) as evaluation and BD Vacutainer® SST™ Tube (BD SST™) as control tubes for some routine biochemistry analytes and some immunoassays.

METHODS: Samples were collected from adult patients admitted to hospital or being treated in hospital clinics. Sixty-four biochemistry analytes were measured in Beckman Coulter AU 5800, and 56 immunoassays in Beckman Coulter DXI 800. All tubes were centrifuged at 19C in Beckman Coulter Power Processor (PP) for 5 minutes at 1,800xg (3,000 RPM). Testing was performed in both tubes at the same time. Descriptive statistics was determined by SPSS 20.0 statistics software. The bias % was determined on the basis of the average of the control tube with the formula of [(Evaluation - Control) / Control] x 100.

RESULTS: When we consider the CAL criteria such as Westgard and CLIA, results of both clinical chemistry analytes ant immunoassays were comparable and showed clinically similar performances between BD Barricor™ and BD SST™ tubes. An exception was potassium in considering BD CAL criteria. Since the literature information points that potassium results may differ in plasma and serum samples, the unacceptable bias % in potassium is not attributed to the BD BarricorTM tube. On the other side; bias % of potassium results are acceptable according to Westgard TE, CLIA TAE and CAP TAE.

CONCLUSION: Comparison of BD BarricorTM and BD SSTTM tubes showed that the former can be interchangeable with BD SSTTM tubes with acceptable bias, which is not clinically significant. This study is of importance with respect to acceptable results even in PP centrifugation conditions (low RPM and xg values).

DEVELOPMENT OF SIX SIGMA METRICS FOR PRE-ANALYTICAL SAMPLE LABELLING ISSUES IN A BUSY PATHOLOGY **DEPARTMENT**

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BACKGROUND-AIM: There is substantial evidence to support the view that the pre-analytical phase although not under the direct control of laboratory maybe the most error prone of all the phases. The aim of this project, was to implement and monitor a six-sigma metric score to assess the quality of specimen and request-form labeling and ultimately patient identification.

METHODS: A working group was established to develop a process which supported the documented identified sample labelling quality issues and develop/assign an appropriate coding structure. All patient samples in the study were registered on the Laboratory Information System (LIS ClinisysTM Ver.5.32). Central to the process was the implementation of a barcode system to facilitate data code capture and QM codes being recorded against individual patient requests. Six sigma scores were calculated from total number of errors recorded versus the total number of requests. This was supported through data extraction linked to MicrosoftTM Excel 2010.

RESULTS: A total of approximately 979,664 samples were received in the Laboratory Department between January and October 2016. Over 56,000 sample labelling issues were identified through the use of QM codes. The highest number of labelling errors identified were QM16 no location specified (35050) and QM15 no clinician specified (18362) followed by QM2 Order communication label misaligned (575). This resulted in an overall sigma score for the quality of sample labelling on samples received in the department as 3.08.

CONCLUSION: The unequivocal identification of the patient is a crucial step in delivery of timely and accurate laboratory results. The sigma score for sample labelling quality performs poorly compared to other industries i.e. airline safety 6.0, baggage handlers 4.0, restaurant billing 4.0. The final clinical impact of sample labelling issues is difficult to determine as the laboratory detection and management of such issues may mitigate the impact.

ID: 12429

COMPARISON OF THE EFFECT OF GEL USED IN TWO DIFFERENT SERUM SEPARATOR TUBES FOR SOME CLINICAL **CHEMISTRY ANALYTES**

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BACKGROUND-AIM: Selection and verification of blood collection tubes is an important preanalytical issue in clinical laboratories. Plastic serum separator tubes are most commonly used in clinical laboratories. Despite their similarity, different branded serum separator tubes may vary in the materials and additives used, which may probably influence test results. In this study, comparison of separator gel containing plastic tubes belong to two different manufacturers with the reference glass tube and assessment for the analytes, glucose (Glu), total protein (TP), albumin (Alb), calcium (Ca), phosphorus (P), sodium (Na), potassium (K) and chloride (Cl) were aimed.

METHODS: Thirtyfive volunteers were included in the study. Samples were taken into three different tubes by a single experienced technologists according to the CLSI protocol. Tube1: Z tube (Becton Dickinson and Company, Franklin Lakes, NJ, USA); Tube2: Ayset Clot Activator&Gel tube (Ayset Medical Devices, Adana, Turkey), Tube 3: BD SST II Advance tube (Becton Dickinson and Company, Franklin Lakes, NJ, USA). Glucose, TP, Alb, Ca, P, Na, K, Cl were analyzed on AU2700 analyser (Olympus, PA, USA). A paired t-test and Wilcoxon signed rank sum test were used to test the significance of differences between the reference tube and test tubes.

RESULTS: The difference between the results of Tube 1 and 2 for Glu, Alb, P, Na, Cl were not statistically significant (p > 0.05) expect for TP, Ca and K (p=0.004, p=0.009, p=0.003, respectively). There was no difference between the results of Tube 1 and Tube 3 for Glu, TP, Alb, Ca, P, Na, K and Cl (p > 0.05).

CONCLUSION: Our study demonstrates that some test results may be affected by the materials and additives used for serum seperator gel tubes. Laboratory specialists should verify the tubes used in their laboratories.

MONITORING PRE-ANALYTICAL ERRORS IN PRIMARY HEALTH CARE

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BACKGROUND-AIM: Errors in pre-analytical phase leads to doubtful and inaccurate results of laboratory testing. Inadequate preparation of the patients and skills of medical phlebotomists are sources of errors in pre-analytics. The aim of this retrospective study is monitoring, documenting and preventing errors in pre-analytical phase for better health care of patients.

METHODS: The study has been done from 2011 to 2016 yrs and involves monitoring, documenting and preventing errors with aspect to phlebotomy in four biomedical laboratories of primary health care. Errors are classified according to IFCC reccomendation as quality indicators: insufficient sample volume, inappropriately labeled sample and sample damage.

RESULTS: The study has shown that the most common errors are insufficient sample volume and sample damage (1.2%). Inappropriately labeled samples were significantly lower and completely eliminated during period of study (2011 was 0.34%, 2016 was 0%; p < 0,01).

Nonsignificantly decrease in number of sample damaged (2011- 0.60 % - 2016- 0.40 %) was shown and insufficient sample volume (2011-0.63% - 2016 -0.52%) were constantly persisting during the period of study.

CONCLUSION: Through permanently improvement of work quality, implementation of certification and accreditation of laboratories according to ISO15189,2014 (QM/QA), education of employees, clear, transparent and available procedures, errors from pre-analytical phase can be minimized. Special attention should be paid on errors that continue to existing in the study. A smaller number of errors in pre-analytical phase means more accurate and more precise results, correct and fast diagnosis, satisfied patients and cost benefit in health care system. Motto should be: no blood sample is better than a bad blood sample.

ID: 12445

EVALUATION OF THE BD VACUTAINER RST BLOOD COLLECTION TUBE FOR IMMUNOASSAY ANALYTES

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BACKGROUND-AIM: Most laboratory errors originate in preanalytical variables. Most important components for accurate laboratory test results are specimen quality and the time required to obtain a suitable specimen. Turnaround time becomes an significant indicator for clinical decision about some critical conditions of patients. The aim of our study was to evaluate the comparability of Vitamin D, parathormone (PTH), cortisol, beta human chorionic gonadotropin (β -hCG) in BD Rapid Serum Tube (RST), BD Serum Seperator Tube (SST II) and BD glass tubes (Z tubes). METHODS: Blood samples were collected from 88 healthy volunteers for immunoassay tests. Samples were taken into 3 different tubes: Tube 1-BD vacutainer Z tube, Becton, Dickinson and Company Franklin Lakes, NJ, USA, Tube 2-BD vacutainer serum seperator tube (SST), Tube 3-BD vacutainer Rapid Serum Tube (RST). Vitamin D, PTH, cortisol, β-hCG were measured with chemiluminescent immunoassay technique on DXI800 autoanalyzer (Beckman Coulter, CA, USA). The significance of the differences between samples were assessed by Paired t-test and Wilcoxon Matched-Pairs Rank test after checking for normality.

RESULTS: There was no difference between the results of Tube 1-Tube 2, Tube 1-Tube 3 and Tube 2-Tube 3 for Vitamin D, PTH, cortisol (p > 0,05). The difference between β -hCG levels of Tube 1-Tube 3 and Tube 2-Tube 3 were statistically significant (p = 0.002, p < 0.001 respectively).

CONCLUSION: In our study, Vitamin D, PTH and cortisol results were comparable with tubes but β -hCG results were different between tubes. It is indicated that immunoassay test results may be affected by the additives used in tubes or clotting time.

BLOOD TESTS DETERMINATION: SERUM OR PLASMA?

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BACKGROUND-AIM: Traditionally, serum is used to determine of blood biochemistry in clinical laboratories. Hemolysis and clotting are the most prevalent preanalytical errors and they are the most frequent reasons for sample rejections. The aim of this study is to compare the hormones and biomarkers results of serum and plasma samples.

METHODS: One hundred venous blood samples were taken from the outpatient clinics of Bakirkoy Dr. Sadi Konuk Training and Research Hospital were collected into BD Vacutainer® SST™ II Advance serum gel tubes and BD Vacutainer® Barricor™ (Becton Dickinson-USA) plasma tubes. AFP, ASO, Vitamin B12, β-hCG, C3, C4, CA125, CA15-5, CA19-9, CEA, Cortisol, CRP, Estradiol, Folic Acid, Free PSA, FSH, FreeT3, IgA, IgE, IgG, IgM, Insulin, LH, Prolactin, Progesterone, Parathyroid Hormon, PSA, TSH, Anti TPO, Anti Tg, DHEAS, Rh were investigated and hemolyzed samples were not included in the study. The Number Cruncher Statistical System 2007 (Utah-USA) software was used for the statistical analysis. Intraclass correlation coefficient (ICC) test was performed in the evaluation of concordance between the plasma and serum tubes, whereas Cohen Kappa concordance levels were used in the evaluation of concordance between the decisions (<0.40: Weak; 0.40-0.59: Medium; 0.60-0.74: Good; 0.75-1.00: Strong). The results were within 95% of confidence interval and the statistical significance was p < 0.05. RESULTS: The results of plasma and serum samples were compared and the levels of corcondance in all tests were determined very strong. ICC levels were found significantly reliable (p < 0.001).

CONCLUSION: Clotting time requirement is not necessary in plasma samples so it helps to improve turnaround time. Using of plasma also expose quality and accuracy of test results owing to the lack of fibrin formation in plasma which is possible in serum samples. Finally, it can be used instead of serum because of the hemolysis possibility due to the sample transportation.

ID: 12462

VENUS BLOOD SAMPLING IN A TERTIARY HEALTH LEVEL HOSPITAL: A NEED FOR IMPROVEMENT?

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BACKGROUND-AIM: Fasting, preferably morning venous blood testing of non-urgent biochemical tests is a widely known recommendation in laboratory medicine. This require is included also in the Slovenian national recommendations on venous blood sampling from 1999. In recent time we noticed an increasing ratio of non-fasting, but non-urgent referred patients, especially on the primary care level. The new EFLM/EAS recommendations also give preference to postprandial blood draw for lipid determinations. Due to this changes we were interested in blood sampling management for non-urgent biochemical tests in our (tertiary health level) hospital.

METHODS: We prepared a cross-section questionnaire about venous blood sampling for non-urgent biochemical tests in our hospital departments. The questionnaire was sent to all (35) hospital sections.

RESULTS: We received 35/35 responses to the questionnaire. 25/35 sections stated to have a ready profile of laboratory investigations on the admission of the patient and 4/35 a partial profile. 18/28 sections indicated that the set of investigations in the profiles is in accordance with clinical pathways. 25/28 sections do the blood sampling before a meal or even in the morning next day, another 1/28 section only in the case of glucose order. For other non-urgent biochemical tests, 16/35 departments perform blood collection at any time during the day or when ordered by a physician. 13/35 sections perform blood collection also in the case with lipids rich or parenteral diet, further 4/34 only sometimes or in emergency case.

CONCLUSION: Due to emergency situations and the admission of patients at any time during the day the work on hospital departments is very differently organised. Our departments are partly trying to consider fasting blood sampling or sampling before a meal. Nevertheless, for nonurgent biochemical tests we notice a too high sampling ratio at any time of the day, as well as for patients on parenteral diet.

NEW CAPILLARY BIOCHEMICAL SAMPLE TESTING IN MINICOLLECT® BLOOD COLLECTION TUBES

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BACKGROUND-AIM: Where small sample volumes are critical, especially for infants, elderly or obese patients, the newly designed Mini-Collect tubes allow highest flexibility and accuracy of capillary blood sampling. The MiniCollect Serum and Lithium Heparin Separator tube is intended to collect, transport, separate and process capillary blood for testing serum and plasma, respectively in the clinical laboratory.

METHODS: A study was done at Laboratory Rainbach (Austria) using MiniCollect tubes with old vs. new design. Altogether, 40 presumably healthy subjects were recruited. Informed consent was given by all donors and the study was approved by EC Upper Austria. Directly after capillary sampling, the tubes were inverted 8 times and processed according to the IFU. After centrifugation for 10 min at 3000g, 28 common biochemical analytes were tested using an AU680 and DxI800 (Beckman). Analysis was done with the instrument's accompanying reagents.

RESULTS: Evaluation of all clinical data and deviations was done on the basis of maximal allowed deviation for a single value according to the guidelines of the German Association of Quality Assurance of Laboratory Testing (Rilibäk). The utilization of tubes with old and new designs did not reveal any clinically nor statistically significant deviations (p < 0.05). The values in both serum tubes resulted in a highest deviation for LDH of 6.9%, and in plasma tubes of 8.7%.

CONCLUSION: From clinical perspective, the MiniCollect Serum and Plasma Separator tubes with new design are substantially equivalent to the tubes with old design. The newly designed tubes provide an essentially enhanced blood collection device for skin-puncture testing. As the fundamental advantage is the integrated scoop for transferring capillary blood into the tube, the supporting information and data obtained from adult populations are more than adequate to establish safety and effectiveness for the pediatric indication.

ID: 12476

NEW MINICOLLECT® 9NC COAGULATION BLOOD COLLECTION TUBES FOR PEDIATRIC SAMPLE TESTING

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BACKGROUND-AIM: Drawing blood from infants or children is mostly critical, particularly when the amount needed to fill a standard coagulation tube by ensuring the correct ratio of blood to additive can't be guaranteed. The MiniCollect Coagulation Tube is intended for collection of citrate anticoagulated whole blood samples for coagulation assays and allows the highest flexibility and accuracy by collecting blood in unprecedented simplicity.

METHODS: Two clinical studies were carried out to compare the performance of the new pediatric tube to a standard VACUETTE Coagulation tube by taking venous blood. Altogether, 20 healthy and 75 hospitalized subjects (Laboratory Rainbach and Hospital Steyr, Upper Austria) were recruited. Informed consent was given by all donors and the study was approved by EC Upper Austria. Directly after blood collection, the tubes were inverted 8 times and processed according to the IFU for MiniCollect tubes. After centrifugation for 10 min at 3000g, common coagulation parameters were tested using an ACL Top 500 (Laboratory Instruments). Analysis was done with the instrument's accompanying reagents.

RESULTS: Evaluation of all clinical data and deviations was done on the basis of the maximum allowed deviation for a single value according to the guidelines of the German Association of Quality Assurance of Laboratory Testing (Rilibäk). The utilization of pediatric tubes with the new design did not reveal any clinically nor statistically significant deviations (p < 0.05). The values in both tubes resulted in maximum deviations of 7.1% for aPTT.

CONCLUSION: From a clinical perspective, the MiniCollect Coagulation tube with the new design is substantially equivalent to a VACUETTE Coagulation tube. The newly designed tube provides an essentially enhanced blood collection device for pediatric sample testing.

NEW MINICOLLECT® GLUCOSE BLOOD COLLECTION FOR CAPILLARY SAMPLE TESTING

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BACKGROUND-AIM: Where small sample volumes are critical, especially for infants, elderly or obese patients, the new MiniCollect tube allows the highest flexibility and accuracy by collecting blood in unprecedented simplicity. MiniCollect FX Sodium Fluoride/Potassium Oxalate Tubes are used for the determination of glucose and lactate in capillary blood.

METHODS: A study was done at Laboratory Rainbach (Austria) using MiniCollect tubes with the old vs. new design. Altogether, 20 presumably healthy subjects were recruited. Informed consent was given by all donors and the study was approved by EC Upper Austria. Directly after capillary blood collection, the tubes were inverted 8 times and processed according to the IFU. After centrifugation for 10 min at 3000g, glucose and lactate were tested using an AU680 (Beckman Coulter). Analysis was done with the instrument's accompanying reagents.

RESULTS: Evaluation of all clinical data and deviations was done on the basis of the maximum allowed deviation for a single value according to the guidelines of the German Association of Quality Assurance of Laboratory Testing (Rilibäk). The utilization of tubes with old and new design did not reveal any clinically nor statistically significant deviations (p < 0.05). The values of glucose concentration resulted in a highest deviation of 1.7%, and the lactate values indicated deviations of 2.2% between both tubes.

CONCLUSION: From a clinical perspective, the MiniCollect FX NaF/KOx tubes with the new design are substantially equivalent to the tubes with the old design. The newly designed tubes provide an essentially enhanced blood collection device for skin-puncture testing. As the fundamental advantage is the guarantee of the sample integrity for high quality results in case of critical sample collections and transport of the tubes, the supporting information and data obtained from adult populations are more than adequate to establish safety and effectiveness for the patient indication.

ID: 12479

CAPILLARY SAMPLE TESTING IN NEW MINICOLLECT® K2EDTA AND K3EDTA BLOOD COLLECTION TUBES

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BACKGROUND-AIM: Where small sample volumes are critical, especially for infants, elderly or obese patients, the new MiniCollect tube allows the highest flexibility and accuracy by collecting blood in unprecedented simplicity. MiniCollect K2EDTA and K3EDTA Blood Collection Tubes are used to collect, transport, store and evaluate capillary blood specimens for hematology tests.

METHODS: A study was done at Laboratory Rainbach (Austria) using MiniCollect tubes with old vs. new design. Altogether, 40 presumably healthy subjects were recruited. Informed consent was given by all donors and the study was approved by EC Upper Austria. Directly after capillary blood collection, the tubes were inverted 8 times and processed according to the IFU. Complete blood counts including 15 parameters were tested using a DxH800 (Beckman). Analysis was done with the instrument's accompanying reagents.

RESULTS: Evaluation of all clinical data and deviations was done on the basis of maximum allowed deviation for a single value according to the guidelines of the German Association of Quality Assurance of Laboratory Testing (Rilibäk). The utilization of tubes with old and new design did not reveal any clinically nor statistically significant deviations (p < 0.05). Comparing the initial values of old and new design, the K2EDTA tubes resulted in a highest deviation for WBC of 0.7% and the K3EDTA tubes of 2.2%.

CONCLUSION: From a clinical perspective, the MiniCollect K2EDTA and K3EDTA tubes with the new design are substantially equivalent to the tubes with the old design. The newly designed tubes provide an essentially enhanced blood collection device for skin-puncture testing. As the fundamental advantage is the guarantee of the sample integrity for high quality results in case of critical sample collections and transport of the tubes, the supporting information and data obtained from adult populations are more than adequate to establish safety and effectiveness for the patient indication.

ANALYSIS OF RESULTS OF HEMATOLOGICAL INVESTIGATIONS RECEIVED FROM UNIVAC AND VACUETTE K2EDTA **VACUUM TUBES**

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BACKGROUND-AIM: Medical laboratories implement different brands of K2 EDTA vacuum tube systems for hematology investigations. The aim of this study was to compare results received from K2 EDTA Univac vacuum tubes (Unimed, Russia) with reference tubes Vacuette (Greiner, Austria). METHODS: Venous blood samples were collected to two brands of vacuum tubes Univac and Vacuette with K2 EDTA and volume 2 ml for 40 patients according CLSI H3-A6 and analyzed in Hematology Analyzer MEK 7227 Nihon Kohden (Japan). Comparison was carried out according CLSI EP-9A and included estimation of Bias (B%), Coefficient of Variation from duplicates (CV%), Total Error (TE) and analysis of distribution using plot of quantiles (O-Q plots). Differences in results were assessed for statistical significance with the Student paired t-test and by F-test for CV% from duplicates. RESULTS: Results of comparisons showed statistical significant difference between samples from Univac and Vacuette tubes (p < 0,05) for Mean Corpuscular Value (MCV), Red Cell Distribution Width (RDW), Lymphocytes and Mean Platelet Volume (MPV). CV% differed for Hemoglobin (HGB), Lymphocytes and Basophils, p<0,05. TE exceeded international Quality Goals for samples taken from Univac for Basophils (p<0,05) and for samples taken from Vacuette tubes - for Lymphocytes (p<0,05). Q-Q plot demonstrated different distribution from normal Q-Q plot for Basophils and Eosinophils.

CONCLUSION: Hematological results received from Univac and Vacuette tubes generally were comparable to offer correct clinical interpretation. Received pre-analytical variability could be considered in medical interpretation of some types of anemic state. Pathological high amounts of Baso and Eos should be additionally analyzed in blood smear to clarify the process like it is practiced in medical laboratories.

ID: 12489

THE ONGOING DEBATE: SERUM VS PLASMA

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BACKGROUND-AIM: The most commonly used sample in the analysis of biochemical parameters is serum. However, heparinized plasma, which reduces the turnaround time, since waiting for coagulation does not required, both reflects the in vivo situation more realistically and does not constitute microfibrin-induced interference. However, especially in some of the analytes, serum and plasma value differences have been detected. In our study, we compared serum and plasma levels of twenty two analytes in different sample tubes.

METHODS: Samples from twenty four patients and twenty healthy volunteers were taken into 4 different tubes named as: glass tube without additive (reference tube), tube containing clot-activator with gel (SST), tube containing lithium heparin without gel (LiH), and tube containing lithium heparin with barrier (Barricor). Those twenty two analytes in serum and plasma were measured in duplicate. For each tube and analyte, reference ranges were verified. Analyte levels in different tubes were compared statistically and clinically with the reference tube. RESULTS: In the levels of albumin, chloride, creatinin, urea, free T3, free T4 and vitamin B12 obtained from 3 different tubes, there was no statistically significant difference in comparison to the reference tube. Among the parameters which were statistically different between three tubes, sodium (-0.75%) in SST, potassium (-7.05%) in LiH, and lactate dehydrogenase (21.60%) and total protein (5.03%) in Barricor were found not clinically acceptable relative to the reference tube.

CONCLUSION: In recent years, the use of plasma matrix has become prominent due to some of its advantages. However, it was seen in our study the total protein, lactate dehydrogenase and potassium levels of plasma were clinically different compared to serum, and hence we have concluded that a proper reference range for plasma levels need to be established.

USE OF AN OVERALL INDICATOR OF PREANALYTICAL PHASE AS A GUIDE FOR CONTINUOUS IMPROVEMENT OF BLOOD DRAWN PROCESS IN 26 PRIMARY HEALTHCARE CENTERS. 7 YEARS FOLLOW-UP EXPERIENCE

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BACKGROUND-AIM: Quality indicators have been proposed in extra-analytical phase as a measure of laboratory performance. When samples are obtained in different healthcare Centers, disaggregated data allows us to find improvement areas and select the best practices for a continuous improvement. Our laboratory receives samples from 26 Primary Healthcare Centers of the Northern Area of Madrid. In accordance with Primary Care Health Board of Directors, in 2009 we began an internal quality program based on the comparative monitoring of preanalytical incidents among different centers.

METHODS: Any incident which involves sample rejection is registered into the Laboratory Information System and the petitioner is informed in a timely manner. On a quarterly basis, the overall prevalence of incidents is calculated by dividing the number of incidents by to the total number of patients (episodes) attended in each Center. This indicator is included in a report along with the Center's annual evolution and graphical comparison with the other Area Centers. This quarterly report is complemented by periodic meetings between the laboratory and the Centers were detailed analysis of incidents is accomplished. An internal audit program guided by the results of the indicator was implemented.

RESULTS: The average prevalence of preanalytical incidents for all Centers was 4.1% in October 2009. During the 7-year follow-up, a 66.6% reduction was achieved, reaching 1.4% in October 2016. This reduction represents a change from the 75th Percentile to 25th percentile of participant's performance in the Preanalytical Phase Spanish Society of Laboratory Medicine (SEQCML) Quality Assessment Program.

CONCLUSION: The use of preanalytical indicators is mandatory for continuous improvement. In this study, the benchmarking exercise among different centers, based on indicator comparison and Improvement actions agreed with the centers, has led to a significant improvement in preanalytical phase performance.

ID: 12502

COMPARISON OF BD VACUTAINER® BARRICOR™ PLASMA BLOOD COLLECTION TUBES FOR VARIOUS BIOCHEMICAL TESTS

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BACKGROUND-AIM: Blood Collection Tubes (BCT)-related interferences in test results can adversely influence patient outcomes, decrease laboratory efficiency, delay test results, and increase the cost per test due to recollection and retesting. Blood from patients who are receiving anticoagulant therapy may take longer to clot. Anticoagulation is an important component of the dialysis prescription. We compared with BD (Becton- Dickinson, Franklin Lakes, USA) Vacutainer Serum Seperator Tubes (SST), BD Vacutainer® Barricor™ Plasma Blood Collection Tubes and BD Vacutainer® LH (Lithium Heparin) Plus Blood Collection as reference tube in dialysis patients to examine whether they effect on some biochemical tests.

METHODS: 32 samples were obtained after the dialysis were included in the study. 11 routine clinical chemistry parameters were analyzed on Beckman Coulter AU 5800. The results of biochemistry tests obtained from BD Vacutainer SSTs, and BD Vacutainer® Barricor™ Plasma Blood Collection Tubes were compared with BD Vacutainer® LH Plus Blood Collection Tubes as reference tubes. The significance of the differences between samples was assessed by paired t-test or Wilcoxon Rank test after checking for normality. Evaluation of clinical significance was performed based on total allowable error.

RESULTS: Results of creatinine, K, calcium, cholesterol were statistical significantly different between the BD Vacutainer SSTs and BD Vacutainer® LH Plus Blood Collection Tubes (p = 0.014, p = 0.000, p = 0.002, p = 0.000, respectively). Results of AST was significantly different BD Vacutainer® LH Plus Blood Collection Tubes and BD Vacutainer® Barricor™ Plasma Blood Collection Tubes (p = 0.009). Statistical significance of test results was not clinically significant for the biochemical parameters.

CONCLUSION: BD Vacutainer® Barricor™ Plasma Blood Collection Tubes provides a fast, clean, high-quality plasma samples, safety results and may lower times and costs.

WHAT IS THE MOST SUITABLE BLOOD COLLECTION TUBE FOR HBSAG, ANTIHCV AND ANTIHIV ANALYSES?

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BACKGROUND-AIM: Human immunodeficiency virus, hepatitis C and the hepatitis B viruses are the most important parameters to for testing in transfusion therapy. BD Vacutainer® RST, PST II, LiH Plasma, SST II and Serum Plus(Ser P) tubes were evaluated for HbsAg, antiHCV, and antiHIV on the Unicel DXI 600 as they relate to the reduction of the number of reanalyses needed and mitigate the clotting time or the affects of the gel and clot activators.

METHODS: Thirty-seven volunteers were recruited for the study and five blood samples were drawn from each, into Ser P. SST II, RST, PST II and LiH PP tubes. Serum/plasma remained in the tubes during the initial analyses. Following the initial analyses, the samples in each tube with the gray zone (0.9 < S/CO < 1.0) and with reactive (positive) HBsAg, antiHCV or antiHIV results $(S/CO \ge 1.0)$ were retested.

RESULTS: Five in SST II, three in PST II and in seven in LiH PP tubes were observed to have falsely elevated HBsAg levels. It is important to note that for HBsAg, no false positive results were observed in RST tubes. Erroneous results were not detected for antiHIV or antiHCV in any tubes. CONCLUSION: Ser P, SST II, RST, PST II and LiH PP tubes without any false positive results were found suitable for antiHCV and antiHIV assays. SST II, PST II and LiH PP tubes require attention for HBsAg analyses given their tendency toward false positive results.

ID: 12524

LACTATE DEHYDROGENASE AND ENZYMATIC CREATININE EVALUATION OF A BLOOD COLLECTION TUBE WITH A **MECHANICAL SEPARATOR**

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BACKGROUND-AIM: A blood collection tube with a mechanical separator was designed to reduce cellular content in plasma and to improve sample stability. In heparin gel tubes an unacceptably high frequency of duplicate errors were described for certain lactate dehydrogenase (LDH) assays. Enzymatic creatinine assay of Barricor plasma was not tested yet.

METHODS: Blood was collected in serum gel tube, Li-heparin gel tube (both Vacuette Greiner) and Li-heparin with a mechanical separator (BD Barricor) from dialysis-patients (n=15) and non-dialysis patients (n=15). LDH (Abbott IFCC) and enzymatic creatinine (Abbott creatinase) were analysed in duplicate with Abbott Architect via total laboratory automation (Inpeco).

RESULTS: Lactate dehydrogenase method comparison of Barricor vs serum (gel) revealed a R2 of 0,95 with an intercept of 19,5. LDH comparison of Barricor vs li-hep (gel) showed an intercept of -36,4 and correlation coefficient was 0,8015. Precision in serum was 3,24SD, precision in li-heparin gel was 17,01SD. Barricor precision was 5,65SD. Centrifugated li-hep plasma and serum stored at 4°C in the primary tube did not affect LDH results after 24 and 48 hours. Centrifugated Barricor plasma stored at 4°C in the primary tube revealed an increase of 17% after 24hours and 25% after 48hours. Enzymatic creatinine method comparison of Barricor vs serum (gel) revealed a R2 of 0,99. Barricor enzymatic creatinine linearity was tested between 73,1 and 607,50 umol/l. Data is linear with the allowable nonlinearity of 0,889%. Short EP5 within-run precision was 1,02SD and total precision was 1,04SD at creatinine level of 73,9 umol/l. At 462,6 umol/l within-run precision was 2,4SD and total precision was 4,37SD.

CONCLUSION: A mechanical separator tube is a suitable alternative compared with gel tubes as less cellular content is present in Barricor tubes, this improves LDH precision. Barricor tube is a suitable tube for enzymatic creatinine analysis.

BECTON DICKINSON VACUTAINER SODIUM CITRATE TUBES FOR PT/INR DETERMINATION: LOW MAGNESIUM STOPPERS ARE A SUITABLE REPLACEMENT FOR PREVIOUS FORMULATIONS

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BACKGROUND-AIM: Magnesium (Mg) ions contained in tube stoppers can leach into anticoagulant solution in tubes. This can cause reagent specific clinically relevant differences in INR results with some reagents but not others. It is recommended that the citrate solution should contain less than 1 mmol/l of Mg. We studied low Mg stoppers by comparison with the previously used formulation.

METHODS: Blood samples were collected from 22 healthy subjects and 68 patients taking warfarin into plastic 2.7ml (0.109M) sodium citrate tubes with either previously used (previous) or new low magnesium (Low Mg) stoppers. Prothrombin times (PT) were determined with 3 reagents using a local mean normal PT and instrument specific ISI. A difference of < 10% was considered clinically acceptable.

RESULTS: Mean PTs of normal subjects for previous formulation followed by low Mg were as follows: Recombiplastin 2G /ACL TOP - 10.7 and 11.1 sec; Innovin/CS2100 10.4 and 10.8 sec: Hepatoprest/CS2100 - 27.3 and 27.2 sec.

Mean INRs of warfarinised patients for previous formulation and low Mg were as follows: Recombiplastin 2G/ACL TOP - 2.68 and 2.88; Innovin/CS2100 2.57 and 2.78: Hepatoprest/CS2100 - 2.86 and 2.88.

The difference between tubes was < 4% for normal subjects and < 9% for warfarin subjects. The mean Mg concentration in citrate from 10 tubes after 2 weeks with citrate in continuous contact with stopper was 2.87 mmol/l in previous tubes and 0.010 mmol/l for low Mg tubes. CONCLUSION: The level of magnesium was very far below the maximum recommended level in low Mg tubes, even after excessive anticoagulant contact with stopper. PT and INR with one reagent were largely unaffected. For two other widely used reagents the differences were within the clinically acceptable limits. The low Mg tubes are a suitable replacement for the previous formulation.

ID: 12565

THE COMPARISON OF DIFFERENT SPECIMEN TYPES FOR THE HIGH SENSITIVITY CARDIAC TROPONIN I ASSAY

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BACKGROUND-AIM: The detection of cardiac troponin I (cTnI) together with other evidence of myocardial ischaemia makes important criteria for the diagnosis of myocardial infarction (MI). Laboratories face increasing demands to improve turnaround time (TAT), particularly in the context of urgent troponin testing in patients presenting with acute chest pain. Our aim was to evaluate the influence of the specimen type in cTnI values.

METHODS: Blood specimens were collected from 30 patients who have high and normal cTI levels in BD (Becton, Dickinson and Company, UK) Vacutainer SST II Advance tubes, BD Vacutainer Barricor LH Plasma and BD Lithium Heparin PST tubes. cTnI measurement from both serum and plasma samples was performed by BCI Access 2 immunoassay analyzer.

RESULTS: The analysis of cTnI occurred within 1 hour after sample collection. All patients gave informed consent. There was not statistically significant difference between specimen types (P > 0.05). However, plasma cTnI concentrations in BD Vacutainer® Lithium Heparin PST tubes were found to be lower than those measured in serum (mean difference of -6,78 %), whereas plasma cTnI concentrations in BD Vacutainer Barricor LH were found to be higher than those measured in serum (mean difference of 4.06%).

CONCLUSION: Serum and plasma appear to be interchangeable as samples for cTnI measurement using the Access 2 assay. Furthermore, the use of plasma reduces the analytical turnaround time and may avoid false positive cTnI results due to residual fibrin.

ID: 12571

USE OF AND CLEANING PROCEDURES FOR VENEPUNCTURE TOURNIQUETS IN DENMARK

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BACKGROUND-AIM: Hospital-acquired infections are estimated to affect around 10% of hospital inpatients and are known to severely complicate the course of hospitalisation and increase mortality risk. Venepuncture tourniquets are widely used, non-sterile reusable equipment and have in several studies been found colonised with a variety of pathogenic bacteria, e.g. coagulase-negative staphylococcus and staphylococcus aureus. The objective of this study was to investigate the national use of disposable and non-disposable venepuncture tourniquets and the standardised procedures – if any – for cleaning the devices.

METHODS: An identical and standardised questionnaire was sent to senior consultants at 12 different clinical biochemistry laboratories in Denmark. The senior consultant either filled in the formula personally or passed it on to a laboratory technician responsible for the laboratory's pre-analytical section and then returned the questionnaire along with guidelines on the area (if any).

RESULTS: All but one laboratory had a local procedure for usage and handling including structured procedures for cleaning, Instructions did however differ considerably: Four out of 12 laboratories used disposable tourniquets, three used non-disposable tourniquets and five used both types. Four laboratories disposed or cleaned the disposable tourniquets after each patient, while five disposed the tourniquets daily. Among the eight laboratories using non-disposable tourniquets one changed the tourniquet after each patient, four cleaned the tourniquets at the end of the day or end of guard or ward round, two cleaned the device once a week, while one laboratory only cleaned if visibly stained or dirty. CONCLUSION: Procedures and guidelines for the use of tourniquets for venepuncture differed considerably. We suggest a national consensus guideline on the usage and cleaning of venepuncture tourniquets to minimize the risk of transmitting pathogens, which could decrease the morbidity and mortality related to hospital-acquired infections.

ID: 12575

COMPARISON OF TWO SERUM COLLECTION TUBES FOR INSULIN DETERMINATION

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BACKGROUND-AIM: The accuracy of serum insulin determination is dependent on preanalytical conditions, affecting the stability of the peptide structure. Becton Dickinson (BD) Vacutainer clot activator serum tube (CAT) and the serum separator tube (SST II advance) are commonly and often interchangeably used serum collection tubes. Our aim was to compare insulin concentration in sera collected in BD CAT and SST tubes and evaluate the equivalence of results for the clinical use.

METHODS: Venous blood from 45 fasting subjects with impaired glucose tolerance and type 2 diabetes mellitus was collected using both BD CAT and SST tubes in sequence. Sera from both tubes, obtained after clotting and centrifugation (10 min, 3000xg) were assayed for insulin with an automated chemiluminescent immunoassay (Centaur XP, Siemens Diagnostic Solutions, USA). The results were analyzed using MedCalc statistical software.

RESULTS: Serum insulin levels ranged from 25,6 to 346,0 pmol/L. Passing & Bablok regression analysis revealed no statistically significant systematic or proportional differences between the two compared collection tubes (regression equation; y = -0.659867 + 1.009806 x; Intercept A = -0,6599, 95% CI = -4,3740 to 4, 2282; Slope B = 1,0098, 95% CI = 0,9673 to 1,0479). Cusum test for linearity showed no significant deviation from linearity (P = 0.59).

CONCLUSION: The result from this study support the use of both serum collection tubes for insulin concentration determination as they give clinically equivalent results.

ID: 12589

QUALITY INDICATORS TO DETECT PRE-ANALYTICAL ERRORS IN PRIVATE LABORATORIES; A PRELIMINARY EXPERIENCE

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BACKGROUND-AIM: Pre-analytical errors are considered to be the most common type of errors in a total testing process (TTS) and therefore can be used as an excellent quality indicator (QA). The aim of the present study was to assess current practice on the use of quality indicators (QIs) in laboratory practice occurring in two distant laboratories.

METHODS: Data on quality indicators(QIs) were collected during a three-month period from two private laboratories: the laboratory LabPlus2 Zagreb(Lab1) and dislocated laboratory LabPlus Split(Lab2). Pre-analitical errors were classified using a harmonized list of QIs with a homogeneous reporting system. The study included 7500(LabPlus 2 Zg) and 4100(LabPlus St) blood sample tubes divided into two groups:collected from patients on site in the laboratory and outdoor patient samples.

RESULTS: The most commonly reported types of pre-analytical errors in samples collected both inside and outside the laboratories in Lab1 and Lab2 are:a) haemolysed, clotted and insufficient samples:34/25 Lab1, 18/11 Lab2;b) wrong or missing identification14/8Lab1,8/5Lab2;c)

missing sample and/or test request, 13/8 Lab1, 8/5 Lab2;d)inappropriate containers 9/5 Lab 1, 5/4Lab2;e)inappropriate blood to anticoagulant ratio 8/5Lab1,4/3Lab2;f) inappropriate transport and storage conditions 5Lab1 3Lab2.

CONCLUSION: These preliminary results demonstrate that the errors occurring are mainly related to procedures performed outside the laboratory, by personnel who are not under the direct control of the laboratory. In order to reduce errors in specimen collection and pre-analytical sample handling development requirements need to be based on providing training and improving interdepartmental cooperation. According to the ISO 15189:2012 quality indicators (QIs) for a patient-centered approach help us to identify potential errors, recognize them quickly, and assists in the implementation of preventive and corrective measures.

ID: 12596

TOURNIQUET INFLUENCE ON IONIZED CALCIUM DETERMINATION: TO BE AVOIDED OR TO BE APPLIED?

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BACKGROUND-AIM: Recommendations regarding tourniquet application for ionized calcium determination (iCa) deserve proper consideration. The aim of this study was to compare the iCa values obtained from samples collected without and with tourniquet application depending on the different release time of the tourniquet.

METHODS: The study included two groups; in the first group two blood samples were collected from 30 volunteers (23 women and 7 men), median age (range) 26 (18-58): one without tourniquet application and one from the other arm with a tourniquet released immediately after the blood has flown. In the second group, two blood samples were drawn from 30 volunteers (22 women and 8 men), median age (range) 34 (26-62) in the same way, but the tourniquet was released after complete tube filling. The blood samples were drawn from the antecubital vein directly into vacuum tubes with gel and clot activator. All tubes were completely filled, centrifuged according to the manufacturer's instructions and left at room temperature until analysis. iCa was measured by potentiometric method on the RapidLab 348EX analyzer (Siemens, Suffolk, UK). Clinically significant difference was evaluated according to RiliBÄK's criteria (acceptable deviation < 7.5%). Passing-Bablok regression and Bland-Altman plot were analyzed in MedCalc 14.8.1 (Ostend, Belgium).

RESULTS: Passing-Bablok regression showed the minimum constant error between samples collected in the first group: y = 0.01(0.01-0.01)0,11) + 1,00(0,92-1,00)x. In the second group, no constant or proportional error was found: y = 0,00(-0,12-0,00) + 1,00(1,00-1,09)x. Bland-Altman plot did not show any clinically significant difference for iCa in samples collected in both groups when compared to RiliBÄK's criteria.

CONCLUSION: There is no clinically significant difference between samples collected for iCa determination without and with tourniquet application.

ID: 12598

COMPARISON OF BD VACUTAINER® SST™II ADVANCE TUBES WITH BD VACUTAINER® BARRICOR™ TUBES IN ACUTE CARDIAC PATIENTS

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BACKGROUND-AIM: Blood from patients who are receiving anticoagulant therapy or with coagulopathies may take longer to clot. Delayed or prolonged clotting may continue into the analytical phase and cause intrument downtime, which delays testing, potentially affecting patient care adversely. Worse, fibrin strands that don't impede intrumentation can lead to erroneous results that go undetected and precipitate patient mismanagement. The aim of our study was to compare the use of BD Vacutainer® SSTTMII Advance tubes with BD Vacutainer® Barricor™ tubes in cardiac patients in the intensive cardiac care unit of our institute.

METHODS: Two types of tubes were tested at the same time point. Blood samples from 50 patients were collected into aforementioned tubes. SST tubes were allowed to clot for a minimum of 30 minutes from the time of blood collection. The centrifugation conditions were set as follows: SST tubes 10 minutes at 1900g, Barricor tubes 7 minutes at 2900g in a swing-bucket centrifuge at room temperature. Barrier formation after centrifugation was visually assessed in every sample. The samples were evaluated for selected chemistry analytes.

RESULTS: Visual comparisons proved that BD Vacutainer® Barricor™tubes perform better barrier formation. Barricor tubes demonstrated clinically equivalent performance for the selected chemistry analytes evaluated in this study, when compared with SST tubes.

CONCLUSION: BD Vacutainer®Barricor™ tubes are designed to enhance sample quality, improve laboratory efficiency, and reduce laboratory turnaround time.

MILKING THE FINGER: THE EFFECT OF (IN)CORRECT FINGER STICK BLOOD SAMPLING ON ROUTINE BIOCHEMICAL **TESTS**

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BACKGROUND-AIM: Finger stick blood sampling is commonly used in pediatric- and adult patients where venipuncture is problematic. Obtaining sufficient volume is challenging. Guidelines warn to avoid excessive pressure which leads to bruising and spurious results. This is difficult to implement in all clinical situations. The aim of this study was to investigate the effect of "milking" versus a correct finger stick blood sample and phlebotomy on routine biochemical tests.

METHODS: Triplicate samples were obtained from 23 healthy adult volunteers after ethical approval and informed consent was obtained. Phlebotomy (Ven) was followed by a correct- (CCap) and incorrect (ICap) finger stick. Ven and CCap were performed according to local guidelines unlike ICap where excessive pressure ("milking") was applied. To standardize sampling and "milking" all blood collections were performed by a single phlebotomist. Triplicate blood samples were analyzed in a single run. The following tests were performed; hemolysis-index (H-index), ALAT, ASAT, creatinine, creatine kinase (CK), magnesium (Mg), phosphorus (P), potassium, sodium (Na) and lactate dehydrogenase (LD).

RESULTS: The following results (mean ± SD, (p-value)) for respectively Ven, CCap and ICap were found. H-index (µmol/L): 3.8 ± 1.6, 23.0 ± 24.0 (<0.01) and 88.1 ± 67.5 (<0.01); ALAT (U/L): 22.9 ± 7.2 , 22.7 ± 7.1 (0.21) and 23.7 ± 7.0 (<0.05); ASAT (U/L): 23.9 ± 4.4 , 25.8 ± 6.7 (<0.05) and 37.1 ± 11.1 (<0.01); creatinine (µmol/L): 69.1 ± 10.5 , 64.1 ± 10.5 (<0.01) and 62.9 ± 10.2 (<0.01); CK (U/L): 108.1 ± 47.4 , 109.7 ± 46.5 (0.08) and 116.4 ± 46.2 (<0.01); potassium (mmol/L): 4.0 ± 0.3 , 4.3 ± 0.4 (<0.01) and 5.0 ± 0.7 (<0.01); LD (U/L) (median (IQR, p-value)): 194 (170-214), 190 (151-212, < 0.01) and 298 (239-443, < 0.05). No clinical significant differences were found for Mg, P and Na.

CONCLUSION: Excessive pressure ("milking") during finger stick blood sampling results in severe hemolysis and interstitial fluid dilution causing clinical significant aberrant results on common routine biochemical tests.

ID: 12626

VERIFICATION OF NEW COLLECTION TUBES FOR DETERMINATION OF IONIZED CALCIUM - CAN WE MAKE BLOOD **SAMPLING EASIER FOR PATIENTS?**

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BACKGROUND-AIM: Before introduction of new collection tube into routine laboratory work it is necessary to verify them. In order to simplify the current blood sampling procedure for ionized calcium determination, the aim of this study was to compare the results obtained in whole blood drawn in a syringe with balanced heparin with the results from so far used heparinized capillary.

METHODS: Study included 78 outpatients who were referred to Department of Medical Laboratory Diagnostics, University Hospital Centre Split, for routine laboratory testing. Blood was collected from antecubital vein in Monovette syringe (Sarstedt, Nümbrecht, Germany), according to National recommendations for venous blood sampling. Syringe contains liquid calcium-balanced heparin and it is suitable for both venous and arterial blood sampling. After venous sampling we collected capillary blood sample from patient's finger, in a capillary with balanced heparin. All samples of whole blood were analyzed on the Rapid point 1265 analyzer (Siemens, Munich, Germany) by direct potentiometry. Statistical analysis was performed using MedCalc (Mariakerke, Belgium). To evaluate clinical significance, we used laboratory RCV (reference change values).

RESULTS: Regression analysis according to Passing-Bablok showed no statistically significant differences between the capillary and syringe: y = -0.06 (95% CI 0.20 - 0.00) + 1.05 (95% CI 1.00 to 1.17)x. Bland-Altman plot showed mean difference on average -0.1 % (limits of agreement -4.8 - 4.7%)) for comparison of capillary and syringe.

CONCLUSION: Verification of the new blood collection system for ionized calcium determination showed there is no statistically significant difference between two compared systems. Bland Altman plot showed no clinically significant difference if compared to RCV value. These results are of a significant value and allow us avoiding capillary blood sampling after venipuncture and consequently making the whole process less invasive for patients.

IMPLEMENTATION OF A NEW DEVELOPED BD PREANALYTICAL QUALITY CHECK EXTERNAL ACCESS IN A REFERENCE **HOSPITAL AND ITS HEALTH AREA**

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BACKGROUND-AIM: Cruces University Hospital Laboratory, conducting around 2.000 samples per day, is the reference laboratory also for two regional hospitals and 55 Primary Care Centers. We implemented a new developed enhanced version of BD Preanalytical Quality Check (PAQC), a quality control tool that provides a comprehensive analysis of the preanalytical phase, showing the adherence to international guidelines and the impact of non-conformities on sample quality, laboratory efficiency and analytical results.

METHODS: This audit tool developed by BD Preanalytical Systems is an iOS-based application that allows the user to record key characteristics procedures from the preanalytical phase (from storage, through collection, transportation and processing). In collaboration with BD, we have been able to enhance the capabilities of this service with a dedicated database that allow us to collect data by internal staff with different tablets (iPads Mini2) and to store that information in a customized database provided by BD that allow us to compare and benchmark the results of multiple observations. We evaluated an outpatient phlebotomy unit, 3 hospital clinical ward and 4 primary health units, 210 venous blood collection procedures observed, and 500 samples injectioned.

RESULTS: BD PACK reports allowed us to identify major errors and improvement areas were detected, incorrect patient identification, order of draw, sample mixing, and underfilled coagulation tubes, according to collection place. The compliance with CLSI/NCCLS GP41-A6 guidance were variable, with a 75% of global adherence. Training sessions for nurses were implemented, focusing on areas where improvement was detected trough the BD PACK reports, and procedures were reviwed.

CONCLUSION: The BD PACK external access by tablets is an easy and quick tool to evaluate different collection sites groups by the internal staff. We consider that the new BD system is ready to be implemented in other institutions.

ID: 12641

WATER INTAKE: IS PATIENT ALLOWED DRINKING BEFORE BLOOD ION ASSAY?

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BACKGROUND-AIM: Water is essential for health; however its needs vary among individuals. Present guidelines for blood collection consider no restriction of water intake before laboratory assays. This study was aimed to evaluate the impact of water intake 1h before assay of some

METHODS: A first blood sample was collected from 20 fasting volunteers (12 h). Immediately after blood collection, volunteers drank 300 mL of water. A second blood sample was collected 1 h after water intake. Ion assays included: calcium (Ca), phosphate (Phos), magnesium (Mg), sodium (Na), potassium (K), and chloride (Cl). Differences between concentrations (mmol/L) were assessed by Wilcoxon ranked-pairs test. The level of statistical significance was set at p < 0.05. Each volunteer provide informed consent to inclusion in this trial, which was performed in conformity with the Declaration of Helsinki and under the terms of relevant local legislation.

RESULTS: A significant increase was observed 1 h after water intake vs. baseline sample for: Ca [2.42 (2.32 - 2.54) vs. 2.38 (2.33 - 2.44)], P = 0.034; Na [143 (139 - 144) vs. 140 (138 - 141)], P = 0.003); K [4.10 (3.90 - 4.28) vs. 3.80 (3.63 - 4.00)], P = 0.005; and Cl [104 (101 - 107) vs. 102] (100 - 104)], P=0.014; whereas Phos decreased [1.26 (1.17 - 1.39) vs. 1.30 (1.26 - 1.48)], P<0.001. Moreover, Mg was not influenced by water intake [0.78 (0.71 - 0.78) vs. 0.74 (0.70 - 0.78)], P = 0.527.

CONCLUSION: The significant variations of ion levels after water intake shows that water drinking before blood collection should be considered as a source of interference. We suggest avoidance of water intake at least one hour before blood collection in order to both prevent spurious results and reduce laboratory variability.

Hemolysis, icterus, lipemia

ID: 12319

INFLUENCE OF HEMOLYSIS/LIPEMIA ON RESISTIN AND MPO ELISA TESTS

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BACKGROUND-AIM. Hemolytic and lipemic samples in research ELISA tests can cause false low/high results. Peptide hormone resistin (RES) is potential marker of metabolic syndrome. Myeloperoxidase (MPO) is glycoprotein related to disorders like multiple sclerosis and atherosclerosis. The aim of our study was to investigate influence of hemolysis and lipemia on determination of RES and MPO using Human Resistin ELISA and Human MPO ELISA (BioVendor, Brno, Czech Republic).

METHODS: Lithium heparin plasma sample was mixed with Lipofundin emulsion for testing of lipemia interference. Hemolysis was achieved by drawing aliquots of heparinized blood through 26 gauge needle. Index of hemolysis (H), lipemia (L) and triglyceride concentrations were measured on Architect (Abbott Laboratories, Abbott Park, Illinois, USA). Hemoglobin concentration was measured with hematology analyzer Sysmex XN-1000 (Sysmex, Kobe, Japan). Concentrations of RES and MPO were determined with Human Resistin ELISA and Human MPO ELISA test kits. All measurements were performed in triplicate.

RESULTS: Lipemic plasma samples ranged from L index of -0.01 to 17.69 and triglyceride concentrations from 0.57 to 50.23 mmol/L. Hemolytic samples ranged from H index of 0.05 to 8.77 or from 0 to 8 g/L hemoglobin. RES concentration had 66% bias from initial concentration already at 1.34 H index or 1 g/L of hemoglobin. Bias of -7.9% was recorded from initial concentration at L index of 0.59 and triglyceride concentration of 2.60 mmol/L. MPO concentrations showed significant bias (58.7%) at the same hemoglobin concentration, while 33.8% bias was recorded for 1.28 L index or triglyceride concentration of 4.66 mmol/L.

CONCLUSION: Interference testing for hemolysis and lipemia on ELISA tests for RES and MPO showed significant biases. Erroneus research results caused by such interferences contribute to misleading conclusions.

ID: 12359

THE HIL-INDEX ANALYSIS: A NATIONAL SURVEY ON THE VALIDATION AND USE ON AUTOMATED EQUIPMENT

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BACKGROUND-AIM: The haemolysis/icterus/lipemia index (HIL-index) analysis is rarely validated due to its integrated, automated use on chemistry/immunochemistry platforms. This means that analysis results either can be withheld erroneously or erroneously released due to an incorrect HIL-index measurement. In vitro haemolysis is the most prevalent preanalytical error, and the proportion of haemolyzed samples received at the laboratory has been reported as high as 3.3% of all routine blood samples. It is therefore important to elude the extent of an un-validated HIL-index analysis.

METHODS: A question naire was sent to all Danish departments of clinical biochemistry (n=17). The question naire was answered by a medical block of the control of the codoctor or a technical specialist for the chemistry/immunochemistry analyses. The questionnaire consisted of 9 questions regarding validation, quality control and report of HIL-index results from chemistry and immunochemistry equipment.

RESULTS: All departments answered the survey. Thirteen answered the questionnaire completely, while four had one or two missing answers. All departments used an automated HIL-index analysis, however on different equipment. Only four departments (23.5%) had validated the HIL-index analysis and performed internal quality control, while five participated in an external quality control program. One department blocked for analysis of the requested analyses if the HIL-index exceeded a predefined value for analytical interference, while 13 departments blocked release of the analysis result.

CONCLUSION: Our findings emphasize the need to validate and to perform quality control measurement of the HIL-index in order to avoid incorrect laboratory test results. Our findings furthermore imply a general need to focus on validation of "hidden" analyses included in an automated solution to assure that the preanalytical sample assessment is performed correct.

CROSS-REACTIVITY OF SERUM INDICES ON ABBOTT ARCHITECT C8000. ROCHE COBAS 6000 AND BECKMAN COULTER AU5800 ANALYZERS: HIL INTERFERENCE PROIECT OF THE WG-PREANALYTICAL PHASE. CROATIAN SOCIETY OF MEDICAL **BIOCHEMISTRY AND LABORATORY MEDICINE**

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BACKGROUND-AIM: Serum indices, hemolysis (H), icteria (I), lipemia (L) are determined automatically on chemistry analyzers. HIL absorbance spectra patterns overlap which could result with HIL cross-reactivity when multiple interferences are present. We aimed to investigate interference cross-reactivity and to compare cross-reactivity of indices between three different biochemistry analyzers.

METHODS: Study included Abbott Architect c8000, Beckman Coulter AU5800 (BC) and Roche Cobas 6000. For each interference, 6 increasing levels of interfering substances were added to serum pool (hemolysis: 0.3-10 g/L hemoglobin (Hb) by needle aspiration, icteria: 35-675 µmol/L of dissolved bilirubin, lipemia: 0.1-1.4 g/L of Intralipid). HIL indices were measured in duplicate before and after addition of second interferent (approximate values H = 5 g/L, I = 400 µmol/L, L = 1 g/L of Intralipid) and biases between those measurements were calculated. BC provides semiquantitative results (5 categories), while Abbott and Roche express indices as corresponding concentrations: hemoglobin (g/L) for H, bilirubin (μmol/L) for I and Intralipid (g/L) for L index. Less than 10% was considered acceptable bias for Abbott and Roche, and for BC agreement of result category.

RESULTS: Hemolysis decreased I index on Abbott and Roche (for 20% and 14%, respectively). On BC, hemolysis increased I index. L index on Abbott was higher (for 35-180%), while on Roche and BC, L index was lower (11-32% for Roche) after adding free Hb. Adding bilirubin had no effect on H index on Abbott, while on Roche and BC, H index was higher (13-35%). Bilirubin also changed L index for more than 30% on all analyzers. I index on Abbott and Roche was lower after adding Intralipid (mean bias 75% and 28%, respectively). Lipemia interfered with H index on all three analyzers (for approximately 14%).

CONCLUSION: Almost all tested interference combinations showed cross-reactivity. Serum indices could be erroneous if more than one interfering substances is present in serum sample.

ID: 12446

G-FORCES DURING PNEUMATIC TUBE SAMPLE TRANSPORT: A CAUSE OF HEMOLYSIS?

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BACKGROUND-AIM: The widely used transport of patient samples through a pneumatic tube system (PTS) in hospitals results in time and cost savings. On the other hand, acceleration (g-)forces associated with the PTS may increase the frequency of hemolysis of blood samples and lead to false elevated blood concentrations of potassium (K) and lactate dehydrogenase (LDH). The aim of this study was to investigate sample integrity during transport through a newly installed PTS.

METHODS: Blood samples were collected in duplicate from six healthy volunteers at the emergency department (ED, ground flour) and the geriatric department (GD, top floor) of the hospital. After 10 minutes clotting in vertical position, the samples were transported to the hospital laboratory either hand-carried or with PTS. Samples delivered through PTS were transported in a PTS carrier together with a datalogger that measured the 3-axis g-forces. Sample hemolysis index (HI), K and LDH were analyzed and results from both methods of transport were compared. The g-forces were also measured during PTS transport from the other departments of the hospital to the laboratory. In this case, no blood samples were being used and the rate of PTS transport was estimated.

RESULTS: None of the samples were hemolyzed (HI ≤ 17). No statistically significant differences could be determined between both methods of transport for blood K (p=0.25 ED; p=0.88 GD) and LDH (p=0.84 ED; p=0.44 GD) concentrations. The peak g-forces for the transport to the laboratory from the ED were up to 9.8g and 14.9g from the GD. These results were similar to those obtained for the other departments (5.8g-14.5g). The mean transport speed was ± 2.5 m/s.

CONCLUSION: Our data indicate that transport of blood samples through the PTS does not affect the quality of these samples and g-forces up to 14.9g are not associated with hemolysis.

ID: 12501

DIFFERENCES IN PREANALYTICAL PROCESS AND AGE OF THE PATIENTS AFFECT THE PREVALENCE OF HEMOLYZED **SERUM SPECIMENS**

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BACKGROUND-AIM: The prevalence of serum samples with a hemolysis index (HI) higher than 0.5 g/L has been proposed as a preanalytical process indicator.

METHODS: In our laboratory, we receive samples with three models of preanalytical processing:

- Outpatients attended at external blood drawn centers (O-EC). These samples are transported to the laboratory by road.
- Outpatients attended at the hospital blood drawn ward (O-H). These samples are transported by pneumatic tube. The ward is separated into two areas: Adults and pediatric, attending an average of 100 children per day.
- Inpatients (I-H) from four different hospitals including a pediatric center. Emergency and critical care units are excluded. These samples are transported by pneumatic tube.

Serum samples were analyzed in Advia 2400, where HI is quantitatively measured. A quality indicator is calculated monthly by dividing the number of samples with HI > 0.5 g/L by the total number of episodes for each group. From January to November 2016, we calculated the 95% confidence intervals and performed chi-square test.

RESULTS: The prevalence of hemolyzed samples were: 0.72% (0.69-0.75%), 1.97% (1.9-2.04%) and 2.17% (2.07-2.26%), for O-EC, O-H and I-H respectively. The Hemolysis indicator is quite different between adults and children (1.37% vs 6.05%), adult inpatients and outpatients (1.8% vs 1.1%) and between adults collected at the hospital (pneumatic tube) and samples collected in community centers (road transport) (1.1% vs 0.72%) (Chi-square p < 0.001 for all comparisons).

CONCLUSION: External quality assessment programs (EQAs) can be used to define specifications for prevalence of hemolyzed samples. Our results suggest that the age of patients, emplacement and transport system are also determinants in hemolysis production. Prevalence of hemolysis in children is four-fold increase when compared to adults. EQAs organizers should take these aspects into account in order to establish homogeneous comparison peer groups.

ID: 12541

SAMPLE REJECTION RATES DUE TO HEMOLYSIS WITH AND WITHOUT THE USE OF PNEUMATIC TUBE SYSTEM FOR TRANSPORT OF BLOOD SAMPLES TO THE EMERGENCY LABORATORY

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BACKGROUND-AIM: Transport of blood samples to the emergency laboratory in a short time period is of ciritical importance. Samples can be transported within the hospital via manual way by hospital staff, or with a pneumatic tube system. Pneumatic systems provide rapid transport of blood specimens to laboratory and decrease turn-around time. But hemolysis ratios are claimed to be higher with pneumatic systems due to sudden changes in direction of the transport containers.

METHODS: The study evaluates the differences in hemolysis, late results and lost sample ratios between intervals when penumatic system was functioning and not functioning. From 24.10.2016 to 05.11.2016, our pneumatic system was not functioning and blood samples were transported manually by hospital staff. From 06.11.2016 to 18.11.2016, our pneumatic system was functional and blood samples were transferred with this system from the emergency department and intensive care units (ICUs) to the emergency laboratory. Ratios of hemolysis were analysed retrospectively for the two time intervals.

RESULTS: During the 12 day period when the pneumatic system was not functioning, 23,270 samples were accepted to our emergency laboratory. The total number of rejected samples was 75 (0.32%). Among the 75 rejected samples, 12 samples were hemolysed (16%). Within the 12 day period when the pneumatic system was functioning, a total of 20,587 samples were accepted to the same laboratory and 62 samples (0.30%) were rejected due to different reasons. Among these rejected 62 samples 0.030 %), 5 samples were hemolysed (8%).

CONCLUSION: Besides it's advantages like shorter turn-around time and being a safer way of transport for the specimens, this transport method can cause hemolysis due to high speed transportation, sudden changes in direction and turbulance effect. Pneumatic systems with the most benefit should be chosen.

ID: 12555

EVALUATION OF SERUM INDICES PROGRAMME ON ROCHE COBAS 8000 ANALYSER

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BACKGROUND-AIM: Analytical interference by hemolysis, bilirubin and lipid with laboratory assays is the most important problem in laboratory medicine. These interfered results may lead to wrong results, repeat tests, incorrect diagnosis and therapy for the patients. We assessed the effects of hemolysis, icterus, and lipemia on laboratory tests by using parameter specific serum indices calculation on autoanalyser.

METHODS: Patient samples (n = 21088) which were received at the laboratory for routine analysis were used in this study. These samples were analyzed on Roche Cobas 8000 autoanalyzer for different parameters (n = 102748) (Cobas, Roche Diagnostics, Switzerland). The Cobas 8000 analyzer is able to detect hemolysis, icterus, and lipemia in samples and can generate quantitative index values for the major interfering substances of hemoglobin, bilirubin, and lipids expressed as H-index (hemolysis), I-index (icterus), and L-index (lipemia).

RESULTS: In present study, interferences were detected in 3764 (3.6 %) of 102748 test results, hemolysis was 97.2 %, lipemia was 0.1 % and icterus was 2.7 %. We observed strong positive interferences by hemolysis on aspartate aminotransferase (AST), lactate dehydrogenase (LD) and direct bilirubin almost at low hemolysis index (HI 15-25). Significant variations of potassium were observed in moderately hemolyzed samples. Bilirubin interference affected creatinine and gamma glutamyltransferase (GGT).

CONCLUSION: The automated determination of interfering substances instead of visual inspection will provide more accurate information. This parameter specific serum indices programme and corresponding comment on potential interference will reduce laboratory error when reporting our test results.

ID: 12557

HEMOLYSIS, LIPEMIA AND BILIRUBIN INFLUENCE ON EMERGENCY BIOCHEMICAL PARAMETERS MEASUREMENT

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BACKGROUND-AIM: Abnormally high concentrations of hemoglobin, bilirubin, or lipids may be a source of error in biochemical parameters measurement. Analyzers evaluate indices and the manufacturers provide information relating to interference limits for each parameter. The aim of this study was to establish thresholds interference of hemolysis, icterus and lipemia in normal and pathological values of key emergency biochemical parameters.

METHODS: For each parameter we studied a range of concentration of hemoglobin, bilirubin or intralipid. Parameters were measured on a Roche Cobas 6000 analyzer. A threshold of 10% variation was chosen to define a significant interference.

RESULTS: Hemolysis: the manufacturer hemolysis index is confirmed for Alb, UA, Ca, CRP, GGT, Glucose, Mg, Myo, NT-ProBNP, S100, Urea, overestimated for ALT, Chol, TP and depend on the concentration of the measured parameters for 6 of them. Indeed, for ALP, AST, Creatinine, Tg and TNThs, the provider index is correct for normal values, but underestimated for pathological values. In contrast, the provider index is correct for a normal lipase value but overestimated for a pathological one. Lipemia: ALT, AST and Alb were strongly affected. The manufacturer lipemia index is confirmed for ALP, AST, UA, Ca, CK, Creatinine, CRP, Chol, GGT, Glucose, HDL-C, LDH, Lipase, Myo, Mg, NT-ProBNP, TP, S100, TNT hs, Urea but seem to be overestimated for low ALT and Alb values. Bilirubin: Only Creatinine was strongly affected. The manufacturer icterus index is confirmed for Alb, ALP, AST, UA, Ca, CK, CRP, Chol, HDL-C, Glucose, LDH, Lipase, Myo, NT-ProBNP, TG, TNThs, Urea; overestimated for ALT and TP and underestimated for high values of GGT and Creatinine.

CONCLUSION: Data interference of hemolysis, lipemia and icterus provided by suppliers are generally correct but often incomplete. This study allows us to improve the accuracy of our laboratory results including hemolyzed, lipemic or icteric samples.

CORRECTION OF FACTITIOUS HYPERKALEMIA IN HEMOLYZED SPECIMENS FROM ADULT EMERGENCY DEPARTMENT USING THE BECKMAN UNICELL DXC8801 ANALYSER DERIVED FACTOR

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BACKGROUND-AIM: Hemolysis in emergency departement (ED) patiens is common due to dificult blood draws. Values of serum K+ become falsely elevated secundary to release of intracellular contents. Correction factors have been proposed for estimating true K+ concentrations in blood samples with evidence of in vitro hemolysis. If reliable correction factor existed for this factitious elevation, repeat K+ measurements might be avoided. The aim of the study was to establish a correction factor for factitious elevated K+ in samples for de adult ED.

METHODS: We used samples from 125 adult ED patients, in which a 2nd sample was drawn due to hemolysis of the first tube. Both hemolysis index and K+ value were mesured with Beckcman and Coulter DxC 880i analyzer. The change in serum measured K+ concentration was plotted versus the change in serum hemolysis index for each pair of samples. Thirty six of the ED patients were submitted to an arterial gasimetry, the K+ value measured in the point of care GEM Premier 4000 blood gas analyser (POC) was plotted against the K+ value of the nonhemolyzed sample and against the corrected K+ value after using the correction factor calculed before.

RESULTS: Firstly we derived a correction factor expressing an increase in potassium concentration in 0,21 (95% confidence interval, 0.17-0.24 mEq/L with p < 0.01) for each hemolysis index increment. When comparing the K+ value of the POC with the nonhemolyzed samples we obtained a 90% correlation. The correlation of the same POC values with those obtained after applying the correction factor to the hemolysed sample value was of 79%.

CONCLUSION: A reliable correction factor for factitious hyperkalemia in a clinical relevant range exists. We suggest that in cases of low hemolysis index, if the corrected value is within the reference range, a second drawn is unnecessary.

ID: 12559

IMPORTANCE OF HEMOLYSIS INDEX IN PREANALYTIC PHASE

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BACKGROUND-AIM: Studying samples in clinical laboratories is a complex process and requires a multidisciplinary approach. In laboratory practice, these processes are defined as preanalytical, analytical, postanalytical, and failure of any of these processes leads to faulty test results. 70% of these errors occur in the preanalytical phase. Preanalytical errors can be associated with a large proportion of the human factor and most can be prevented. One of the most common of these errors is hemolysed samples. In the evaluation of hemolysis, it has been increasing use of the hemolysis index. In this study, we aimed to discriminate according to the departments where hemolyzed samples came and to determine the change of sample rejection rates by using serum hemolysis index in our laboratory.

METHODS: Biochemical samples from the Dicle University Hospital Laboratory, in 2016, were retrospectively analyzed from the laboratory information system and the hemolysis index positive sample rate was calculated. Departments were grouped as inpatient services, policlinics and emergency units and hemolysis index positive sample rates from each department were calculated separately. Also, hemolysisinduced rejection rates were compared at 6 months before and after the date when the automated hemolysis index began to be used in our laboratory.

RESULTS: In 2016, the hemolysis index was positive in 10.4% of the samples in our laboratory. Hemolysis index positive samples; 63.8% of them came from inpatient services, 28.5% from policlinics and 7.6% from emergency units. Using the hemolysis index, a significant decrease in hemolysis-induced rejection was noted (p < 0.05).

CONCLUSION: Reduction of the rejection rate of samples with visually hemolysis by using automated hemolysis index may be effective in decreasing the cost and reducing the duration of the result by decreasing unnecessary test repetitions in terms of parameters that are not affected by hemolysis. Departments with high hemolysis rates can be improved with periodic in-service training.

INCIDENCE AND DISTRIBUTION OF HEMOLYZED BLOOD SAMPLES IN THE STAT LABORATORY

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BACKGROUND-AIM: In vitro hemolysis may interfere in laboratory tests and is currently the main cause of preanalytical error, thus increasing the repetition of blood draws and producing adverse clinical and economical outcomes. Laboratories should detect and reliably quantify hemolysis in every sample by an automated estimation of the Hemolysis Index (HI). In our stat laboratory, up to 410 requests are processed daily of which 280 belong to samples for biochemical tests. Hemolysis forces us to cancel some of their results. The aim of this retrospective study was to analyze the incidence of hemolysis in samples received throughout a year in the stat laboratory, their monthly distribution, as well as the departments with the highest rates of hemolysis.

METHODS: A total of 102,243 blood biochemistry samples were received from 1.12.2015 to 30.11,2016. HI was assayed by bichromatic spectrophotometric readings and calculated using specific algorithms (Architect c16200, Abbott). Percentages of hemolyzed blood samples (HI>50, corresponding to hemoglobin > 50 mg/dL) were calculated monthly for every department.

RESULTS: Throughout the study period, there were 10.09% of hemolyzed blood samples. In the ED, ICU and Cardiology seasonal significant differences were detected between Jul-Oct and the other 4-month periods, but not in the other departments. The hemolyzed samples percentages were: ED 12.58 (total samples 49955), ICU 7.19 (9517), Outpatient Care 3.2 (3835), Pediatric ED 23.8 (3622), Vascular surgery 7.7 (2242), Cardiology 7.7 (2045).

CONCLUSION: The incidence of hemolyzed samples was higher in children and in samples from the ICU, probably due to a difficult extraction in the former, and because of usual collections from arterial lines in the latter. Our greatest challenge is the Emergency Department, whose samples represent half of our activity. For them, it would be useful to review protocols, study the impact of sample type, the effect of transport and the elapsed time to reach the laboratory.

ID: 12593

INFLUENCE OF HEMOLYSIS, ICTERIA AND GLUCOSE ON ACTIVATED ASPARTATE AND ALANINE AMINOTRANSFERASE (AAST AND AALT) AND NON-ACTIVATED ASPARTATE AND ALANINE AMINOTRANSFERASE (AST AND ALT) ACTIVITIES

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BACKGROUND-AIM: The aim of this study was to evaluate interference of hemolysis, icteria and glucose on activated aspartate and alanine aminotransferase reagents (aAST and aALT) in comparison with non-activated enzyme forms (AST and ALT) in serum and plasma samples.

METHODS: The study was carried out in University Department of Chemistry, Medical School University Hospital Sestre Milosrdnice, Zagreb, Croatia (July-October 2016). Hemolysis was achieved by mechanical trauma. Seven aliquotes of EDTA blood sample were drawn through the needle for increasing number of times; hemolyzed plasma was separated after centrifugation (H index 0.4-14.9). For icteria and glucose interference testing, serum pool was spiked with exogenous bilirubin (Sigma-Aldrich, MO, USA) and 554 M glucose solution to achieve a final concentrations of 0-1000 µmol/L for bilirubin and 0-115 mmol/L for glucose. Enzyme activities, glucose, bilirubin and HIL indices were measured in duplicate on the Architect c8000 analyzer (Abbott, IL, USA) using original reagents. Bias calculated against the initial value was compared with external quality control criteria (ALT, aALT: 12%; AST, aAST: 15%).

RESULTS: For AST and aAST, hemolysis caused significant positive bias at the lowest level of hemolysis (bias: 29.6% and 32.4%, respectively). ALT and aALT activities were affected only in highly hemolyzed samples (H index: 8.9, bias: 17.2% for ALT; H index: 14.9, bias: 24.3% for aALT). Significant bias was observed in highly icteric samples for ALT (bilirubin: 745 µmol/L, bias: -38.9%), AST and aAST (bilirubin: 1017 µmol/L, bias: -70,7%; 22,8%, respectively). Icteria didn't cause significant changes in aALT activity. For glucose interference testing, all bias values were bellow acceptance criteria.

CONCLUSION: Both forms of AST and ALT are affected in the same way by hemolysis (false increased) and glucose (no interference). High concentration of bilirubin interferes with AST and aAST, ALT but not with aALT.

A DIFFERENT APPROACH FOR EVALUATING BIOCHEMICAL TEST RESULTS: A MACHINE LEARNING ALGORITHM - C4.5 **DECISION TREE**

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BACKGROUND-AIM: There are more errors in preanalytic phase than analytic phase that is focused recently by biochemistry specialists. Having an idea about the quality of samples is the most cost-effective case. The levels of hemolysis, lipemia and bilirubin are the most commonly used parameters to evaluate quality of samples. In clinical laboratories, it needs to be more effective information programs to evaluate test results. We aimed to create an evaluation model and a machine learning algorithm that could be used by biochemical specialists to evaluate quality of samples and test results. Also we compared the decisions obtained from our information program and specialists.

METHODS: Demographical and analytic data were collected from 1847 patients analyzed in Dokuz Eylul University Central Laboratory between 01.01.2013 and 30.06.2013 and were evaluated using guidelines and specialists' opinion. The data were used as a training set and the model was created by using the C4.5-Decision Tree algorithms in WEKA® (Waikato, New Zealand). We compared the decision tree algorithms and specialists' evaluations.

RESULTS: The kappa score was 0,711 after the investigation interrater agreement between the algorithm and specialists' evaluation. The model sensitivity was 57,5% and the specificity was 100%. The more valuable parameters for creating decision tree were hemolytic index, chloride, calcium, potassium, sodium and glucose.

CONCLUSION: It has been seen that our decision support system could categorize the test results as "approval" or "not" and could specify the error probabilities because of its high specificity. "Hemolytic index value" was found the first branch point in the decision tree model and was also found as the most valuable parameter for test reporting.

ID: 12612

ESTIMATING POTASSIUM CONCENTRATIONS IN SIMULATED HEMOLYTIC SAMPLES UNDERESTIMATES THE TRUE POTASSIUM CONCENTRATION

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BACKGROUND-AIM: Hemolytic samples are one of the most challenging pre-analytical issues in laboratory medicine. To estimate the in vivo potassium concentrations in blood samples with evidence of in vitro hemolysis correction factors have been proposed. Most correction factors have been estimated from artificially derived hemolytic samples and, due to different techniques used to induce hemolysis, a wide variety of correction factors has been reported (range 0.2-0.5 mEq/L, per increase of 1 g/L in hemoglobin concentration). We aimed to estimate a correction factor for the increase in potassium concentration due to in vitro hemolysis in serial samples obtained from hospital patients.

METHODS: We retrospectively extracted five consecutive potassium concentrations and corresponding hemolytic indices from our laboratory records for two periods of two months (n1=18.000 and n2=22.000). Potassium and free hemoglobin concentrations were measured on COBAS analyzers. We assumed that a hemolytic sample is either preceded or followed by a non-hemolytic sample, where the potassium concentration of non-hemolytic sample served as baseline. For each sample pair with a hemolytic sample the ratio between the change in potassium concentration and the change in hemolytic index was calculated.

RESULTS: According to our model, the increase of 1 g/L in hemoglobin concentration results in an increased potassium concentration of 0.6 mEg/L.

CONCLUSION: We present an alternative approach to calculate correction factors for estimating in vivo potassium concentrations in hemolytic samples. Our results suggest a greater increase of potassium levels due to in vitro hemolysis than estimated by studies that used hemolytic samples produced by artificial means. As a result, correction factors as calculated by using artificial means underestimate the true potassium concentration in samples with evidence of in vitro hemolysis. Therefore, the use of correction factors is not recommended.

Sample stability

ID: 12379

A COMPARISON OF THE PERFORMANCE OF A NON-GEL PLASMA BLOOD SEPARATION TUBE, BD BARRICOR™, WITH GEL SEPARATOR SERUM AND PLASMA TUBES FOR THE MEASUREMENT OF A RANGE OF IMMUNOASSAYS & CARDIAC **MARKERS**

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BACKGROUND-AIM: Blood collection tubes that contain a gel barrier offer advantages, e.g. transportation & sample stability, however some analytes can interact with the gel over time altering their concentration e.g. TDMs. The gel itself can block instrument probes, and in separated plasma samples, cells in the supernatant can reduce analyte accuracy & sample stability. The BD Vacutainer® Barricor™ Plasma Blood Collection tube has a non-gel barrier reducing this potential for analyte and instrumentation interactions. Evaluations were conducted of the BD Barricor™ tube in comparison with gel tubes for selected special chemistry analytes and cardiac markers.

METHODS: Blood was collected into BD Barricor™, BD PST™II (Plasma/Gel) and BD SST™II Advance (Serum/Gel) tubes. Special chemistry analytes (385 subjects) and cardiac markers (95 subjects), were measured on a number of instruments. Within-tube stability was also measured for some cardiac markers. Results for the BD Barricor™ samples were compared with BD PST™II and BD SST™II results using Deming regression to calculate mean biases and 95% limits.

RESULTS: BD Barricor™ tubes were equivalent or acceptable when compared with BD PST™II and BD SST™II Advance tubes for the measurement of β-hCG; C3; Cortisol; CRP; Estradiol; Ferritin; Folate; FSH; Free Thyroxine; Free Triiodothyronine; Haptoglobin; IgA, IgG and IgM; Luteinizing Hormone; Progesterone; Rheumatoid Factor; Testosterone; TSH; Total PSA; Total Thyroxine; Total Triiodothyronine; Transferrin & B12. BD Barricor™ tubes were equivalent for the measurement of the cardiac markers CKMB; Total CK; Cardiac Troponin I; Cardiac Troponin T. Samples that had been stored in BD Barricor™ tubes for 24h at RT were equivalent when compared with initial time for CKMB, Cardiac Troponin I and Cardiac Troponin T

CONCLUSION: BD Barricor™ tubes are suitable for the measurement of cardiac markers and a wide range of special chemistry analytes on a number of instrument platforms

ID: 12395

DEFINING A STANDARDISED CENTRIFUGATION PROTOCOL FOR A RANGE OF BD VACUTAINER® BLOOD COLLECTION **TUBES**

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BACKGROUND-AIM: Centrifugation is key in the creation of high quality samples and conditions differ depending on tube type. With the intro $duction \ of \ BD \ Vacutainer^{\circledast} \ Barricor^{\texttt{TM}}, centrifugation \ recommendations \ for \ the \ complete \ BD \ array \ of \ tubes \ range \ from \ 1300 \ to \ 5000g \ and \ 3 \ to \ 5000g \ and \ 3 \ to \ 5000g \ array \ of \ tubes \ range \ from \ 1300 \ to \ 5000g \ and \ 3 \ to \ 5000g \ and \ 3 \ to \ 5000g \ array \ of \ tubes \ range \ from \ 1300 \ to \ 5000g \ and \ 3 \ to \ 5000g \ and \ 3 \ to \ 5000g \ array \ of \ tubes \ range \ from \ 1300 \ to \ 5000g \ and \ 3 \ to \ 5000g \ array \ of \ tubes \ range \ from \ 1300 \ to \ 5000g \ and \ 3 \ to \ 5000g \ and \ 3 \ to \ 5000g \ array \ of \ tubes \ range \ from \ 1300 \ to \ 5000g \ and \ 3 \ to \ 5000g \ array \ of \ tubes \ range \ from \ 1300 \ to \ 5000g \ array \ of \ tubes \ range \ from \ 1300 \ to \ 5000g \ array \ of \ tubes \ range \ from \ 1300 \ to \ 5000g \ array \ of \ tubes \ range \ from \ 1300 \ to \ 5000g \ array \ of \ tubes \ range \ from \ 1300 \ to \ 5000g \ array \ of \ tubes \ range \ from \ 1300 \ to \ 5000g \ array \ of \ tubes \ range \ from \ 1300 \ to \ 5000g \ array \ of \ tubes \ range \ from \ 1300 \ to \ 5000g \ array \ of \ tubes \ range \ from \ 1300 \ to \ 5000g \ array \ of \ tubes \ range \ from \ 1300 \ to \ 5000g \ array \ of \ tubes \ range \ from \ 1300 \ to \ 5000g \ array \ of \ tubes \ range \ from \ 1300 \ to \ 5000g \ array \ of \ tubes \ range \ from \ 13000g \ array \ of \ tubes \ range \ from \ 13000g \ array \ of \ tubes \ range \ from \ 13000g \ array \ of \ tubes \ range \ from \ 13000g \ array \ of \ tubes \ range \ from \ 13000g \ array \ of \ tubes \ range \ from \ 13000g \ array \ of \ tubes \ range \ from \ 13000g \ array \ of \ tubes \ range \ from \ 13000g \ array \ of \ tubes \ range \ from \ 13000g \ array \ of \ tubes \ range \ from \ range \ range \ from \ range \ range \ range \ from \ range \$ 10min. Various centrifugation conditions can lead to laboratory inefficiency by not maximizing automated throughput or by requiring manual processes. One strategy is to standardize centrifugation protocols (g force, time & temperature) for all tube types. This study evaluated 3000g for 5min at 20°C for a range of chemistry serum and plasma, with/without gel, and coagulation tubes.

METHODS: Duplicate BD Vacutainer® Serum CAT, SST*MII Advance (Serum/Gel), PST*MII (Plasma/Gel), Lithium Heparin, Sodium Citrate & Glucose tubes and one BD Barricor™ tube were collected from 40 healthy subjects. One tube of each type was centrifuged under BD recommended conditions and the second at 3000g for 5min at 20°C along with the BD Barricor™. Samples were visually inspected for quality indicators before testing. B was assessed by retesting after 24h at 4°C.

RESULTS: Using potassium as a key indicator of sample quality, initial results demonstrate no significant difference between recommended and standardized conditions for each tube type. BD CAT: 3000g, $5min(4.28 \pm 0.27 \text{ mmol/L})$ vs. 1300g, $10min(4.31 \pm 0.28 \text{ mmol/L})$, p = 0.308; BD SSTTMII: 3000g, 5min $(4.32 \pm 0.28 \text{ mmol/L})$ vs. 2000g, 10min $(4.32 \pm 0.275 \text{ mmol/L})$, p = 0.872; BD PSTTMII: 3000g, 5min $(3.93 \pm 0.28 \text{ mmol/L})$ vs. 2000g, 10min (3.94±0.30 mmol/L), p=0.417; BD Lithium Heparin: 3000g, 5min (3.89±0.30 mmol/L) vs. 1300g, 10min (3.90±0.30 mmol/L), p=0.538; BD Barricor™: 3000g, 5min (3.97±0.30 mmol/L). Further, complete barrier formation was achieved and integrity maintained in all samples.

CONCLUSION: The standardized centrifugation condition of 3000g for 5min at 20°C is acceptable for BD Vacutainer® Serum CAT, SSTTMII, PST™II & Lithium Heparin for the determination of potassium.

ID: 12397

INFLUENCE OF PROLONGED COAGULATION TIME AND STORAGE ON THE HUMAN SERUM METABOLOME

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BACKGROUND-AIM: Blood sample-based tests through their minimal-invasive accessibility, cost-effectiveness, and high coverage of human biochemical entities are a prime approach for diagnosis, prognosis, and prediction of diseases, identification of drug targets, and monitoring of therapeutic success. Serum represents one of the most commonly used sample types in clinical routine measurements. Therefore, the quality of these samples is of paramount importance for the generation of credible results. Since many small biochemical compounds, also called metabolites, are sensitive to pre-analytical variation, metabolite profiling is a well-suited technology to assess the quality of serum samples.

METHODS: Human serum samples of healthy volunteers were subjected to different pre-analytical confounding conditions, i.e. prolonged coagulation time of 6h or prolonged storage of serum at room temperature (RT) for 24h. Mass-spectrometry based metabolomics, MxP® Broad profiling, as well as a targeted MxP® Quality Control Serum assay were applied for metabolomics analysis.

RESULTS: Prolonged coagulation time and storage of serum resulted in significant (p < 0.05) increase in the levels of 20% and 14% of serum metabolites, respectively. Likewise, the levels of 4% and 7% of analyzed metabolites decreased significantly (p < 0.05) upon prolonged coagulation and storage, respectively. Compromised serum samples were identified by the targeted MxP® Quality Control Serum assay with very high accuracy.

CONCLUSION: It was shown that the serum metabolome is sensitive to prolonged coagulation and storage at RT. Hence, in order to ensure reproducible and credible results in clinical research and, in particular, in "omics" studies it is mandatory to implement a thorough sample quality management. The MxP® Quality Control Serum displays promising results with respect to evidence-based sample selection and quality-driven sample stratification.

ID: 12398

EFFECT OF STORAGE TIME AND TEMPERATURE ON RETICULOCYTE COUNTS AND DERIVED PARAMETERS

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BACKGROUND-AIM: Reticulocyte counts provide essential support to the diagnosis and classification of anemia, but these cells mature in vitro after sampling. We evaluate the effects of sample storage time and temperature on reticulocyte counts (Ret count), reticulocyte Hb content (RetHe) and immature reticulocyte fraction (IRF).

METHODS: We prospectively selected 50 patients with reticulocyte counts in a range representing diverse erythropoiesis status, <20*109 /L - > 100 *109/ L. Hemogram (CBC) was analyzed within 2 hours from collection in a XN analyzer (Sysmex Diagnostics, Kobe, Japan). After the baseline CBC was performed samples were divided into two aliquots, one was stored at room temperature (20-22 °C, A) and another at 4 °C (B). Additional CBC were performed on aliquots at 6 and 24 h after storage (t6, t24). For mean values of each measurand and condition (time and temperature) mean percentage deviation (MPD) was calculated related to the value after collection (t0) and compared with standards for desirable bias (TEa) and reference change value (RCV). MPD = [(tx-t0)/t0] x 100% Patients were divided based on Ret counts at t0, aplasia, normal or reticulocytosis; we recorded % of discrepancy in the classification when CBC at t6 and t24 was used to evaluate erythropoiesis.

RESULTS: All parameters measured in aliquots A had MDP higher than those in aliquots B both at t6 and t24, surpassing TEa and RCV. Aliquots B t24h: Ret count had MDP 20%, higher than TEa (16.8%), lower than RCV (31%); IRF had MDP 26% higher than TEa (19%) lower than RCV (34%). RetHe MPD was 3.8% (t6) and 4.5% (t24) both lower than TEa and RCV. 11% and 23% of patients initially with normal erythropoiesis were classified as aplasia (aliquots A t6 and t24, respectively). Aliquots B 6% (t6) and 12% (t24).

CONCLUSION: Time and temperature are critical to obtain reliable results of reticulocyte parameters. A delay in processing samples could produce misleading results in the evaluation of erythropoiesis.

EFFECT OF STORAGE TIME AND TEMPERATURE ON COMPLETE BLOOD COUNTS

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BACKGROUND-AIM: K2EDTA anticoagulated blood samples are used in the Hematology Laboratory, but cellular elements have limited stability. We evaluate the effects of sample storage time and temperature on complete blood count (CBC).

METHODS: We prospectively selected samples from 35 patients. Hemogram (CBC) was analyzed within 2 h from collection in a DELLDYN Sapphire (Abbott Diagnostics). After the baseline CBC was performed samples were divided into two aliquots, one was stored at room temperature (20-22 °C, A) and another at 4 °C (B). Additional CBC were performed after storage at 8, 24, 48 and 72 h. White Blood Cell Count (WBC), Hemoglobin (Hb), Red Blood Cell (RBC) count, Hematocrit (Hct), Mean Cell Volume (MCV), Mean Cell Hemoglobin (MCH), Mean Cell Hemoglobin Concentration (MCHC), RBC distribution width (RDW), Platelets (PLT) and Mean Platelet Volume (MPV) were studied. Mean and 95% CI for the average changes observed in CBC on storage of all aliquots were plotted and differences with baseline were evaluated using t Student (parametric) or Wilcoxon (nonparametric) tests; P < 0.05 was statistically significant.

RESULTS: In samples A significant changes occurred after 8 h for Hct, MCV, MCH, MCHC, RDW and MPV (P = 0.0001) and after 24h for PLT (P=0.003). In samples B significant changes occurred after 8 h for MCV, MCHC and MPV (P=0.0001); after 24 h (Hto, P=0.0001) and after 48 h (RDW P = 0.0016). Hb and RBC remained stable in aliquots A and B the whole period. WBC remained stable in aliquots A the whole period and changed in aliquots B after 72 h (P = 0.014).

CONCLUSION: Hb, RBC and WBC are stable parameters; results for erythrocyte and platelet indices are not reliable after 8 h. Cells tend to swell and parameters reflecting cellular volume are affected from storage at different temperatures. Only fresh whole blood, analyzed in less than 8 hours from venipuncture, should be used in our daily practice to assure a correct evaluation of erythropoiesis and thrombopoiesis.

ID: 12406

WITHIN-TUBE STABILITY OF SELECTED ROUTINE CHEMISTRY ANALYTES AND IMMUNOASSAYS IN BD VACUTAINER® BARRICOR™ PLASMA BLOOD COLLECTION TUBES COMPARED WITH BD VACUTAINER® PST™ II AND SST™ II ADVANCE TUBES AT MULTIPLE TIME POINTS POST-CENTRIFUGATION

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BACKGROUND-AIM: Cellular contamination in plasma can affect the stability of certain analytes. The mechanical separator technology in BD Vacutainer® Barricor™ Tubes helps reduce cellular contamination in plasma as compared to current gel separator tubes. Studies evaluated the stability of selected chemistry analytes and immunoassays in BD Barricor™ Tubes compared with BD PST™ II and BD SST™ II Tubes at multiple time points.

METHODS: Ninety-two subjects participated in the study, which evaluated within-tube stability for selected chemistry analytes and immunoassays. The mean bias with 95% limits was calculated for each analyte to assess clinical equivalence or acceptable performance for BD Barricor™, BD PST™ II and BD SST™ II Tubes at 24h, 3 days, or 7 days versus 0h. For analytes that were not stable at 24h in BD Barricor™ or BD PSTTM II Tubes, a second study was conducted with 40 subjects to determine stability at 6h, 12h, and 18h from centrifugation with room temperature storage. BD SSTTM II Tubes were not evaluated for analyte stability < 24 hours.

RESULTS: Within-tube stability was noted for 7 days in BD Barricor™ Tubes with these exceptions: folate was stable for 24h and CO2 and glucose were stable for 18h. For BD PSTTM II Tubes, 7-day within-tube stability was observed for all analytes except LDH and K, which were stable for 24h, Phos, which was stable for 3 days, and CO2 and glucose, which were stable for 18h. For BD SST™ II Tubes, 7-day within-tube stability was observed for all analytes except CO2, complement C3 and K, which were stable for 3 days; triglycerides and folate were not stable at any time point $\geq 24h$.

CONCLUSION: Within-tube stability of 7 days was observed in BD Barricor™ Tubes for all analytes and immunoassays except folate, which was stable for 24h and CO2 and glucose, which were stable for 18h. BD Barricor™ Tubes demonstrated better stability than BD PST™ II Tubes for analytes impacted by cellular contamination.

SPUTUM SAMPLES STABILITY – DATA REGARDING SHIPMENT CONDITIONS (DURATION AND TEMPERATURE) AND THE INFLUENCE OF THOSE PARAMETERS ON SAMPLES VIABILITY

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BACKGROUND-AIM: The study was performed to measure the impact of temperature conditions and shipment duration on the viability of the sputum samples. The classic approach is to transport the sputum samples as soon as possible to the laboratory, usually in max. 2 h in ambient conditions, due to the loss of some of the most sensitive pathogens as H. influenzae, H. parainfluenzae and Str. pneumoniae.

METHODS: Sputum samples from five regions from Romania placed at various distances to Synevo Central Lab (Bucharest) were collected in sterile containers and shipped refrigerated in max. 12 h to SCL, using gel-packs. Samples were collected from patients with non-cystic fibrosis bronchiectasis. The temperature was monitored with thermologgers. Gram stain smears were used for sputum sorting. Only adequate sputum samples were plated, incubated, and bacteria were identified using Maldi Biotyper Brucker.

RESULTS: Between March 2015 and October 2016, form 452 sputum samples received, 44 samples (9.73%) were rejected as saliva or saliva contaminated and 260 samples (57.52%) were positive. Pathogens identified in those samples were: Haemophilus influenzae (9.62%), Haemophilus parainfluenzae (7.69%), Moraxella catharrhalis (1.54%), Pseudomonas aeruginosa (59.23%), Staphilococcus aureus (13.85%), Stenotrophomonas maltophilia (1.15%), Streptococcus pneumoniae (6.92%). Negative samples were 148, on all of the plates growing non-pathogen microflora. Shipping temperature was between 3-8 C, with a mean temperature of 6.2 C.

CONCLUSION:

- 1. All the sputum samples transported in refrigerated conditions were viable
- 2. Low temperature was not a factor for sample rejection
- 3. A 12 h duration for refrigerate shipping ensure samples viability
- 4. Sensible species as Haemophilus influezae, H. parainfluenzae and Streptoccocus pneumoniae were identified in 24.23% of the sputum samples, a normal percentage of recovery

ID: 12441

PREANALYTICAL STABILITY AND STORAGE PRESERVATION IN DIFFERENT BLOOD COLLECTION TUBES OF MICROBICIDE AS MEASURED BY FLOW CYTOMETRY

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BACKGROUND-AIM: Phagocytosis of bacteria is followed by digestion using production of Reactive Oxygen Species (ROS). This production can be impaired in rare genetic diseases or under exhaustion in severe diseases. Production of ROS can be easily measured by flow cytometry using DihydroRhodamine123 (DHR3) producing Rhodamine123 (R123) in presence of H2O2. However, functional tests need to be performed in short delay and bacteria capture needs opsonisation. Several protein interactions are calcium dependent and are inhibited by chelators. Phagocytosis usually measured by lithium-heparin tube but cannot be stored for more than 12h. In order to assess which sample is best for microbicidal activity measurement with good preservation, we compared the stability of phagocytosis test over time and between (lithiumheparin and EDTA anticoagulant).

METHODS: Polymorphonuclears (PMN) and monocytes are challenged with E coli or PMA and labelled with monoclonal antibodies anti CD14, anti CD16 and DHR123 in one step on whole peripheral blood for 20 minutes in 37°C water bath. The sample are fixed and red blood cells are lysed and resuspended in PBS-bovine serum albumin 10 g/L. EDTA samples were supplemented with Calcium. The method was validated on fresh sample and after some delay over 4 days.

RESULTS: E Coli induced good DHR123 production by blood PNN collected on Heparin or EDTA reconstituted with Calcium. By repeating the E coli stimulation 10 times on two samples on the same day, by the same operator, we could observe a good repeatability for PMN CD16 labelling (CV = 2.8 and 4.0%). R123 fluorescence repeatability was measured in 20 EDTA samples stored at 4 °C for four consecutive days not so good on PMN (CV = 19.2 and 54.3). Despite rapid degradation of PMN, we observed stable results within the first 24h of preservation.

CONCLUSION: EDTA (containing ca++ buffer) is suitable for routine testing of microbicidal activity that can be performed within 24h of preservation at 4°, provided calcium reconstitution.

THE DIFFERENCE OF PRO-GRP TESTING USING TWO COAGULATION TUBES OF BD COMPANY IN ABBOT 12000 PARTICLES CHEMILUMINESCENCE DETECTION SYSTEM

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BACKGROUND-AIM: To assess the difference of Pro-GRP testing using normal serum tube and inertia separation gel-coagulation tube of BD Company in Abbot I2000 particles chemiluminescence detection system.

METHODS: Collected blood samples from 60 cases outpatients, which blood sampling into two tubes including normal serum tube (Code: 367957) and inertia separation gel-coagulation tube(Code: 367812) of BD Company, blended the sample according the handbook and placed 10 minutes, then obtain the serum by centrifugal (1300g, 10min, 25°C). Detected the Pro-gastrin-releasing peptide(Pro-GRP) of serum in Abbot I2000 particles chemiluminescence detection system in 30 minutes and 60 minutes. Compared the differences of two tubes groups in two time pionts by paired t-test.

RESULTS: There was no difference in two tubes groups in 30 minutes(p = 0.901), the mean bias was 3.5%, also it had no difference between 30 minutes and 60 minutes in normal serum tube group(p = 0.773), the mean bias was 7.9%. There was difference in two tubes groups in 60 minutes (p < 0.001), the mean bias was 18.4%, also it had difference between 30 minutes and 60 minutes in inertia separation gel-coagulation tube group (p = 0.01), the mean bias was 13.3%.

CONCLUSION: Normal serum tube was more bebefit to test Pro-GRP in Abbot I2000 particles chemiluminescence detection system, if using inertia separation gel-coagulation tube, the sample must be tested in 30 minutes after centrifugal.

ID: 12480

STABILITY OF POTASSIUM (K), SODIUM (NA), CHLORIDE (CL) AND HEMOLYSIS INDEX (HI) IN SERUM AFTER PROLONGED (8 HOURS) CONTACT WITH BLOOD CELLS

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BACKGROUND-AIM: According to Croatian Chamber of Medical Biochemists 6 hours (h) from blood sampling is acceptable time for measuring serum electrolyte concentration in primary tube. We aimed to evaluate the stability of K, Na, Cl and HI in serum primary tube, during 8 hours at room temperature.

METHODS: Venous blood was collected from 50 hospital patients. Analysis was carried out 2, 4, 6 and 8 hours after the initial measurement in serum in centrifuged and decapped primary tube on Abbott Architect c8000 chemistry analyser. Friedman ANOVA and RM ANOVA tests were used for statistical analysis. Level of significance was 0.05. Mean bias (%) was calculated for each parameter at different time points and compared with desirable specifications based on biological variation for total error (TE) and imprecision, respectively, as follows: K: 5.61%, 2.3%; Na: 0.73%, 0.3%; Cl: 1.5%, 0.6%. HI acceptance criteria was 14.93% (coefficient of variation of pooled serum after 20 serial measurements). Percentage of samples in which acceptance criteria weren't met at different time points was calculated. Stability was considered acceptable if > 90% of samples met acceptance criteria at that time point.

RESULTS: Initial concentrations were: K: 4.3(2.4-7.3) mmol/L, Na: 139 ±4 mmol/L, Cl: 105 ±6 mmol/L, HI: 0.035 (0-0.25). There was a statistically significant positive bias for Na (4h: 1%) and Cl (8h: 2%) (P < 0.001). K was stable for up to 2h and 8h according to criteria based on imprecision and TE respectively. Two hours after initial measurement, TE criteria weren't met in 10% (Na) and 28% (Cl) of samples and criteria for imprecision weren't met in 35% (Na), 54% (Cl) and 30% (HI) of samples.

CONCLUSION: Clinically significant change of K, Na and Cl occurs already after 2h in primary tube at room temperature. To achieve optimum quality of results, the degree of hemolysis (HI) should not be estimated in centrifuged and decapped primary tubes stored for longer than 8h.

STABILITY OF ENZYME ACTIVITIES IN SERUM SAMPLE – ALANINE AMINOTRANSFERASE (ALT) AND ASPARTATE AMINOTRANSFERASE (AST) AND THEIR ACTIVATED FORMS (AALT, AAST)

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BACKGROUND-AIM: Activated alanine aminotransferase (aALT) and activated aspartate aminotransferase (aAST) are IFCC recommended methods with pyridoxal-6-phosphate as a reaction activator, unlike ALT and AST. Manufacturer declares the stability of serum sample for enzyme activity at room temperature and 4°C without specification of sample type (primary tube or aliquot). The aim of this study was to evaluate stability of aALT, ALT, aAST and AST in primary tube and aliquot at both temperatures.

METHODS: Study was carried out in University Department of Chemistry, Medical School University Hospital Sestre Milosrdnice (Zagreb, Croatia) from May to June 2016. Manufacturer's declared stabilities are: ALT, aALT: 3 days; AST, aAST: 4 days at room temperature and ALT, aALT; AST, aAST: 7 days at 4°C. Four serum samples were used for the study: aliquot stored at room temperature and at 2-8°C and sample in primary tube at both temperatures. Enzyme activities were measured daily during 10 days in duplicate on Architect c8000 analyser (Abbott, Illinois, USA) using original reagent kits. Mean value between two measurements and bias (%) for each sample regarding the initial activity were calculated. Acceptance criteria was defined as external quality control criteria (ALT, aALT - 12%; AST, aAST - 15%).

RESULTS: Enzyme stability for ALT and aAST confirmed manufacturer's declarations, aALT activity didn't meet the acceptance criteria: it was stable 1 day (aliquot; day 2: bias = 33.3%) and 4 days (primary tube; day 5: bias = -12,7%) at room temperature and 6 days (aliquot; day 7: bias = 15.6%) at 2-8°C. It's activity in primary tube at 2-8°C wasn't changed during the tested period. In primary tube sample at room temperature, AST activity was stable 3 days (day 4: bias = 18,3%) while in other samples manufacturer's specifications were confirmed.

CONCLUSION: ALT and aAST are more stable enzymes than aALT and AST. Enzymes are stable longer when samples are stored at 2-8°.

ID: 12494

INVESTIGATION OF POTENTIAL QUALITY IMPROVEMENTS USING BD VACUTAINER® BARRICOR™ FOR PRIMARY CARE **GLUCOSE SAMPLES**

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BACKGROUND-AIM: Accurate glucose analysis for primary care requires the use of fluoride plasma samples to preserve glucose levels for analysis. Should other Biochemistry tests be required, then an extra sample and form are usually required, resulting in extra processing for both primary care source and the laboratory. The newly introduced BD Vacutainer® Barricor™ tube has a novel mechanical separator which can improve plasma sample quality post-centrifugation, potentially making it useful for glucose preservation should separation occur quickly. This study aimed to compare use of this tube with current BD Vacutainer® Fluoride/EDTA tubes from primary care.

METHODS: Patients attending a local GP surgery were consented to provide an additional (Barricor™) blood sample. These samples were separated immediately on-site (4000g for 3 min). Both BarricorTM and Fl/EDTA samples were transported to the laboratory and processed under the same conditions.

RESULTS: Matched FI/EDTA and Barricor™ tests results (n = 30) were analysed for statistical and clinical significance. Results showed that BarricorTM tube glucose results were significantly higher than Fl/EDTA tubes (p < 0.01).

CONCLUSION: Use of Barricor™ tubes with immediate separation appears to be superior in maintaining plasma glucose levels than Fl/EDTA tubes with later separation in the laboratory. As Barricor™ tube plasma can also be used for many other analytes, there are economic advantages to be obtained from (1) no requirement or cost from taking an extra Fluoride plasma tube, and (2) processing efficiencies due to reduced laboratory workflow.

INVESTIGATION OF POTENTIAL QUALITY IMPROVEMENTS WHEN USING BD VACUTAINER® BARRICOR™ FOR SAMPLES **COLLECTED FROM PRIMARY CARE**

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BACKGROUND-AIM: Laboratory services to primary care are often compromised by restricted transport and delayed sample separation. Unreportable results needing repeat samples leads to extra stress on GP surgeries and patients alike. The newly introduced BD Vacutainer® Barricor™ tube has a novel mechanical separator which can improve plasma sample quality post-centrifugation and potentially reduce analytical errors. This study aimed to compare use of this tube with current BD Vacutainer® SST™ tubes from primary care.

METHODS: Patients attending a local GP surgery were consented to provide an additional (Barricor™) blood sample. These samples were separated immediately on-site (4000g for 3 min). Both Barricor™ and SST samples were transported to the laboratory and processed under the same conditions.

RESULTS: Matched SST and Barricor tests results were analysed for statistical (p < 0.01) and clinical significance. Results for Na (n = 442), K (n=375), URE (n=444), Ca (n=163), ALP (n=374) & ALB (n=374) were significantly lower with Barricor™ tubes. Results for Cl (n=335), CO2 (n = 335), PO4 (n = 43) & folate (n = 81) were significantly higher with Barricor™ tubes. Though analytically different, there would be no clinical impact on patient care. However, 67 (15%) potassium results were not reported in the SST sample due to a breach in transport delay. 6 SST samples had a folate under the ref range when the BarricorTM result was normal.

CONCLUSION: The use of the BD Barricor™ over the current SST resulted in no significant clinical differences for the majority of analytes reviewed to date. However, use of Barricor™ tubes should reduce repeat testing for K and folate. Further work is required to evaluate other analytes and to review the benefits in line with reduced GP collections.

ID: 12499

IDENTIFICATION OF INDICATORS FOR PTS MONITORING IN ROUTINE

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BACKGROUND-AIM: Pneumatic Tube Systems (PTS) are commonly used in hospitals for shipping blood samples to diagnostic laboratories. The setting of PTS must be correctly performed in terms of speed to avoid hemolysis of biological samples, which could be the origin of interferences for numerous hematological and biochemistry dosages. Nevertheless, increased hemolysis levels are commonly associated with blood samples shipped through the PTS. Unfortunately, currently, no methodology is clearly defined to determine the quality procedures to monitore the PTS in routine use.

METHODS: In this study, we aimed to identify indicators, enabling monitoring of 10 PTS lines used in routine at Hospices Civils Hospital in Lyon (France) to transport biological samples. In the first part of the study, we measured the impact of "speed" on the absolute count of acceleration/deceleration (expressed in g) using MSR 165 detectors. For all analysis, the paired t-test was used to compare these parameters, and the P value was calculated.

RESULTS: For the first time, we have identified relevant indicators, independent from the blood samples themselves, enabling biologists to identify potential incidents occurring on PTS in routine use. They allow biologists to differentiate hemolysis due to PTS internal malfunction from other causes (issue during sampling itself, for instance). The findings also clearly demonstrated that using such a tool, the PTS lines were behaving differently, and should be considered and checked independently for routine monitoring.

CONCLUSION: To conclude, PTS is a safe mean to transport blood products allowing a clear reduction of the sample-processing time. However, it must be checked, in routine, with independent indicators as defined by this study, in order to avoid alteration of biological samples quality.

IMPROVING GLUCOSE MEASUREMENTS: VALIDATION OF THE NEW GRANULATED CITRATE PHLEBOTOMY TUBE

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BACKGROUND-AIM: Current laboratory procedures for gestational diabetes mellitus (GDM) screening are sub-optimal and can result in misdiagnosis as stringent cut-off values are used with a single oral glucose tolerance test (oGTT), while measurement of glucose concentrations is complicated by in-vitro glycolysis. Recently, it was recognized that glycolysis is directly and completely inhibited in citrated phlebotomy tubes, as opposed to the commonly used Sodium-Fluoride tubes. Two types of citrated tubes are available, either with a liquid additive (e.g. Vacuette® Glucomedics) or granulate additive (for Europe exclusively Vacuette® FC Mix).

METHODS: Both tubes were tested in 22 healthy volunteers. Glucose concentrations were measured after different incubation times (0-48 hours) and temperatures (~20°C, 37°C). FC Mix tubes were clinically validated in 40 pregnant women undergoing oGTT. As a reference NaF-oxalate tubes handled according to the World Health Organization (WHO) recommended method (immediate cooling and centrifugation within 30 min) were used.

RESULTS: Glucose concentrations measured in Glucomedics tubes show a significant bias of 4.6% (CI 3.2-6.1) compared to reference tubes. For FC Mix tubes no significant deviation was observed (bias 0.4%; CI -1.0-1.7). Furthermore, glucose concentrations are stable for at least 48 hours at ~20°C and 24 hours at 37°C. Validation of the FC Mix tube for use in oGTT demonstrated a small bias of 0.06 mmol/L at t=0 min before (CI 0.03-0.13) and t = 120 min after 75g glucose load (CI -0.02-0.21).

CONCLUSION: Glucose concentrations are significantly overestimated when applying the manufacturer's correction factor for dilution in Glucomedics tubes. The new FC Mix tube handled according to normal laboratory routine performs equal to the WHO method for optimal pre- and analytical conditions, also for screening for GDM by oGTT. Thus, FC Mix appears to be a feasible alternative for reliable results for diagnoses in diabetes care.

ID: 12509

EFFECT OF RE-CENTRIFUGATION ON THE TROPONIN ANALYSIS

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BACKGROUND-AIM: Cardiac Troponin I (cTnI) has become an essential marker in both diagnosis and monitoring of myocardial injury. Fibrin clots and microparticles are two factors that affect cTnI results. That kind of interferences can be prohibited by re-centrifugation or use a clot activator. Aim of this study is to investigate the effect of re-centrifugation on the Troponin analysis by using different kind of tubes.

METHODS: 60 patients whom had chest pain are recruited into the study. Samples were drawn in BD Vacutainer SST tubes, centrifuged at 4000 rpm in 15 minutes, after 30 minutes of collection. Patients were regrouped with the regard of their cTnI levels; 30 patient had high troponin levels (case), 30 patient had normal troponin values (control). After that, a 5 microliter serums of patients were transferred to BD Vacutainer plastic serum tube. These two tubes were re-centrifuged in 4000 rpm for 15 minutes. Measurements are performed in Access analyzer (Beckman Coulter) with chemiluminescene immunoassay method. Statistical analysis was performed with SPSS 21.0 programme.

RESULTS: Mean cTnI levels of the case group, cTnI-SST-recentrifuged and cTnI plastic serum tube were 32.69, 31.72 and 29.59, respectively. There was a significant difference between mean cTnI levels of case group and cTnI-plastic serum tube group (p:0.021). Mean cTnI levels of the control group, cTnI-SST-recentrifuged and cTnI plastic serum tube were 0.02 for all groups. There was not a significant difference among groups.

CONCLUSION: It is known that invisible microfibers or other particle matter in incompletely centrifuged serum interferes with troponin assays. It is seen a significant difference between mean cTnI levels of case group and cTnI-plastic serum tube group (p:0.021). Positive troponin values are important for the patients with cardiac pain. However, our study should be improved with the higher number of samples.

EFFECT OF RE-CENTRIFUGATION ON THE ELECTROLYTE ANALYSIS

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BACKGROUND-AIM: Centrifugation is required to remove all microclots and fibrin strands from serum, Erroneous results may occur for numerous chemistry and immunochemical assays in the presence of such materials. Re-centrifugation of tubes is not recommended by CLSI and other tube manufacturers. Re-centrifugation of gel separator tubes disrupts the barrier and may allow mixing of cell components. Potassium is the one of the analytes which is affected by re-centrifugation. In this study, we aimed to investigate the effect of re-centrifugation on the electrolyte analysis. METHODS: One hundred and twenty patients which had no history of electrolyte disorders, had participated the study. Blood samples were taken into the BD Vacutainer SST tubes, centrifuged in 4000 rpm for 15 minutes after 30 minutes of collection. After that, a 5 microliter serums of patients were transferred to BD Vacutainer plastic serum tube. These two tubes were re-centrifuged in 4000 rpm for 15 minutes. Measurement of electrolytes were re-performed with ion-selective technique in Beckman Coulter AU 680 autoanalyzer. Statistical analysis was performed in SPSS 21.0 programme.

RESULTS: Mean Na level of first measurement, Na-SST-recentrifuged and Na-plastic serum tube were 139.27 ± 3.39,141.70 ± 8.75 and 141.97 ± 8.90, respectively. Mean K level of first measurement, K-SST-recentrifugated tube and K-plastic serum tube were 4.27 ± 1.05 , 4.48 ± 1.14 and 4.37 ± 1.05 , respectively. There was a statistically significant difference between the mean Na level of first measurement and Na level of-SST-recentrifugated tubes. (p:0.000) There were statistically significant differences between the mean levels of K in both three type of measurement (p:0.000). CONCLUSION: As expected, re-centrifugation in both processed SST's and plastic tubes resulted in both falsely elevated potassium and sodium.

ID: 12522

STABILITY OF THE SAMPLES FOR THE DETERMINATION OF AMMONIUM ION

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BACKGROUND-AIM: Ammonium derives from the protein metabolism and from the action of the intestinal bacteria on the proteins of the diet. Its deterioration takes place in the liver by means of the urea cycle, and, afterwards, it is eliminated with the urine through the kidneys. Hiperammonemia can have important repercussions at a brain level, so it is really important to analyse it in the Accident & Emergency laboratories. Our aim is checking the stability of the sample to determine the ammonium ion 2 hours after its extraction.

METHODS: 100 samples of plasma-EDTA from external consultation patients in our hospital have been analyzed in the reception and centrifuge and 2 hours later, cold maintaining. Method used: - InfinityTM Ammonia Reagent, analyst AU680 (Beckman Coulter®): direct enzymatic test based on the next reaction: NH4+α-ketoglutarate+NADH--> Glutamate+NAD+H2O Enzyme: Glutamate dehydrogenase (GLDH)

RESULTS: Comparing the two different measures of ammonium, it is possible to obtain a coefficient of correlation: r = 0,988 and a coefficient of determination: r2 = 0,976. First analysis (X), 2 hours later (Y). – Average (μmol/L): 39,42(X); 42,78(Y) – Median (μmol/L): 34,50(X); 36,50(Y) Through the regression model Passing-Bablok, it is obtained a curve b = 1,029 (confidence gap 95% from 1,000 to 1,095) and an ordinate in the origin of 2,059 (confidence gap 95% from -0,405 to 3,000). Regression line: Y = 1,029X + 2,059 (X = first analysis, Y = 2 hours later) First analysis (µmol/L): [50; 100; 200] 2 hours later (µmol/L): [53,51; 104,96; 207,86] % of difference: [6,56; 4,72; 3,78]

CONCLUSION: There aren't statistically significant differences either in the curve or in the ordinate of origin.

Accepting a coefficient of variation <10%, in the studied conditions, the samples keep stable without any important clinical significance.

ID: 12533

COMPARISON OF THE STABILITY OF BIOCHEMICAL ANALYTES IN SERUM FROM BD VACUTAINER® SERUM SEPARATOR TUBES AND PLASMA FROM BD VACUTAINER® BARRICOR™ TUBES

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BACKGROUND-AIM: Preanalytical factors such as transportation conditions, storage temperature or improper handling affecting the patients' results should be taken into account. Our aim was to evaluate the effects of duration before/after centrifugation, re-centrifugation, and storage conditions on the stability of 19 parameters in different tubes.

METHODS: Samples collected from 40 healthy volunteers in the morning after 8 hours fasting and were allocated into 6 groups. First and second groups were centrifuged immediately and stored at room temperature (RT) or 4°C until analyzed at 0, 2, 6, and 12 h. Third and fourth groups were stored at RT or 4° C for 2, 6, 12 h then were centrifuged and analyzed. Fifth and sixth groups were centrifuged after, stored at RT or 4°C and re-centrifuged at 2, 6, and 12 h before analysis. 19 commonly requested biochemical parameters were analyzed with Beckman Coulter AU 5800. The amount of change observed from the baseline results for each condition tested were calculated as relative bias percentages, which were compared to the total change limit [√(2.77 CVa)^2 + (0.5 CVi)^2] for analytical performance and reference change value [2.77√ $(CVa^2 + CVi^2)$ for clinical performance.

RESULTS: At a glance only ALT, magnesium and uric acid were stable in SST under every condition; while albumin, ALP, ALT, AST, chloride, direct bilirubin, GGT, magnesium, total bilirubin, total protein, uric acid were stable in Barricor™ tubes. Many parameters were stable in SST both at RT and 4°C when centrifuged immediately. Late centrifugation was worse than re-centrifugation at room temperature. BarricorTM was better than SST in every aspect.

CONCLUSION: Duration between centrifugation and analysis, standing time before centrifugation, standing conditions, and re-centrifugation may cause serious bias in results which should be taken into consideration for central laboratories receiving samples from peripheral units.

ID: 12544

DOES TEMPERATURE HAVE AN EFFECT ON COAGULATION PARAMETERS?

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BACKGROUND-AIM: In this study we aimed to detect the effect of different temperatures on coagulation parameters in our emergency laboratory with the use of cooling and non-cooling centrifuge machines.

METHODS: Duplicate samples were collected into sodium citrate tubes from 45 patients were centrifuged at the same time with noncooling (group 1) and cooling centrifuges (Group 2) in Ankara Numune Training and Research Hospital emergency laboratory, Inner temperatures of the centrifuges were recorded during the study. Afterwards, PT, aPTT, D-dimer and Fibrinogen measures were carried out. Data obtained were analysed with suitable statistical techniques.

RESULTS: No statistically significant difference was detected between groups in any test parameter (PT, aPTT, D-dimer and Fibrinogen) ((p> 0,05).

CONCLUSION: Our study showed that there isn't any effect of the inner temperatures of cooling and non-cooling centrifuges on coagulation test results. But from other previous studies, it is obvious that several laboratory tests are being affected from temperature; so cooling centrifuges should be available at the laboratories.

ID: 12552

CEREBROSPINAL FLUID SPECTROPHOTOMETRY. DO WE NEED TO HURRY?

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BACKGROUND-AIM: Cerebrospinal fluid spectrophotometry (SPFM) is a laboratory assessment used in diagnostic work up of subarachnoid hemorrhage. We aimed to investigate consequences of delayed processing of CSF samples.

METHODS: 46 samples delivered to the laboratory until 30 minutes from collection were enrolled in the study. If sufficient amount of CSF has been obtained, sample was divided into 2 aliquots (A and B). In the first aliquot (A) routine biochemical and cytological examination was performed. SPFM examination was immediately performed in centrifuged aliquot. Values of net oxyhemoglobin absorbance (NOA) and net bilirubin absorbance (NBA) were calculated. Sample B was left in the laboratory at room temperature under daylight and after 60 minutes was centrifuged and SPFM was performed. Wilcoxon non-parametric test (paired version) was used for comparison between groups. We classified all samples (in both groups A and B) as "positive", "negative" or "inconclusive" according to decision limits as recommended in

RESULTS: Median erythrocyte count was 13.5 (0-87040/µl). Changes in NOA and NBA levels in samples A in comparison with samples B did not reach statistical significance (p=0.68, 0.21 resp.). We found one case classified as "positive" when processed immediately, but aliquot with delayed processing was classified as "inconclusive" due to decrease of NBA.

CONCLUSION: We found no statistically significant changes in NOA or NBA values in CSF samples analyzed immediately in comparison with samples analyzed 60 minutes after. However in one case sample A and sample B were differently classified. Thus, samples with borderline values should be classified carefully especially when delayed processing is conceivable.

THE STABILITY OF PROSTATE-SPECIFIC ANTIGEN IN WATER EXTRACT OF SEMEN FROM DRY SPOTS

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BACKGROUND-AIM: Sample preparation of Prostate-Specific Antigen (PSA) in dry spots could be used for diagnostic purpose in Laboratory and Forensic Medicine. The aim of the study was to investigate stability of PSA in water extract of semen, dried up on gauze (WESDG).

METHODS: Semen of volunteers (high concentration) and semen diluted in distillated water in proportions of 1+1 (middle concentration) and 1+19 (low concentration) was put on sterile gauze (0.5 sm x 0.5 sm) in volume of 1 µL and dried in temperature 18-20 °C for 3-4 hours. Samples were extracted with 100 μL of distillated water in +4 °C for 18 hours. The extract was aliquoted to six portions per each level of concentration and stored at +4 °C for up to 3 days. PSA amount was measured by an Immunoenzyme method (IEM) in the three obtained concentrations (29.4 µg/L, 17.3 µg/L and 7.7 µg/L) twice daily during three days. The average, within- and between series imprecision and percentage of lost PSA activity were calculated.

RESULTS: The within series CV% (repeatability) was in about 2.0-3.4 % for high, 3.2-5.2 % for middle and 3.7-8.0 % for low concentrations of PSA. Reproducibility between series during three working days was 6.0 % for high, 11.1 % for middle and 18.2 % for low concentrations. Activity of PSA decreased from 1st to 2nd day to 93.2 % in high, 91.6 % in middle and 82.0 % in low concentrations, and at the end of 3rd day it was 86.4 %, 78.2 % and 60.1 %, respectively.

CONCLUSION: PSA activity in water extract of semen on dry spots decreased by time in up to 40.0% in three days and up to 18.0% in one day depending of concentration as stored at +4 °C. The precision of measurements was concentration dependent also and ranged between 2.0 % and 8.0 %. Thus investigation of PSA in WESDG demonstrated accepted stability for one working day for correct expertise in different contents of semen.

ID: 12580

STABILITY INVESTIGATION OF URINARY NEUTROPHIL GELATINASE-ASSOCIATED LIPOCALIN

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BACKGROUND-AIM: It is well known that urinary neutrophil gelatinase-associated lipocalin (uNGAL) is an early biomarker of acute kidney injury. The aim of our study was to investigate short-term and long-term stability of uNGAL.

METHODS: Levels of uNGAL were measured by chemiluminescent microparticle immunoassay on ARCHITECT i2000SR (Abbott Laboratories, USA) in first morning urine void of 20 patients with chronic kidney disease. Samples were transported to the laboratory on ice within 15 minutes after collection and immediately measured per 5 repeats (first series). Besides, every sample was aliquoted and stored at the temperature -22 °C, +4 °C and +22 °C during 4 hours, 24 hours, 48 hours and 7 days per each temperature regime and measured per 5 repeats in each series. Additionally result were compared in duplicates for 20 patients per each temperature and time of storage and estimated in pairs using Dahlberg formula, The average, within- and between series imprecision were calculated. Statistical significance was estimated with the Student paired t-test. Coefficient of variation (CV%) compared with estimating of significant difference by F-test.

RESULTS: Within series CV% was in about 1.6-6.1% depending on concentration of uNGAL without significant differences of storage conditions (p>0.2). The concentrations of uNGAL in samples stored for four hours at +22 °C, for two days at +4 °C, and one week at -22 °C did not differ compared with results of uNGAL measured immediately (p > 0.1). The levels of uNGAL in samples stored for two days at +22 °C and for seven days at +4 °C were different from initial concentration (p < 0.04).

CONCLUSION: Concentrations of uNGAL are stable for four hours at +22° C, for two days at +4 °C, and at least one week at -22 °C, that allows sample transportation in this conditions of storage.

SIMPLIFYING ACTH PREANALYTICAL PROCEDURE

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BACKGROUND-AIM: Adrenocorticotropin (ACTH) concentration is unstable due to proteolytic degradation. In practice, recommended preanalytical procedure that includes collecting samples in pre-cooled tubes, transporting on ice and using cooled centrifuge, can present major logistical problem. Recently, new test tubes containing EDTA and protease inhibitor aprotinin (Greiner Bio-One) have become available.

Our aim was to investigate the effect of EDTA/aprotinin additive on ACTH concentration at room temperature (RT) analyzed at different time points in comparison with ACTH concentration obtained according to recommendations.

METHODS: Study was performed according to CLSI guideline GP-34A. Samples were collected from 20 volunteers in: (I) EDTA tubes using recommended procedure analyzed immediately (EDTAice); (II) EDTA/aprotinin tubes, centrifuged and analyzed immediately at RT (AprotininRT); (III) EDTA/aprotinin tubes, centrifuged and analyzed after 2 h at RT (AprotininRT2h) and (IV) EDTA/aprotinin tubes, centrifuged and analyzed after 4 h at RT (AprotininRT4h). ACTH measurements were performed with electrochemiluminescence method on Roche Cobas e601 analyzer. The difference between EDTAice and other three tubes was tested using paired samples t-test. ACTH concentration was expressed as mean (standard deviation). RESULTS: ACTH concentrations in EDTAice, AprotininRT, AprotininRT2h, AprotininRT4h were 3.56 pmol/L (1.50), 3.72 pmol/L (1.55), 3.64 pmol/L (1.48) and 3.54 pmol/L (1.44), respectively. Paired samples t-test revealed significantly higher ACTH concentration in AprotininRT and AprotininRT2h (P < 0.001 and P = 0.020, respectively), while there was no difference in AprotininRT4h (P = 0.582) compared to EDTAice. CONCLUSION: According to our results, ACTH can be sampled at RT in EDTA/aprotinin tubes and sample processing can be delayed for up to 4 h. Also, ice-chilling of sample is not effective as EDTA/aprotinin additive in stabilization of ACTH concentration, questioning if recommended procedure should be revised.

ID: 12613

STABILITY OF URINE SPECIMENS KEPT AT ROOM TEMPERATURE AND IN REFRIGERATOR FOR FOUR HOURS

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BACKGROUND-AIM: Urine is a very important biological material for diagnosis, treatment and following of many diseases. It is preferred that the urine analysis is performed in fresh urine. However, in some cases, such as a device failure, analysis may not be possible immediately. It may take several hours to perform the analysis. In this study, we investigated the effect of delayed urine analysis on specimens kept at the room temperature and in the refrigerator for four hours.

METHODS: Fresh urine specimens (n=50) separated three aliquots. One of them were immediately analysed on an Iris Diagnostics iQ200. The other aliquots were analysed after were kept at room temperature and in the refrigerator four hours. The agreement between results at the room temperature and in the refrigerator and the initial values was evaluated with the use of concordance correlation coefficients (pc) and Cohen's kappa coefficients (κ). A pc > 0.90 and κ > 0.80 was accepted as good agreement, indicating that the analytes were stable.

RESULTS: There was no agreement at room temperature and in the refrigerator and the initial values for protein, nitrite and pH.

CONCLUSION: Urinalysis must work with fresh samples. If a delay in analysis causes some changes in several parameters.

ID: 12621

SHORT-THERM STABILITY OF ROUTINE HAEMATOLOGY PARAMETERS AFTER REFRIGERATION

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BACKGROUND-AIM: Storage time and temperature may significantly affect routine haematology results. There is no unambiguous criteria for whole blood stability at 2-8°C. Our aim was to determine short-therm stability of routine haematology parameters in whole blood samples stored in different time intervals within 48 hours at 2-8 °C.

METHODS: Blood was collected from 20 patients using K3EDTA Vacuette tubes (Greiner Bio-One GmbH, Kremsmünster, Austria). Routine haematology parameters were measured using the Sysmex XT 1800i analyzer (Sysmex Corporation, Kobe, Japan) immediately upon receipt.

Whole blood samples where stored at 2-8°C and re-analysed after a 6, 12, 24 and 48 hours after baseline measurements. Paired samples t-test was used for statistical comparisons to baseline results. The level of significance was set at P<0.05. Mean biases from baseline results were compared to Ricos desirable biological specifications to define clinically relevant variations.

RESULTS: Statistically different results compared to baseline values were found for: WBC after 6, 12 and 48 hours (P=0.008, P=0.035 and P=0.012, respectively); hematocrit after 48 hours (P=0.031); MCV after 24 and 48 hours (P=0.008 and P<0.001); MCHC after 48 hours (P<0.001); platelets after 6 hours (P=0.038); MPV after 6, 12, 24 and 48 hours (P<0.001); neutrophils (%), lymphocytes (%) and eosinophils (%) after 48 hours storage (P=0.001, P=0.016 and P=0.015, respectively). MPV exceeded the predefined criteria of 2.3% for clinical significance in all the time points tested (4.9% after 6; 7.5% after 12; 10.3% after 24 and 14.1% after 48 hours). WBC, MCHC and lymphocytes (%) exceeded the criteria for desirable bias after 24 hours storage.

CONCLUSION: All the routine haematology parameters tested, except MPV, showed acceptable stability when stored at 2-8 °C within 24 hours, compared to predefined desirable specification for bias in our laboratory conditions.

ID: 12628

IS HEPARIN PLASMA THE ULTIMATE SAMPLE MATERIAL FOR ANALYSIS?

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BACKGROUND-AIM: In order to change the type of sample for analysis from serum to heparin plasma, we conducted a study to examine the quality of the samples and the stability of the analytes in the different types of sample.

METHODS: 55 samples were collected from randomly chosen patients on hemodialysis. Two types of tubes were used, serum with gel barrier, and heparin plasma with gel barrier. The tubes were carefully mixed, left on room temperature and later centrifuged according to the recommendations of the manufacturer. After the centrifugation, none of the samples had hemolysis, or were inconsistent in any way. All the samples were used as primary samples on the analytical system. The analyses were performed consecutively, on COBAS Integra 400 plus analytical system. All tests were performed with analytical precision and accuracy required by the MKC EN: ISO 15189 standard. The analytes tested were: Na, K, Ca, P, Fe, UIBC, Glucose, ALP, CRP and urea.

RESULTS: For the statistical evaluation we used Pearson Correlation and the t-test, calculated by excel. For Na and K Pearson Correlation was 0.92 and 0.87 and p < 0.001. For Ca, Fe, Glucose, and ALP Pearson Correlation was 0.95, 0.98, 0.99 and 0.99 and p < 0.01. For UIBC Pearson Correlation was 0.99 and p < 0.05. For P, CRP and urea Pearson Correlation was 0.98, 0.99 and 0.94 and p > 0.05.

CONCLUSION: No statistically significant difference was determined between heparin plasma and serum for Na, K, Ca, Fe, UIBC, Glucose and ALP. For P, CRP and urea the reason for the statistically relevant difference must be reconsidered, perhaps in the possible interaction of the analytes with the gel. Generally, heparin plasma proved to be a stable sample material for the analytes in question.

ID: 12632

EFFECTIVENESS OF LIQUID CITRATE BUFFER-FLUORIDE MIXTURE IN SARSTEDT S-MONOVETTE® GLUCOEXACT TUBES AS AN INHIBITOR OF IN VITRO GLYCOLYSIS

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BACKGROUND-AIM: Since glycolysis affects glucose determination in vitro, NACB and ADA recommend to immediately place sample tubes in ice-water slurry and to separate plasma within 30' or to use an effective glucose stabilizer.

For this reason a study was designed to evaluate glucose concentration in different Sarstedt S-Monovettes maintained at room temperature (R.T.) for 2h, compared to reference glucose according to NACB-ADA.

METHODS: Blood from 113 volunteers (36M, 77F), was collected into lithium heparin (LH), NaF/ Na2EDTA (NaF) and NaF/citrate buffer (Gluco-EXACT) tubes. GlucoEXACT tubes contain a liquid additive and requires a proper tube filling and the use of a correction factor (1.16). Reference plasma glucose was determined in LH tube placed in an ice-water slurry, centrifuged at 4°C with plasma separation from the cells within 30'. Samples were maintained at RT for 2h after drawing. Glucose testing of all samples of the same subject was performed in duplicate in the same analytical run using an hexokinase method.

RESULTS: Median glucose concentrations were 5.10 (IQR:4.90-5.50) mmol/L in reference tubes, 5.20 (4.92-5.52) mmol/L in GlucoEXACT tubes and 4.61 (4.40-5.10) mmol/L in NaF tubes after 2h at RT. Mean absolute bias was +1.12% (95% CI: 0.65-1.58%) for glucoEXACT tubes and -8.11% (-8.80-7.42%) for NaF tubes. Mean bias was within the desirable analytical goal $(<\pm 1.8\%)$ in 56.6% of glucoEXACT and in 3.5% of NaF tubes. ANOVA has shown statistically significant difference between glucose concentration in reference tube, NaF and glucoEXACT tube (P < 0.0001 and P = 0.0001, respectively).

CONCLUSION: GlucoEXACT tube showed to be superior to NaF alone in glucose stabilization after 2h at RT Tubes with only enolase inhibitors, such as NaF, should not be used to prevent glycolysis. If the NACB-ADA recommended treatment of blood sample is not possible the use of an acidified tube, such as glucoEXACT, is needed.

ID: 12635

STABILITY AND HOMOGENEITY OF WHOLE BLOOD SAMPLES IN CROOALM HEMATOLOGY SCHEME

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BACKGROUND-AIM: The observed impact of the commercial control material on discrepancies between different instruments in hematology has encouraged the Croatian Centre for Quality Assessment in Laboratory Medicine (CROQALM) to improve hematology scheme by ensuring fresh blood for quality control. Because of its reduced stability it is very important to assure samples which are stable during analysis and homogenous across all prepared aliquots. The aim of the study was to show tested stability and homogeneity of homemade samples for CROQALM hematology scheme during 2016.

METHODS: CROQALM hematology scheme is performed three times a year. Control sample for all rounds in 2016 was fresh blood from single donor with simulation of abnormal case in the second round by dilution. Donations, aliquots and testing were conducted in Croatian institute for transfusion medicine. Homogeneity and stability were tested on hematology analyzer (Ruby-Abbott/USA) for red blood cells (RBC), white blood cells (WBC) and platelets (PLT) according to ISO 13528:2005(E). Acceptance criteria for both homogeneity and stability was Ss ≤ 0.3*Q (Ss is between-samples standard deviation is standard deviation for proficiency testing based on CLIA Acceptable Test Performance Criteria.

RESULTS: In three rounds during 2016 results of stability assessment have shown that the most unstable were WBC with stability varying from 48 to 72 hours. PLT were stable from 5 to 6 days and RBC 6 days. Stability was not altered when fresh sample was manipulated in order to simulate abnormal case. In all three cycles of CROQALM hematology scheme the homogeneity met the acceptance criteria.

CONCLUSION: According to tested stability and in order to avoid impact of control material on participant's results, samples must be delivered to all participants within 2 days after preparation and analyzed immediately upon receipt.

ID: 12642

PLASMA LACTATE MEASUREMENT AS AN EXAMPLE FOR ENCOUNTERED GAPS BETWEEN ROUTINE PRACTICE AND MANUFACTURES' SAMPLE-HANDLING INSTRUCTIONS

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BACKGROUND-AIM: Clinical laboratories are required to adhere to manufacturers' recommended sample handling instructions. However recommendations do not always reflect current practice and deviations necessitates extensive validation studies. This report uses plasma lactate testing, integral to sepsis risk assessment protocols, as an example. Our supplier recommends that sample be transported without ice and analyzed within 15 minutes of collection. At our institution sample transit may take up to 30 minutes. This study examined the effect of placing samples on ice

METHODS: Replicate samples were collected from patients (n=50) (with lactate request) and from normal subjects (n=50). One tube placed on ice, all transported to laboratory in less than 15 minutes. One tube kept at room temperature processed within 15 minutes, whereas the ice-stored tube was processed within 30 minutes. Lactate measured using Roche Diagnostics Cobas® analyzer. Additionally, to assess concordance between

lactate results and laboratory evidence of sepsis, one month retrospective lactate and associated blood culture results were obtained from patients presenting to the Emergency Department (ED) and suspected of sepsis. Statistical analysis performed using Microsoft Excel® software

RESULTS: Lactate results ranged from 0.8 and 12.4 mmol/L when processed normally compared with 0.8 and 12.1 mmol/L when stored for 30 minutes on ice. Correlation was (r=0.99, P<0.05%), and bias ranged from 0.0 to -0.4 mmol/L. 31.9% of ED patients had lactate values \geq 2.0 mmol/L, considered a trigger for sepsis risk assessment, compared with 68% with lactate of \leq 1.9 mmol/L. Percentage of patients with positive blood cultures was only 15%

CONCLUSION: Transporting samples on ice for lactate measurement produces a comparable result to manufacturer recommended shorter room temperature transit time. The discordance between percentage of positive cultures and elevated lactate may be due to different etiology or to falsely elevated lactate levels due to delayed sample transit time.

ID: 12646

STORAGE CONDITION EFFECTS ON NON-CHOLESTEROL STEROLS (NCSS) STABILITY AND QUANTIFICATION

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BACKGROUND-AIM: Cholesterol homeostasis disorders may cause dyslipidemia contributing to the development of different pathologies. NCSs serve as cholesterol synthesis markers (desmosterol and lathosterol), and cholesterol absorption surggate markers (campesterol, stigmasterol and ®-sitosterol). The study examined the most common storage condition effects, in order to ensure a reliable method and laboratory results. METHODS: Human serum and plasma pools were used for method optimization and validation, as well as stability studies. Freeze-thaw cycles were done with and without antioxidant addition. GC-flame ionization detection method (GC-FID) was used for NCSs quantitation.

RESULTS: Intra-assay variabilities were: desmosterol 4.30%, 4.02%; lathosterol 4.54%, 3.41%; campesterol 4.26%, 3.09%; stigmasterol 5.72%, 9.55%; *sitosterol 3.39%, 2.75%, while inter-assay variabilities were: desmosterol 7.86%, 7.70%; lathosterol 10.97%, 6.88%; campesterol 3.05%, 7.75%; stigmasterol 7.07%, 5.80%; *sitosterol 5.15%, 5.98% for serum and plasma, respectively. Recovery studies showed satisfactory percentage errors for each NCS: desmosterol b=0.976, b=0.934; lathosterol b=1.069, b=1.057; campesterol b=1.044, b=1.009; stigmasterol b=0.875, b=1.029; *-sitosterol b=1.055, b=1.005 in serum and plasma, respectively. Derivatized samples were stable up to 7 days at -20 °C. Different NCS concentrations were observed after the 1st freeze-thaw cycle, in antioxidant-free samples, and after the 4th cycle in antioxidantenriched samples.

CONCLUSION: Data on sample storage conditions and samples stability allow reliable results, minimizing the preanalytical and analytical variations, as proven by the validation results.

ID: 12647

WHEN SCREENING FOR DOWN SYNDROME, DO WE THINK ABOUT THE PREANALYTICS?

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BACKGROUND-AIM: On national level, only several specialized laboratories provide screening for Down syndrome. Our first aim was to confirm manufacturer claims that stability of free βhCG (free beta subunit of human chorionic gonadotropin) and PAPP-A (pregnancy associated plasma protein A) in serum at room temperature is 8h.

Requirements for sending samples by delivery service should depend on analyte stability. Most samples are being delivered within 24 or 48h. Our second aim was to investigate stability of free β hCG and PAPP-A in serum at room temperature within 24h and 48h.

METHODS: Samples were collected from 30 women who came for Down syndrome screening in tubes with clot activator. Free βhCG and PAPP-A were measured (Roche Cobas e601) in primary samples: initially (I) and after 8h (II) and also in aliquoted samples: after 24h (III) and after 48h (IV) (all samples were stored at room temperature). Data were not normally distributed (Shapiro Wilk test) and were expressed as median (inter-quartile range). Differences between measurements were examined by Wilcoxon test.

RESULTS: Free βhCG median concentration in initially measurement was 51,75 ng/mL (24,17-70,90), after 8h 53,45 ng/mL (25,58-74,69), after 24h 53,81 ng/mL (25,30-75,53) and after 48h 53,52 ng/mL (27,36-81,35). PAPP-A median concentration in initially measurement was 3495 mUI/L (2108-6267), after 8h 3562 mUI/L (2100-6378), after 24h 3712 mUI/L (2195-6484) and after 48h 3928 mUI/L (2307-6275).

Wilcoxon test showed statistically significant difference in free β hCG and PAPP-A concentration between (I) (II) (p < 0,001), (I) (III) (p < 0,001), (I) (IV) (p < 0.001).

CONCLUSION: This study revealed that manufacturer claims about free \(\beta hCG \) and PAPP-A stability at room temperature within 8h are not confirmed. Also, free \(\beta\) HCG and PAPP-A concentrations increase after 24h and 48h at room temperature. Therefore, delivery protocol should be revised according to the investigated stability.

Demand management

ID: 12401

DEMAND MANAGEMENT AND TEST REQUEST RATIONALIZATION AT THE "DEPARTMENT OF GENERAL INTERNAL MEDICINE WITH A RECEPTION POLYCLINIC TRACT WITH RESUSCITATION AND OBSERVATION OF PATIENTS"

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BACKGROUND-AIM: The hospital laboratories total laboratory costs depend on the optimal and selective use of laboratory tests. In order to rationalize and reduce costs, the ordering of laboratory examinations has been examined in the "Division of General Internal Medicine with a Reception Polyclinic Tract with Resuscitation and Observation Patients" (IPA) in the University Clinical Center of the Republic of Srpska. METHODS: Using a laboratory information system (LIS), the obtained results are ordinary tests for external patients who were examined in the IPA in the period from July to October 2016. Results are presented relatively as the share of ordinary tests in relation to the total number of requested tests for the most common laboratory tests commissioned with reference to tests outside the reference range.

RESULTS: In the observed period it has been ordered 9105 tests or an average of 6 tests per patient, in the total number of 1648 patients sent from the IPA, with about 30% of ordinary tests fell outside the reference range. There was a high frequency of ordering tests such as: blood count (BC), glucose (Glu), C-reactive protein (CRP), Troponin-T (TNT), CK, CK-MB. The frequency of their ordering was about 50% compared to the total number of ordinary tests. The percentage of these tests outside the reference range was higher in relation to the required number of tests: BC-30.5% (1224), Glu-66.8% (530), CRP 56.6% (446), CK-27.2 (711), CK-MB-12.5% (744) of TNT 45.0% (759).

CONCLUSION: The high degree of correspondence frequency ordering of particular laboratory tests indicates indiscriminate and schematic laboratory tests placing. In order to provide optimal patient examinations it's necessary for IPA to follow the latest guidelines of diagnostic algorithms, and at the same time to avoid unnecessary costs of laboratory diagnostics.

ID: 12409

ROUTINE PREOPERATIVE TESTING: IS IT REALLY RELEVANT AND NECESSARY?

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BACKGROUND-AIM: Preoperative testing (POT) is not appropriate in patients without significant systemic disease (ASA ≤ II) undergoing lowrisk surgery and those without risks factors for which diagnostic testing can not provide clarification of surgical risk. (American Society of Anesthesiologists www.choosingwisely.com). The aim of our study was to know our inadequacy degree in our preoperative testing and estimate in ASA \geq 3 patients the rate of pathological expected results based on clinical history (CH) examination.

METHODS: POT results (INR, Hemoglobin, Glucose and Creatinine) as well as ASA scores were retrieved from every patient for at random complete week in May 2016 via our LIMS. For each test every pathological result (PATH) and if it was expected or not, based on CH review and/or similar previous 6 months results, was registered. Cost of our POT was estimated in 22€ according to our Regional Health Taxes Law. RESULTS: TOTAL 141. Ex/Unex (INR;HEM;GLU;CRE):5/-;7/10;27/24;10/4; ASA ≤ 2 87; ASA ≥ 3 34; ASA Unknown 20.

87(62%) POT were inadequate (ASA ≤ 2 patients). This would imply 1.914€ weekly savings in our Lab (more than 95.000€ yearly savings if we extrapolate). Only 6% of PATH in ASA ≤ 2 patients would be unexpected being most of them Glucoses lower than 130 mg/dL. For ASA ≥ 3 patients all the INR PATH were expected. The low number of unexpected PATH obtained in this group means that most of these POT studies are inappropriate. In fact, a majority of preoperative assessments could be just based on previous findings and/or CH examinations. None INR PATH in the whole cohort was unexpected. Similarly, none of the unexpected PATH was a critic or a panic result.

CONCLUSION: Preoperative testing is associated with a high inadequacy degree since it is ordered not following clinical criteria and adds to significant avoidable cost for Healthcare Institutions. Besides, unexpected pathological findings are negligible and without barely real clinical impact.

PATHOLOGY TEST DEMAND MANAGEMENT THROUGH INFORMATION TECHNOLOGY

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BACKGROUND-AIM: The adequacy of requests for pathology tests is a key element in the quality of medical laboratory outcomes, in terms of patient safety, efficiency and effectiveness. The group of laboratories belonging to the public network of the Catalan Health Service carried out a previous study about pathology test demand variability showing important differences in requests for inpatients not justified by evidence-based medicine. The aim of the present work is to assess the impact of a demand management strategy applied in the computerized requisition system. METHODS: Limits on repetitive requests for inpatients were studied for the majority of tests. Time limits were established according to scientific evidence and/or consensus with physicians. The tool was designed and then developed by the computer system (SAP Argos Asistencial) team. After its validation in one of the laboratories of the group, the tool was implemented in the others throughout 2015. When a physician requests the test, if the requisition is affected by a time restriction rule, a pop-up alert appears and the last test results are displayed. The final decision about test cancellation or acceptance is in the hands of the physician.

RESULTS: During 2015 the group of laboratories received a total of 4.542.566 requests and 49.675.849 tests were performed. Among them 749.791 and 9.019.216 respectively were for inpatients. Examples of test rejection percentages (median of laboratories): Cholesterol 95.9, HDL-c 85.5, LDL-c 89.6, triglycerides 83.1, iron 87.6, ferritin 88.9, transferrin 91.4, cobalamin 91.3 and folate 87.6. Restriction time (days) was 7 for cholesterol and triglycerides and 30 for the rest of examples.

CONCLUSION: This strategy is very useful in managing pathology test demands for inpatients, and could be applied to other types of patients after the establishment of corresponding time restrictions.

ID: 12414

CONTINUOUS MONITORING OF DEMAND MANAGEMENT IN THE REALM OF ELECTRONICAL REQUEST BASED ON **CUSTOMISED PANELS**

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BACKGROUND-AIM: Design of custom-tailored electronical request forms through clinical profiles has been always a potential goal when it came to implementing test adequacy strategies. The aim of our study was to set up several indicators in order to monitor appropriateness of these formularies.

METHODS: In February 2011 a personalised e-form was agreed with Infectious Diseases Unit that was finally implemented in August 2011. This panel included 4 clinical profiles (2 diagnostic and 2 monitoring) that entails 90% of the outpatients clinical situation. Additionally, several tests not included in the profiles but frequently used by the Unit were displayed (FATs: Frequently Asked Tests). The rest of the tests from the full catalogue were only available through a search engine. A number of management indicators were monthly evaluated up to October 2016 (COS/REQ: Cost € per request; APTT/PT; FT4/TSH; PROF/REQ; AMY/REQ and CRP/REQ: Clinical profiles, Amylase and C-reactive protein requested per number of requests respectively). According to first results, different strategies were established in June 2013.

RESULTS: Feb2011-Jul2011 (COS/REQ; APTT/PT; FT4/TSH; PROF/REQ; AMY/REQ; CRP/REQ): 109,9; 100; 0; 45,4; 49,3. Aug2011-May2013: 121,3; 100; 100; 0,82; 87,1; 92,4. Jun2013-Oct2016: 83,3; 1,9; 14,5; 0,82; 0; 29. APTT/PT decreases after split Basic Coagulation FAT into Oral and Heparin Coagulation FATs. AMY/REQ and PCR/REQ decrease after getting rid of Amylase and CRP in all clinical profiles. FT4/TSH decreases after displaying Study (only TSH) and Control (TSH + fT4) of thyroid function as FATs. PROF/REQ increases after form development. COS/REQ decreases at the end.

CONCLUSION: Despite its potential, customised panels and clinical profile-driven requesting can result, if not implemented and managed carefully, to an increase rather than a decrease in inappropriate requesting.

ID: 12419

A PILOT STUDY TO IMPROVE THE APPROPRIATENESS OF VITAMIN D TESTING IN PRIMARY CARE

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BACKGROUND-AIM: In this study, we initially carried out an audit to review the appropriateness of vitamin D ordering compared with the National Osteoporosis Society Guidelines. Subsequently we designed a demand management intervention in the laboratory and then followed this up with a re-audit to determine impact.

METHODS: Over a 4 week period in March 2016, all request forms (166) for vitamin D analysis were reviewed upon arrival in the laboratory against a checklist based on the standards. Based on these findings decision was made to implement a policy where laboratory will only process request that meets the criteria for appropriate ordering set out in the National Osteoporosis Society Guidelines. GPs were informed about this new policy by circular. After the implementation of guidelines, re-audit was performed. Requests with inadequate details were held and reports were issued with the comment requesting additional clinical details in order to process. The samples were stored for up to 2 weeks awaiting further communication from referring clinicians to avoid any negative impact on patient care. Microsoft Excel was used to analyse data.

RESULTS: Only 14.5% (24) of 166 requests in the initial 4-week audit had recognised indications for vitamin D testing. The remainder had either inadequate or no clinical details at all (142 or 85.5%). After the implementation of guidelines a re-audit was performed and vitamin D requests were reviewed over the period of 4 weeks in August 2016 were reviewed. In total 266 requests were received, of these only 66 (25%) requests met the criteria and were processed.

CONCLUSION: A substantial proportion of vitamin D testing in primary care appears not to be justified by international guidelines. As vitamin D analysis is expensive implementation of criteria based on guidelines would limit inappropriate analysis and save health-service resources without affecting patients' health.

ID: 12487

URINARY ALBUMIN A POWERFUL TOOL NOT SUFFICIENTLY REQUESTED IN PRIMARY CARE IN SPAIN

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BACKGROUND-AIM: Our objective was to study the inter-practice regional variability, appropriate demand and temporal evolution in the request of urinary albumin (MAU) by general practitioners (GPs) in Spain.

METHODS: A cross-sectional study was conducted, enrolling clinical laboratories that attend Health Departments (HDs) inhabitants, belonging to the Spanish Autonomous Communities (AACCs). Laboratories were invited to report the number of MAU requested by GPs during 2012 and 2014. The MAU rate per 1000 inhabitants and the index of variability (Percentile90/Percentile10) were calculated, and compared between the groups of AACCs with more than 4 HDs participants (2014 edition) and time periods (2012 and 2014). Data are shown as median (interquartile range). In 2014, to investigate whether the MAU was appropriately requested to manage diabetes and arterial hypertension patients, the real request was compared to the theoretically ideal number, according to prevalence of known diabetes mellitus and arterial hypertension in Spain and guideline recommendations.

RESULTS: 76 laboratories participated in the 2012 edition and 110 in 2014, corresponding to 17679195 and 27798262 inhabitants (37.8% and 59.8% of Spanish population). The number of MAU requested per 1000 inhabitants was similar in both editions (78.2 (60.1) to 85.4 (55.4); P=0.235); the variability index was the same (4.6). There were significant differences between the 10 groups of AACCs with more than 4 participants and the eleventh with the others, ranging from 46.0 (33.1) to 125.8 (64.3) (P < 0.05) MAU per 1000 inhabitants. The theoretical thresholds for diabetes and arterial hypertension management were respectively 78 and 159 MAU per 1000 inhabitants. No laboratory reached it.

CONCLUSION: There was a high variability in the request of MAU that did not increase in a two year period, was different between AACCs and was not enough to manage diabetes and arterial hypertension management.

"REFLEX TEST" APPLICATION ON THYROID FUNCTION TEST REQUESTS AND EXAMINATION OF THE EFFECT ON HEALTH **EXPENDITURES**

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BACKGROUND-AIM: Thyroid function tests (TFT) are the most frequently requested endocrine tests from clinical laboratories. Although the guidelines published by the American and British Thyroid Associations suggest the use of thyroid stimulating hormone (TSH) as a first step test for thyroid diseases, algorithms for these tests are not considered. If the criteria are met according to the first test result, the request of the new test and the performed of it called reflex test. In our study, we aimed to investigate the effect of health expenditure of the TFT reflex test application which we initiated in our hospital.

METHODS: Patients whose serum TSH results were within range considered as euthyroid. The request of at least one of the free triiodothyronine or free tetraiodothyronine tests in addition to the TSH test in euthyroid patients was also considered unnecessary test. Cost analysis of unnecessary tests was performed six months before and six months after the reflex test application. The change in unnecessary test request rates was assessed by the "significance test of the difference between the two percent". A value of p < 0.05 was considered statistically significant.

RESULTS: After the reflex test, unnecessary test for all outpatient clinics decreased from 40.65% to 1.19% (p < 0.001). The unnecessary test rate from internal medicine clinics decreased from 27.4% to 0.86% (p < 0.001), while the other clinics' rate decreased from 52.18% to 1.54% (p < 0.001). With the cost analysis made, the unnecessary test request cost was reduced from 10.507 € (before reflex test) to 180 € (after reflex test) by the application of reflex test for six months.

CONCLUSION: The reflex test which is defined according to various guides and algorithms by hospitals, clinicians and laboratorians have positive effects on health care system due to its cost effectiveness. Therefore the use of other reflex tests and algorithms keep our interest on this topic as laboratory professionals.

ID: 12517

TRYPTASE: MANAGING THE INCREASING DEMAND OF A COMPLEX MEASURAND

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BACKGROUND-AIM: Tryptase is frequently requested in a hospital setting for '?anaphylaxis' and according to NICE Clinical Guideline 134 is appropriate with timed samples recommended at 0h, 3h and 24h.

METHODS: We undertook an audit with data from 145 patients to determine if; tryptase request frequency had increased over 18 months, whether the test was requested appropriately, and if so, whether NICE guidelines were followed.

RESULTS: The total number of requests from 1 Feb 2015 to 31 Jul 2016 was 183 from 153 presenting cases. Request frequency gradually increased across the study period with peaks in May and September. A majority were from emergency medicine or critical care (64), with the other main sources being dermatology (13) and endocrinology (13).

Sixteen request forms provided no clinical information making vetting problematic and 7 had clinical information that did not support a clinical need for tryptase. At an estimated cost of 4.67GBP per test, in addition to send away resources, this is an important finding.

In 24 episodes (19 patients; 13%) a raised tryptase was found. Patients with a raised tryptase had a diagnosis of allergy (1), anaphylaxis (9), hypotension (1), mastocytosis (1), myelodysplasia (1), urticaria (5), and indeterminate cause (1). A clinical diagnosis of anaphylaxis was given in 37 episodes, of which 9 had at least one other sample sent to the laboratory (between 2-4h post-presentation or at 24h) but only 4 sent the appropriate repeat specimens at 3h and 24h. Therefore, approximately 89% did not accurately follow NICE guidelines.

CONCLUSION: The audit suggests that the demand for tryptase is on the rise and highlights what clinical indications to expect for appropriate vetting of tryptase requests. However, we note there have been several inappropriate requests and lack of guideline compliance in a majority of cases. Clinical staff education is required to improve the suitability of future requests.

COMPUTER PHYSICIAN ORDER ENTRY (CPOE) INTERVENTIONS AND NT-PROBNP DEMAND MANAGEMENT

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BACKGROUND-AIM: Two particular strengths of Computer Physician Order Entry (CPOE) systems are, first, they include real-time decision support rules and second, interventions are sustained over time with little effort. The aim of our study was to adequate NT-proBNP test demand from Emergency Department (ED) through two different sequential strategies: 1) Re-design of the electronic request form and 2) Clinical Decision Supporting Rule (CDSR) regarding previous result and minimum retest interval for NT-proBNP in ED context.

METHODS: In February 2011 CPOE system was implemented in our Laboratory. In June 2011 (First intervention) NT-ProBNP was removed from the ED electronic form making it available only through a search engine. In March 2013 (Second intervention) a Hard Stop CDSR (automatic rule without exceptions) was implemented as follows: If there was an NT-proBNP result higher than 2.000 pg/mL in the previous year, test order would be cancelled and prior result would be displayed. In this way, requestor would know that recent heart failure is the most likely cause of patient dyspnea in ED, saving a very expensive test analysis. However, test was always available, if clinically necessary, via phone call to on-call pathologist. For each intervention period, median of number of NT-proBNP requested per 100 patients from ED was calculated.

RESULTS: February 2011 to May 2011 (Basic CPOE implementation): 12,7; June 2011 to February 2013 (Remove test from the form): 5,0 (-60,6% reduction); March 2013 to October 2016 (Hard Stop CDSR): 2,3 (-54,0% reduction). Global decrease was -81,9%. Neither quality of healthcare nor patient outcomes were altered during this post intervention time period after asking our providers repeatedly.

CONCLUSION: CPOE has allowed us to implement several strategies through a multifaceted approach, which appears to be most effective (in terms of test cost savings) and sustained in time unlike the rest of classical educative interventions.

ID: 12570

BETTER PRESCRIPTION SUPPORT FOR BETTER APPROPRIATENESS LABORATORY TEST REQUESTS

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BACKGROUND-AIM: Appropriateness of laboratory test requests is a challenge for laboratory manager. We know that the inappropriate laboratory test requests may over 25%. In absence of electronic prescription of laboratory assays in our hospital, we aimed to assess the impact of remodelling of laboratory profiles and computerization of this support on laboratory test requests.

METHODS: New strategy was proposed by Medical Biochemistry department and approved by protocols and good practices committee of Rouen University Hospital. The first change consisted of two laboratory profiles modifications on paper prescription ("Hydro-electrolytic" and "Liver function") in agreement with French nomenclature of laboratory tests (NABM). Second change was computerization of this support to collect physicians' test prescription. To assess modification effectiveness, the ratio of profile's test/most frequent profile's test requests were calculated and compared for pre- and post-modification periods. One-way ANOVA followed by Student-Newman-Keuls multiple comparison test were used to compare ratio using MedCalc software.

RESULTS: There was statitically significant decrease of requests for 3 of 5 tests included in "Hydro-electrolytic" profile. Reductions of creatinine, urea and glucose prescriptions were respectively more than 2, 2 and 17 percentage points. On "Liver function" profile, we observed decrease of bilirubin and @-glutamyltransferase requests with respectively less than 3 and 2 percentage points. There were no difference for plasma protein, bicarbonate, glutamate-pyruvate transaminase and alkaline phosphatase prescriptions.

CONCLUSION: New prescription support induced decrease of routine assays performed by laboratory. We assess that this strategy could decrease test requests by more than 4.5% per year (ie 100 000 tests) on most frequent biochemistry assays.

THE BEGINNING OF PREANALYTICAL PHASE: EVIDENCE BASED MEDICINE AND RATIONAL TEST REQUESTING

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BACKGROUND-AIM: Evidence Based Medicine is based on physician's clinical experience with available best evidence and patient's data in the diagnosis and treatment of patients. Unnecessarily requested tests increase the cost and also result in time wasting, over treatment and additional test requesting and worry for the patient. The aim of this study is to rewiev the effect of the simple arrangements by HIMS on rational test requesting and contribution to the costs, according to the evidence based medicine.

METHODS: Effectiveness and Efficiency Working Group was constituted with delegates from hospital management, clinics and laboratories. The WG primarily examined the clinicians' laboratory test request habits. Primarily personal test panels were removed from HIMS. According to the guidelines, in the HIMS, test requesting pages were divided into two groups, first and second level tests. Additionally, if the clinician requests same tests within a week for the same patient, a pop up warning on the request page was provided. The percent differences in test request rates before (Jan.-Nov. 2015) and after (Jan-Nov. 2016) arrangements was assessed by the proportion of test numbers to the total patient numbers (emergency patients + inpatients + outpatients).

RESULTS: With the arrangements made, despite the number of patients admitted to the hospital during this period increased by 3%, mean difference % of fT3, AntiTg, fPSA, CA125, CA19-9, CEA, CA 15-3, Lipase, Anti HBs, HBc IgM, HBe Ag, Anti HBe, Anti HBc Total, CMV IgG, Toxo IgG, Rubella IgG, folic acid, ASO and RF were decreased 41%, 33%, 48%, 23%, 20%, 15%, 25%, 39%, 67%, 25%, 17%, 26%, 22%, 39%, 26%, 20%,23%, 34%, 36%, respectively.

CONCLUSION: On the basis of evidence-based medicine, by the simple arrangements made on the HIMS test requesting page contributed to the effective and efficient use of laboratory tests. Laboratory cost increases, time wasting, over treatment and additional test requesting and worry for the patient can be prevented by these simple arrangements.

Preanalytical cases

ID: 12426

PRE-ANALYTICAL VARIABLES IN COAGULATION TESTING: FOCUS ON HIGH HEMATOCRIT

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BACKGROUND-AIM: High hematocrit (Hct) is one of less frequently considered preanalytical variables in coagulation testing. It influences anticoagulant to plasma ratio and thus clotting times. The proper ratio of citrate to blood in vacuum tubes should be 1:9. According to The Clinical and Laboratory Standards Institute (CLSI) H21-A5 guidelines labs should adjust the amount of anticoagulant for patients with hematocrit values > 0.55. We present a case of high Hct influence on coagulation screen and provide a practical citrate adjustment solution 'how to do it in real life'.

METHODS: On January 2016, a 30 years old cyanotic male with congenital heart disease is admitted to Central Hospital (Pärnu, Estonia) for conservative treatment. He had slightly increased blood pressure, irregular heartbeat, oxygen saturation 80%. Recurrent epistaxis solved with discontinuation of aspirin usage. Coagulation screening tests revealed INR >6, aPTT > 200s. Because clinical picture didn't match laboratory data patient was referred for laboratory consultation to explain abnormal coagulation tests.

RESULTS: Complete blood count (WBC 4.5x109/L, RBC 9.4x1012/L, Hb 268 g/L, Hct 0.78, PLT 50x109/L, MPV unmeasurable) clearly showed an effect of high Hct. Needed citrate volume (C, mL) was calculated according to CLSI formula: C = (1.85x10-3)x(100-Hct)xV (V - original tube volume). It was transfered to an empty tube without additives using a sterile insuline syringe, what allowed to retain vacuum in the tube for blood collection with correct citrate concentartion. Coagulation screen repeated from the citrate adjusted sample revealed INR and aPTT results within reference ranges.

CONCLUSION: The need of laboratory advisory services is evident, as clinicians might not be aware of preanalytical errors. Provided simple citrate volume correction technique might be useful in routine practice of blood collection, especially in cases with Hct values > 0.55.

EXCESSIVELY HIGH LEVEL OF BETA 2 MICROGLOBULIN IN URINE SPECIMEN, IS IT A SIGN OF LABORATORY ERROR OR **ANY PATHOLOGY?**

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BACKGROUND-AIM: Beta-2 microglobulin (B2M) is a small molecular weight protein that is found on the surface of the cells. It filters readily through the glomerular capillary wall, and then almost totally reabsorbed and catabolized in the proximal tubules. The reference range of B2M in urine samples is 0-0.3 µg/mL. Increased levels in the urine indicate renal tubule disease. B2M can be used as a marker to assess the renal tubular maturation in the human neonate. To B2M measurement, the urine specimen should be refrigerated until analysis is performed because of B2M can rapidly degrade when pH below 6. Excessively high levels of B2M are not often seen in labora-

METHODS: In October 2016, a random urine specimen was come from gynecology and obstetrics clinic to the central laboratory of our university hospital. According to patient identification number in hospital information system, she was 24 year-old (gravida 1 para 0), 18 weeks pregnant, healthy woman. There was no additional information about the patient. B2M level in the urine specimen was analyzed by turbidimetric method (Binding site, UK) and it was found as excessively high level (17,3 mg/L and 1572 mg/g creatinine). The values of calibration and quality control of analytic method were optimal. After the measurement was repeated three times, laboratory specialist communicated with the physician and then she can be learned that the urine specimen was obtained from bladder of a single male fetus presenting with oligohydramnios.

RESULTS: Finally, it was understood that this high level of B2M was derived from fetal megacystis that is an abnormally enlarged bladder appearing after 10 weeks of gestational age (GA), when the fetus starts to produce urine.

CONCLUSION: B2M level was elevated in fetal urine specimen. This condition was not preanalytical error. It is recommended that the patient's anamnesis information should be entered into the system in full.

POCT and preanalytics

ID: 12421

PREVALENCE OF PATIENT MISIDENTIFICATION MADE DURING BEDSIDE GLUCOMETRY MEASUREMENTS IN A LARGE **UNIVERSITY TEACHING HOSPITAL**

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BACKGROUND-AIM: Glucometers are widely used for monitoring inpatient hyperglycaemia at the point of care, but are known to be associated with pre-analytical errors including incorrect patient identification. The aim of this study is to determine the prevalence and types of patient misidentification errors occurring in a hospital-wide networked glucometry system in a large Irish teaching hospital so that targeted remedial measures could then be designed and implemented.

METHODS: Glucose results accompanied by the patients Medical Record Number (MRN) over a 1 month period from 1-30 November 2016 were extracted from the RocheTM CobasTM IT 1000 database into a MicrosoftTM Excel database for further analysis.

RESULTS: 14612 glucose results were generated by glucometers all around the hospital. Among those 4030 (28%) were QC and 10582 (72%) were patients results. 171 (1.6%) of the patient readings had preanalyical errors that could be detected by the Cobas IT system. There were 6 main groups, consisting of (1) the use of invalid MRN (n = 67, 39.2%), (2) no MRN entered (n = 53, 31.0%), (3) chart tracking barcode scanned as patient MRN (n = 33, 19.3%), (4) nonsense MRN (n = 15, 8.8%), (5) a staff member's personnel number entered as MRN (n = 11, 6.4%) and (6) a SymphonyTM Emergency Department (ED) IT system admission code (n=1, 0.5%). In respect of location, Staff in ED are responsible for the majority of the errors (n = 25) out of a total of 887 readings (x % error rate), followed by Ward A (n = 27) with a 680 readings/ month and Ward B (n = 14) with an 1184 readings /month (y % error rate). In some cases ID numbers for former staff had been used to operate glucometers.

CONCLUSION: This study demonstrates a high prevalence of patient misidentification and points to common reasons which should assist with development of better error reduction strategies.

OPERATIVE PROCEDURE'S APPLICATION IN THE MONITORING OF PRE-ANALYTICAL PHASE, NATIONAL AND INTERNATIONAL STANDARDS FOR THE POCT MANAGEMENT AND SUPERVISION

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BACKGROUND-AIM: Point-of-care testing (POCT) is defined as medical diagnostic testing performed outside the central clinical laboratory and near the site of patient care in order to improve quality of care. In AOUP the initial management of 43 Werfen blood gas analysers and 115 Roche professional glucose meters was not proper due to the lack of quality assurance programs. It was mandatory to ensure compliance with International Standards ISO and Italian regulatory requirements.

METHODS: The procedure was according to Clinical Laboratory Standards Institute (CLSI), ISO 22870 and Italian regulatory requirements. POCT network included: Laboratory Director (LD, responsible for the overall operation) or his authorised representative, Hospital Unit Medical Direction (HUMD), Operative Group (OG: laboratory/departments personnel that supervises/controls daily activities, including the responsibility for the instrument QC and verification of the pre-analytical phase), and POCT Multidisciplinary Directional Group (MDG: Laboratory, HUMD, Nursing Direction, HTA, Clinical Area), which evaluate POCT introduction/maintenance including designated authority, responsibility, and accountability.

RESULTS: Overall supervision and management of the POCT activity through remote monitoring of POCT devices; alternatively, periodic reviews of POCT performance conducted by OG and DL. OG takes care of appropriate use of the devices, device maintenance, pre-analytical requirements, quality control program documentation, and other requirements that may become apparent over time. Periodically, it carries out alignment preliminary checks among analyzers positioned in different departments.

CONCLUSION: With this Operative Procedure (OP), all PoCT are included, before the implementation, in a risk management/quality assurance program, starting pre-analitycal phase. A multidisciplinary organizational structure was put in place for proper functioning and optimum utilization of each POCT unit.

ID: 12591

REMOTE MANAGEMENT IN POINT OF CARE TESTING PROJECT. BLOOD GAS ANALYSIS AND PRE-ANALYTICAL PHASE

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BACKGROUND-AIM: Blood Gas Analysis (BGA) represents the complex PoCT out of the Laboratory, in a clinical facility: the multidisciplinary interaction between Laboratory, medical doctors and nurses. Quality control, pre-analytical phase control, traceability/documentation of the instruments'operating and training activity (for operators that are not used to work in a Laboratory), together with the networking/connection to information systems of BGA systems: the objectives of this work.

METHODS: BGA fostered Medicine Laboratory good practices' utilization. For decades, within PoCT, BGA technologies needed to be utilized by non-Laboratory personnel: technological innovation tried to solve the process' weaknesses, including the pre-analytical phase. AOUP has 43 BG analyzers (35 GEM Premier 4000 and 8 GEM Premier 3500 Werfen, Instrumentation Laboratory, Milan). The analyzers are interfaced with the Laboratory, through the internal intranet. The Operative Group (OG: Laboratory and Departments personnel) supervises/controls all daily activities, including the responsibility for the instrument quality control.

RESULTS: Inadequate maintenance, quality controls not carried out and/or badly managed, unreliable analytical data, difficult management (mainly in a critical setting): existing problems are now solved with the application of a new organizational model with dedicated Operative Procedure, thanks to the supervising system, to the evolved functions (remote instrumentation control, full actions traceability on supervising system and on blood-gas analytical system, operators training certification, etc.), to the utilization of BGA technology with intelligent software and Laboratory support for the management of the decentralized diagnostic activity.

CONCLUSION: During daily activity, operators do not need to undertake the research/resolution of anomalies/errors activities anymore, thanks to remote supervision and pre-analytical control phase. It follows that there is timesaving and better utilization of human resources.

PERFORMANCE OF PARALLEL ANALYSIS TO INCREASE THE PREANALYTICAL QUALITY OF POCT GLUCOSE **MEASUREMENTS**

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BACKGROUND-AIM: Since POCT glucose measurements play an important role in monitoring of the patient, there is a need for focus on preanalytical factors in POCT measurements in the hospital setting. Quality assurance by determination of precision alone is not sufficient, as the preanalytical phase greatly influences the test result. Thus, in Denmark GP's are instructed to regularly perform parallel analysis between POCT instruments and the laboratory to secure the quality of POCT measurements. We want to test, whether it is feasible to perform the same preanalytical quality assurance in a hospital setting. We hypothesize that there is indeed a need for increased focus on the preanalytical phase among hospital personnel, and that performing parallel analyses will improve the quality of POCT test results.

METHODS: At Odense University Hospital Hemocue 201 DM RT analyzers have been chosen as the standard POCT device for glucose measurements, and in 2017 a large number of Hemocues will be connected to Agure middleware to ensure automatic upload of results. During this process we aim to implement parallel analysis – initially as a pilot project at a few clinical wards.

RESULTS: Since the Hemocues are not yet connected, no results have been obtained from clinical wards. However, when performing OGTT (oral glucose tolerance testing) in our ambulatory, the fasting blood glucose concentration has for some time been measured by Hemocue and in parallel by the laboratory method. By comparing these results (all below 10 mmol/l), a mean difference of 0,46 mmol/l is found, and in 34,2% of 196 parallel analyses, results deviate beyond the limit of acceptance (<12,2%). An even larger number of results deviating more than acceptable is to be expected when performing parallel analysis on non-fasting patients.

CONCLUSION: We conclude that there is indeed a need for parallel analysis and focus on preanalytical factors when performing POCT glucose measurements in the hospital setting.

Other

ID: 12179

DIAGNOSIS IN RELATION TO PRE-PRE ANALYTICAL LABORATORY ERRORS IN BIOCHEMISTRY LABORATORY

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BACKGROUND-AIM: Pre-pre-analytical laboratory errors (LE) are not impressive that people working in healthcare really want to consider about, but they are actuality and the numbers aren't small. Given the importance of biochemistry laboratory tests on the overall medical decision-making process, pre-pre-analytical LE make a key contribution to the overall risk of error in healthcare. The study was conducted for a period of three months in a Biochemistry, Himalayan Institute of Medical Sciences, Dehradun India offering treatment for in- and out-door patients. In total randomly 10000 patients were screened who were only for Biochemistry investigations and tabulated for LE. The study was divided into two parts: (i) related to physiological factors-laboratory request forms and (ii) patient samples.

METHODS: The methods were opted with the registration number in the hospital followed by requisition forms required for patient's identification data. In-patient's phlebotomies were performed by biomedical Scientists -nurses, doctors and health care assistants from different wards of the hospital while out-patient's phlebotomies were collected at collection center by qualified technicians.

RESULTS: The percentage of pre-pre analytical LEs in out-patients were more as compaired to in-patients in related to request forms. Errors in patients address were the most common pre-pre analytical LE followed by clinical information's. It was also observed that in out-patients the location was also an important pre-pre analytical LE. Transcription errors contributed to the preponderance of pre-pre analytical LE. In the patient samples most frequently detected pre-pre analytical LE were order of collection followed by urine not properly collected as per laboratory standards. Improper mixing with anticoagulant was also identified as an LE.

CONCLUSION: The majorities of pre-pre analytical LEs are avoidable by providing clear instruction, regular education, and also regularly controlling all parts of the pre-pre analytical phase.

VANCOMYCIN AND GENTAMICIN INTERFERENCE ON RESULTS OF CLINICAL CHEMISTRY TESTS ON ABBOTT ARCHITECT **C8000 ANALYZER**

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BACKGROUND-AIM: Toxic concentrations of vancomycin and gentamicin can be observed in nephrology patients. Little is known on influence of high drug concentrations on results of clinical chemistry tests. In this work we aimed to investigate interferences of vancomycin and gentamicin on results of 25 commonly measured biochemistry tests on Abbott Architect c8000.

METHODS: Study was carried out in University Department of Chemistry, Medical School University Hospital Sestre Milosrdnice (Zagreb, Croatia) from June to August 2016. For each drug, 10 aliquotes of serum pool were prepared. In order to cover toxic concentrations, pool serum samples were spiked with drugs to obtain: 0-50 µg/mL of gentamicin and 0-200 µg/mL of vancomycin. Measurements of biochemistry tests were done in duplicate on the analyzer Architect c8000 and drug concentrations was measured on the analyzer Architect i2000 SR (both Abbott, Illinois, USA). For each tested concentration, bias was calculated against the initial measurement. Acceptance criteria were defined as measurement uncertainty of the commercial control with value close to the measured range of the pool sample.

RESULTS: For gentamicin interference testing, all bias values were bellow established acceptance criteria. For vancomycin, significant changes were observed for potassium, direct bilirubin and IgA. The potassium bias at the highest vancomycin concentration of 204.4 µg/mL exceeded acceptance criteria (bias = -4.5%, acceptable 4%). For direct bilirubin significant bias was detected already at low vancomycin concentration of 2.98 µg/mL (bias = 9.7%, acceptable 8%). For IgA, no apparent trend was observed, and exceeded bias values are attributed to the increased method imprecision.

CONCLUSION: Gentamicin didn't interfere with the results of clinical chemistry tests. Direct bilirubin concentration is falsely increased in the presence of vancomycin, while potassium is affected at high concentrations.

ID: 12410

THE ROLE OF EXTRA-ANALYTICAL SECURITY BARRIERS IN LABORATORY OUTCOMES

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BACKGROUND-AIM: In recent years, the automation of Clinical Laboratory has made a huge change in its organization that has generated changes in the laboratory risk map, and therefore an impact in the security barriers (SB) to decrease the frequency and the severity of adverse events. Exposure of the case: When the automation of laboratory began we introduced specific SB focused on sample identification. We use bar code (BC) plus a suffix to differentiate the specimen like serum, plasma EDTA, plasma citrate, among others. Also, we added sample collection instructions in which we indicate the colour of the cap, blood sampling and conservation conditions. Furthermore, on the side of the label it is shown the type of anticoagulant, for instance: plasma citrate-blue. Nevertheless, two patient safety incidents were detected. We observed the following results in two patients and in different samples. Patient 1/Patient 2(serum $plasmacitrate): \ glucose \ (mg/dL)96-70/105-94, \ total \ proteins \ (g/dL):6.5-5.7/6.3-5.7, \ sodium \ (mmol/L):136.6-165.6/139.8-168.9, \ potassium \ (mmol/L):136.6-165.6/139.8-168.9)$ (mmol/L):4.0-3.7/4.2-4.0, chlorine (mmol/L):105.1-83.9/107.3-85.7. Objective: Identify the causes of the incident and encourage improvements in the patient safety

METHODS: Barriers analysis and risk identification

RESULTS: Despite the new process specific BS (in and out laboratory staff training, differentiated colour cap, type of anticoagulant and BC identification) we have detected an error in identification specimen that alter laboratory results. As a consequence, we added another BS. This new BS consist in collecting all the samples of those patient which sodium result was more than 160 mmol/L, to confirm the correct identification between anticoagulant and label.

CONCLUSION: The Clinical Laboratory must designed a risk map covering the entire process, from preanalytical phase to postanalytical, and take account of developments and changes in the field of patient safety to prevent a recurrence of adverse event and not to reach and/or harm a patient.

SAMPLE REIECTION REASONS IN BIOCHEMISTRY AND HEMATOLOGY LABORATORIES

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BACKGROUND-AIM: In this study, sample rejection reasons aimed to be analyzed according to the sample tube types among the samples sent to laboratories.

METHODS: All samples accepted to the biochemistry and hematology unites of Pamukkale University Hospitals Central Laboratory were examined retrospectively for eighteen months. Distribution of rejected samples were classified according to preanalytic errors (wrong tube, incorrect barcode, excess amount of sample, insufficient sample, coagulated sample, hemolyzed sample, etc.) and tube versions like biochemistry tubes with gel, HbA1c tubes and whole blood tubes for CBC with EDTA, coagulation tubes, and sedimentation tubes. Distribution of preanalytic error types in the total sample size and in each sample tube type were expressed as percentages.

RESULTS: Rejection ratio was 1.12 % (15267/1356750) among all the samples sent to laboratory. Rejection ratios were 1.63% (2480/151756) for coagulation tubes, 1.55 % (1564/100842) for sedimentation tubes, 0.3% (114/38170) for HbA1c tubes with EDTA, 1.15 % (6465/560738) for biochemistry tubes with gel and 0.92 % (4644/505244) for whole blood tubes for CBC. The most frequent rejection reasons were coagulated sample (72.00%), insufficient sample (22.43%), and wrong tube (3.07%) for coagulation tubes; coagulated sample (43.63%), excess sample (26.77%), and insufficient sample (21.68%) for sedimentation tubes; wrong tube (78.07%), coagulated sample (15.79%) and insufficient sample (5.26%) for HbA1c tubes; incorrect/no barcode (42.28%), hemolyzed sample (26.20%) and insufficient sample (15.70%) for biochemistry tubes; and coagulated sample (84.40%), insufficient sample (9.62%), and wrong tube (3.99%) for CBC tubes.

CONCLUSION: Sample rejection reasons in the laboratory vary according to sample tube type. In the phlebotomy trainings given to the blood samples drawing units, circumstances for each tube type must be highlighted.

ID: 12442

SPECIMEN REJECTION IN CLINICAL LABORATORY DUE TO VARIOUS TYPES OF PRE-ANALYTICAL ERRORS

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BACKGROUND-AIM: Controlling pre-analytical variables is critical since this has a direct influence on the quality of results and on their clinical reliability. Preanalytical errors, along the process from the beginning of test requests to the admissions of the specimens to the laboratory, cause the rejection of samples. This study was undertaken with an objective to evaluate the types and frequency of preanalytical errors in clinical laboratory of our centers.

METHODS: All the samples received in the Clinical laboratory of University Hospital "St.George", Hospital "Selena" and Immunology laboratory of University Hospital "Kaspela" over a period of one year (September 2015-September 2016). Test requests and blood samples of clinical chemistry, immunoassay, hematology, coagulation were evaluated. Types of inappropriateness were evaluated as follows: improperly labelled samples, hemolysed, clotted specimen, insufficient volume of specimen and total request errors.

RESULTS: Of 571,100 samples received in the laboratory, preanalytical errors, as per the above mentioned categories was found in 2082 samples. The total rejection rate was 0.55 %. The rejection rate of coagulation group was significantly higher (2.30%) than the other test groups (P < 0.001) including insufficient volume of specimen error rate as 1.5 %. The most common error was clotted samples (0.18% of the total samples) followed by quantity not sufficient (0.086%), wrong sample (0.05%), without label (0.005%) and wrong label (0.005%).

CONCLUSION: The errors were especially attributable to unintelligible requests of inappropriate test requests, improperly labelled samples for inpatients and blood drawing errors especially due to insufficient volume of specimens in a coagulation test group. Rectification can be done by regular education of the staff.

ANALISYS OF THE PREANALITYCAL PHASE FOR A CLINICAL LABORATORY IN SLOVENIA HAVING AN EN ISO 15189 **ACREDITATION**

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BACKGROUND-AIM: In preanalytical steps the major source of mistakes in laboratory diagnostics arise from patient preparation, sample collection, sample transportation, and sample storage. In this study we analyzed the preanalytical quality indicators for the Department of laboratory diagnostics of the general hospital Ptuj during a period from 2014 to the end of 2016. The department of laboratory diagnostics is the first and currently the only clinical laboratory with an EN ISO 15189 accreditation in Slovenia.

METHODS: The analysis was accomplished using descriptive statistics with an average study population of 65 000 laboratory requests per year. Five quality indicators were evaluated according to EN ISO 15189 and IFCC Working group "Laboratory Errors and Patient Safety". We used the percentage and the sigma-scale methods to evaluate the quality indicators and process performance.

RESULTS: For the preanalytical phase an average error rate of 0,32% with a sigma of 4,9 was determined, whereas all error rates remained below the target limits. Lowest error rates of 0,03-0,05% with sigma values from 4,8 to 5,0 arise for the critical indicator "patient identification". On the contrary, the highest error rates of 0,36 - 0,51 % with sigma value from 4,1 to 4,2 were determined for the indicator "clotted sample or incorrect anticoagulant-blood ratio" and "hemolysed sample", with error rates of 0,93 - 1,04% and sigma value of 3,9 respectfully.

CONCLUSION: Five quality indicators representing the most frequent preanalytical errors were determined and analyzed. The results provide sound evidence that the control mechanisms for the most critical process (patient identification) are well established. In addition the procedures and processes associated with the specimen collection are acceptable but in need of further improvement.

ID: 12463

NEGATIVE INTERFERENCE OF IN VITRO UNINTENDED CLOT PRESENCE UPON COAGULATION TESTS, DISCLOSED BY NEW SIMPLE, POST ANALYTIC PROCEDURE

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BACKGROUND-AIM: As laboratory diagnosis is crucial in clinical decision-making, the management of pre analytical errors becomes crucial for improving the quality of laboratory performance, being relevant for the clinical outcome, as well. The accidental presence of clots (in vitro) in the pre analytical phase of the coagulation represents reasons for coagulation specimen rejection, given that the reliability of test results can be adversely compromised. It is thus worthwhile the development of procedures that could sort and remove non-compliant specimens. We propose an in vitro approach of the interaction between clot and the haemostatic system. The main objective of the current study was to mitigate the clotting time issue, by developing a new procedure for post-analytical reevaluation, to enable accurate test results delivery.

METHODS: The study was conducted in the Central Haematology Laboratory of the "Sf. Spiridon" Emergency Clinical Hospital, during a 4-month period. The selection criteria was based on possibly false results upon prothrombine time (PT) and activated partial thromboplastin time (aPTT), samples suspected of having in vitro fibrin and/or clot. Out of the 671 coagulated samples investigated, 518 (77.19%) were identified pre analytic. Withdrawing the biological samples into control tubes lacking anticlotting agents, we managed further a post-analytic identification of fibrin and/or clot through a new run-over protocol.

RESULTS: For the 153 (22.80%) samples identified in the post analitic phase, in case of TP, p=0.416 for 132 (86.27%) samples, while for aPTT, p = 0.035 for 101 (66.01%) specimens.

CONCLUSION: The main benefit of this post-analytical run-over procedure is represented by the in vitro identification of the sedimented clots, without any influence upon preanalytical phase, nor adittional costs or specimen collection.

IT'S JUST URINE! RESULTS FROM A PREANALYTICAL SURVEY IN PRIMARY HEALTH CARE IN NORWAY

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BACKGROUND-AIM: In 2013 Noklus started yearly preanalytical surveys among their participants to identify areas in need of improvement. 99% of Norwegian general practice offices (GP) participate in Noklus. The Norwegian health department aims to reduce the use of antibiotic by 30% within 2030. Urinary tract infections are often treated with antibiotics, and it is important that treatment is done based on a correct diagnosis set on the basis of correct sampling.

METHODS: The yearly preanalytical survey in 2016 was about routines and procedures concerning urine-sampling for culturing and dipstick. The survey was a questionnaire containing multiple choice questions. The participants got a written feedback with their own results compared to all participants.

RESULTS: 1635 participants, mainly GP offices, received the survey, and 63% responded. Only 13% answered that their patients often/always got written information about proper urine collection. 69% often/always examine urine with dipstick independent of clinical information, and 45% never/rarely rejected to examine the urine-sample even if the urine was stored in room temperature for more than 2 hours.

CONCLUSION: The patients rarely gets written information in how to do correct urine-sampling. The incorrect handling of urine-samples in the laboratories, can lead to errors and incorrect treatment of the patients. Based on the survey-results, Noklus intensifies their guidance concerning how and when to do urine-sampling. Sufficient patient information is essential. In effort to reduce errors Noklus have made a written patient guideline in multiple languages in how to do correct urine-sampling. For the laboratory the survey-report contained recommendations on best practice with referrals to procedures and guidelines.

ID: 12485

ASCORBIC ACID INTERFERENCE ON THE PERFORMANCE OF ICHEM VELOCITY AND COMBUR10TEST®M URINE **CHEMISTRY STRIPS**

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BACKGROUND-AIM: iChem Velocity (iCV) test strips manufacturer claims that ascorbic acid (AA) concentrations greater than 20 mg/dL could interfere with glucose, nitrite and blood. On the other hand, the manufacturer of Combur10Test®M (C10M) claims that AA does not interfere with glucose and blood. The aim of the study was to evaluate AA impact on the glucose, hemoglobin, nitrite and bilirubin measured with iCV and C10M urine strips.

METHODS: Iris iChemVELOCITY (Iris Diagnostics, Chatsworth, USA) and Cobasu411 (Roche, Mannheim, Germany) were used to analyze associated test strips. Stock solutions of each tested analyte were prepared. The materials used were: anhydrous glucose (Kemig d.o.o), hemoglobin (whole blood) sodium nitrite (Kemika d.o.o), bilirubin (Sigma/Aldrich) and vitamin C500 (Worwag pharma GmbH&Co.KG). Specific analyte concentrations (glucose: 2.7; 5.8 and 16.8 mmol/L, hemoglobin: 0.03; 0.06 and 0.10 mg/dL, nitrite: 0.1; 0.2 mg/dL, bilirubin: 37; 70 umol/L) were prepared using negative urine pool sample and AA solution in order to achieve specific concentration in each tested sample (0; 20; 30; 50; 100; 200; 500 mg/dL). Interference was confirmed if the result was changed in comparison with pool without AA.

RESULTS: AA interferes with glucose measured on C10M at 50 mg/dL and above 200 mg/dL on iCV, with hemoglobin at 20 mg/dL on both tested strips, with nitrite at 50 mg/dL on iCV and above 200 mg/dL on CM10 and with bilirubin at 50 mg/dL on both tested strips. iCV test strips are the most impacted by AA when hemoglobin, bilirubin and nitrite are tested and C10M test strips are the most impacted by AA interference when glucose, hemoglobin and bilirubin are tested.

CONCLUSION: Despite manufacturers' claims our results demonstrate negative effect on tested analytes at varying concentrations of specific analyte and AA. That is why the possibility of the AA detection in urine offered by iCV could be of great help in order to avoid misdiagnosis.

MELANIN AS PREANALYTICAL FACTOR RESPONSIBLE FOR UNSUCCESSFUL PCR ANALYSIS OF BRAF MUTATIONS

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BACKGROUND-AIM: BRAF mutations are predictive marker for targeted therapy with BRAF-inhibitors in patients with metastatic melanoma. BRAF mutations are most often determined by real-time PCR. Melanoma specimens may be highly pigmented with abundance of melanin which is known inhibitor of PCR reaction. Melanin inhibits PCR by binding to thermostable DNA polymerases and reducing its ability to extend newly synthesized DNA. The aim of this study was to determine if melanin is responsible for unsuccessful PCR analysis of BRAF mutations. METHODS: DNA was isolated (QIAamp DNA FFPE Tissue, Qiagen), from archived formalin-fixed paraffin-embedded (FFPE) melanoma tissue and assayed by real-time PCR (7500 Real Time PCR System, Applied Biosystems) for BRAF V600E and BRAF V600K mutations using specific TagMan probes. For statistical analysis Mann-Whitney U test or | 2 test were used, depending on type of variable.

RESULTS: A total of 218 samples were analysed and among them, 20 were highly pigmented with abundant melanin. Analysis was considered unsuccessful if gene reference assay Ct was >30 and \otimes Ct for BRAF mutation was >9,96. Highly pigmented samples had higher gene reference assay Ct values compared to non-highly pigmented samples (median Ct 30.17 and 27.29, p < 0,001). Frequency of samples with unsuccessful BRAF analysis was significantly higher among highly pigmented samples compared to non-highly pigmented samples (30% vs 10%,

CONCLUSION: Our results show that presence of melanin can be responsible for unsuccessful PCR analysis of BRAF mutations in melanoma tissue samples. Possible solution to overcome melanin inhibition is to dilute sample DNA added to PCR reaction which should be tested in further studies.

ID: 12505

SUCCESS IN PREANALYTICAL EQA

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BACKGROUND-AIM: Labquality is an international provider of professional external quality assessment (EQA) services. In 2014 Labquality launched four new EQA programs for the preanalytical phase in order to provide a unique means for laboratories and POC units to assess a larger part of the total laboratory testing process. The preanalytical programs include clinical chemistry, phlebotomy and POCT, microbiology

METHODS: Real life scenarios are used as case studies in the preanalytical EQA programs. The results are grouped by the profession of the participants. For this study we gathered the results from all reported rounds of clinical chemistry, altogether from five rounds and 15 cases. Since biomedical laboratory scientist (BLS) and team reply were the biggest profession groups, we compared the results of these two groups to the results of all participants. The success of determining the expected corrective action and finding the expected preanalytical error(s) defined by the expert was assessed for all cases.

RESULTS: The BLSs gave the expected corrective action in 51.2% (range 0-80.0%) and found the expected preanalytical error(s) in 33.2% (2.9-97.6%) of the cases on average. Respectively, the teams acted as expected in 52.5% (0-100%) and determined the expected preanalytical error(s) in 34.4% (0-96.2%) of the cases on average. All participants agreed with the expert's corrective action in 48.4% (6.1-83.7%) and preanalytical error(s) in 33.1% (3.6-97.4%) of the cases on average.

CONCLUSION: Both BLSs and teams did better in determining the expected corrective action and finding the expected preanalytical error(s) compared to all participants on average. Overall, the teams succeeded better than the BLSs. Therefore (re)thinking of the organizational procedures might be most helpful when implementing the knowledge of the whole staff.

CHALLENGES OF URINE ANALYSIS IN NURSING HOMES. RESULTS OF A PREANALYTICAL EXTERNAL OUALITY ASSESSMENT (EOA) SENT TO NURSING HOMES IN NORWAY

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BACKGROUND-AIM: The external quality assessment (EQA) scheme of Noklus had urine as the yearly preanalytical survey in 2016. The purpose of the survey was to identify deviation from best practice, and to improve the preanalytical phase as well as the analytical. The participants got a written report with the most important findings, their own results compared to all participants, and references to recommendations of best practice and guidelines. The laboratory advisors use the results to intensify their guidance at problem areas.

METHODS: 92 % of the nursing homes in Norway (about 1100) participate in Noklus. The survey was a questionnaire about prescribing, sampling and handling of urine specimen from elderly people for urine dipstick and culturing. Asymptomatic bacteriuria is a common condition for elderly living in nursing homes. They often use multiple medications and have low fluid intake. Cognitive failure can complicate sampling. The participants answered: always, often, rare, never or not relevant to questions concerning their own practice, competence and labelling of the specimen. RESULTS: 613 participants from laboratories in nursing homes responded (63 %). The poster presents results from the most important findings, and the main message given to the participants in their report. 72 % answered that they often or always examined fetid and turbid urine with dipstick. 77 % never or rare took this decision in consultation with the doctor. Urine samples from elderly are often examined routinely and not because of clinic. CONCLUSION: This survey has contributed much knowledge about lack of compliance with guidelines. Improvement of practice in the pre-pre analytical and preanalytical phase can give more reliable results of the urine specimen and prevent unnecessary antibiotic treatment. The results give the laboratory advisors important knowledge to the educational work in nursing homes.

ID: 12516

INTEGRATED EQA – WAY TO COMBINE PRE-ANALYTICAL, ANALYTICAL AND POST-ANALYTICAL SCHEMES

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BACKGROUND-AIM: It has been proved that most errors in laboratory medicine occur in the pre-analytical and post-analytical phases. ISO 15189 Standard requires that interlaboratory comparison programmes shall have the effect of checking the entire examination process, including pre-examination and post-examination procedures. Model of Quality Indicators (MQI) developed by IFCC Working Group on Laboratory Errors and Patient Safety has been tested through an EQA. Schemes for pre-analytical and post-analytical phases have been introduced by EQA providers already while integrated EQA will start from 2017.

METHODS: Integrated EQA service is a completely new approach and may include pre-analytical cases (written cases, images, videos) to be evaluated, traditional specimens and specimens including interfering factors to be analyzed, post-analytical cases related to scope of scheme. Instruction letter guides participants to evaluate possible pre-analytical cases, analyze specimens and evaluate possible post-analytical cases. Participants report the pre-analytical findings, analyzed results and post-analytical findings to internet result form. Integrated EQA service provide integration possibility for laboratory information systems (LIS) to EQA portals.

RESULTS: The first integrated EQA rounds will be sent out from the beginning of 2017. In EQA evaluation report, participants get statistics of all cases and analyzed samples. Pre- and post-analytical findings are listed but not scored and analyzed results from specimens are compared to target values as usual. Integrated EQA scheme always includes expert comments to provide additional information for the participants.

CONCLUSION: Integrated EQA schemes have been developed to meet requirements of the ISO 15189 and promote use of QI. LIS integration to the EQA organizer portal will provide opportunity transfer EQA results more quickly and with less manual work making it similar to the reporting of patient results.

PHLEBOTOMISTS PERCEPTION OF AN INTERACTIVE WEB-BASED PROGRAMME – THE FUTURE OF PREANALYTICAL **LEARNING**

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BACKGROUND-AIM: We evaluated phlebotomist's experience of a web-based programme for venous blood specimen collection according to the CLSI phlebotomy guideline. The web-based programme on phlebotomy (www.larandelandsting.se) was launched in 2013 and replaced a traditional two hour lecture launched in 2008. The web-based programme contains instructive movies, interactive assignments and clickable explanatory text. The total time to complete the programme, including a quiz, is approx. 1 h.

METHODS: 783 phlebotomists (laboratory technicians, registered nurses, specialist nurses, enrolled nurses) from the Vasterbottens County Council in Sweden participated in the evaluation of the web-based programme performed from 2013 to 2016. Phlebotomists perception about the web-based programme was investigated by eleven questions with four answer alternatives; total agree, partly agree, disagree, and do not know. Each question also included an open-ended complementary response option. The responses were analysed using descriptive statistics and content analysis.

RESULTS: Overall, phlebotomists were content (76 % of all) with the web-based program, with an increase from 74 % in 2013/2014 to 84 % 2015/2016. Phlebotomists perceived that the web-based programme performed well and also allowed for direct feedback and reflection. Some suggested constructive programme improvements. 58% of the phlebotomists totally agreed that it was easy to navigate within the program, and asked for improved instructions and more straightforward navigation. Some also described software difficulties.

CONCLUSION: The majority of the phlebotomists were very positive to the web-based programme on venous blood specimen collection. We conclude that the benefits of properly designed web-based programmes on health care practices supersedes traditional lecture educational programmes in usefulness and functionality. Included programme questionnaires for follow-up of participant's experiences are necessary for continuous optimization of programme functionality.

ID: 12527

AUTOSAMPLER VERIFICATION – A PROOF TO END THE UNNECESSARY SAMPLE MIXING IN HEMATOLOGY

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BACKGROUND-AIM: To ensure accurate results in hematology it is essential to minimize preanalytical variability. One of the possible preanalytical factors affecting laboratory results is surely adequate sample mixing which allows the sample homogeneity prior to analysis. Therefore, the aim of this study was to investigate if there is a difference in hemoglobin concentration (HGB) and blood cell count between samples homogenized manually before the analysis and those mixed only by the autosampler

METHODS: Samples remained after the routine analysis (N=40) were randomly selected and analyzed on fully automated hematology analyzer Sysmex XN-1000 (Sysmex, Kobe, Japan) with and without prior homogenization. All samples were firstly mixed on the roller for 5 minutes, placed in the rack and then manually inverted for 8 times. When the analysis was performed, samples were left to stand at room temperature in vertical position during 4 hours and then analyzed directly. Mixing was this time done exclusively by the autosampler which does it by inverting each tube 8 times. For each sample bias was calculated for HGB, red blood cell (RBC), white blood cell (WBC) and platelet (PLT) count. Analysis with prior homogenization was considered as reference procedure. Eglibility criteria for accuracy according to the manufacturer were $\pm 1.0\%$, $\pm 1.5\%$, $\pm 3.0\%$ and $\pm 4\%$ for HGB, RBC, WBC and PLT, respectively

RESULTS: For analyzed samples calculated bias for HGB, RBC, WBC and PLT count was 0.85%, 0.95%, 1.50% and 2.73%, respectively. Therefore, since all eglibility criteria were fulfilled, there is no difference in HGB and blood cell count between samples homogenized manually before the analysis and those mixed only by the autosampler

CONCLUSION: Results show that an additional manual sample mixing for Sysmex XN-1000 before the analysis is not necessary except for the routine sample quality check. To ensure that manual mixing could be also ceased for other analyzers with autosamplers, firstly verification study must be performed to test autosamplers performance.

RESULTS OF THE STANDARDIZATION PROCEDURE FOR THE MANAGEMENT OF UNSUITABLE SAMPLES FOR HEMOSTASIS **TESTING**

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BACKGROUND-AIM: The sample integrity is essential for accurate hemostasis results. Using simultaneous multi-wavelength scanning and sample liquid-sensing technologies, Sysmex® CS-2000i Hemostasis System detects unsuitable samples due to hemolysis, icterus, lipemia (HIL) and improper volume. The aim of this study is the evaluation of the management procedure of unsuitable samples applied in our Laboratory to both working modes: routine and emergency.

METHODS: According to the procedure of our Laboratory, the identification of unsuitable samples for hemostasis analysis is performed during the preanalytical phase by visual inspection (under filled or clotted samples, HIL) and during the post analytical phase by recording the flagged results on Sysmex® CS-2000i. According to the criteria of our Laboratory, the sample results which are flagged as HIL or as improper volume are not accepted, and the sample is identified as unsuitable. All unsuitable samples were recorded during the period July-November 2016. Statistical analysis: Paired-Samples T was applied. P < 0.05 is considered as statistically significant.

RESULTS: During the audit period, the proportion of unsuitable samples is statistically significantly higher in the following three cases: emergency working mode as compared to routine mode (10.6 vs 4.9%, P=0.002), preanalytical phase as compared to post analytical phase (70.3 vs 29.7%, P=0.0001), preanalytical phase as compared to post analytical phase during both working modes (routine mode: 73.3 vs 26.7%, P = 0.001; emergency mode: 67.8 vs 32.2%, P = 0.002).

CONCLUSION: The applied management procedure is considered as successful, since the higher proportion of unsuitable samples is detected during the preanalytical phase, irrespective of the working mode, and therefore, the analysis of samples that will be rejected as unsuitable during the post analytical phase is avoided.

ID: 12534

PERFORMANCE CRITERIA BASED ON RESULTS OF THE NEW PREANALYTICAL PHASE SPANISH SOCIETY OF MEDICINE LABORATORY (SEQC) EXTERNAL QUALITY ASSURANCE PROGRAMME

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BACKGROUND-AIM: A new approach of Preanalytical Phase External Quality Assurance Programme of the Spanish Society of Medicine Laboratory (SEQC) based on Quality Indicators (QI) began in 2014. Previous results were used to assess the main factors affecting preanalytical phase quality, and helped setting preanalytical phase performance criteria.

METHODS: Participants are asked to register rejections and rejection causes of the main specimens, observed during one month, four times a year. Around 50 laboratories participated in each of the exercises carried out from 2014 to 2016. QIs were calculated as percentage of rejections respect to the total activity of the most frequently measured test in each sample, although in some cases they were referred to the total request number. From the results of laboratories, different percentiles were calculated. The percentile averages of the twelve participations obtained between 2014 and 2016 were set as typical performance. We suggested 25th percentile (p25), 50th percentile (p50) and 75th percentile (p75) as the optimum, desirable and minimum specification, respectively.

RESULTS: Main QIs and their performance criteria expressed as p25-p50-p75, respectively:

- Total rejections/total requests(%): 1,387- 2,179- 3,147
- Rejections for unlabeled samples/total requests(%): 0,000-0,007-0,047
- Rejections for misidentifications/total requests(%): 0,001- 0,010- 0,034
- Serum sample rejections/creatinine tests(%): 0,438-1,059-2,081
- Whole blood-EDTA rejections/complete blood counts(%): 0,280-0,472-0,757
- Plasma coagulation Citrate sample rejections/prothrombine time tests(%): 0,752- 1,691- 2,714
- Random urine not received/total requests(%): 0,337- 0,831- 1,342

CONCLUSION: External Quality Assurance Programme of the preanalytical phase allows definition of performance criteria based on the state of the art, thus helping laboratories identify and reduce errors in the preanalytical phase.

ID: 12539

LUMINEX® ANTIBODIES DETECTION AND PROZONE EFFECT

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BACKGROUND-AIM: Human leukocyte antigen (HLA) antibodies develop in many allograft recipients, with associated graft loss that may occurs years later. Luminex® Technology have improved the sensitivity and specificity to identify HLA antibodies and to define forbidden donor antigens. Sometimes false-negative reactions occur in Luminex® assay. This phenomenon is known as the "prozone effect", due to the presence of HLA-specific IgM antibodies or complement component C1, by a competition for the alloantibody between the fluorescent anti-IgG conjugate and serum complement. Sera treatment with ethylene-diamine tetraacetic acid (EDTA) can abrogate the prozone effect, unmasking potentially clinically significant HLA antibodies. We explored this effect in our kidney transplant candidates and transplanted patients.

METHODS: We performed Luminex® Single Antigen test (LSA I and II, One Lambda, Canoga Park, CA) for HLA class I and class II antibodies among 45 serum samples from immunized renal waiting list patients and transplanted patients, comparing the median fluorescence intensity (MFI) values obtained in the EDTA-treated and non-treated conditions, to describe the impact of prozone effect on HLA antibodies profile. RESULTS: EDTA treatment abolished the drop/rebound effect, evident in immmunized patients with MFI value > 10000, while no differences exist in patients with lower MFI levels (<10000). The treatment increased MFI values of both class I and II HLA antibodies, resulting in an overall increase of the proportions of IgG positive single reactions.

CONCLUSION: The prozone effect potentially affects the results of Luminex® detection. Falsely low or negative results, especially in case of dense IgG binding, may impair accuracy of LSA test. Our study confirmed the role of complement activation in LSA assays and reinforced the utility of EDTA treatment, expecially in immunized subjects. providing a basis for the establishment of more selective strategies to contrast the prozone effect.

ID: 12540

EVALUATION OF PREANALAYTICAL CAUSES OF REJECTION FOR BLOOD GAS TESTS IN THE EMERGENCY LABORATORY IN A SIX MONTH PERIOD

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BACKGROUND-AIM: Blood gas test is one of the most common tests carried out in emergency laboratories. As it is mostly ordered from critically ill patients, it is important to give the accurate test result in a short time period. Blood gas samples are mostly arterial and collected with heparinized injectors, the test is vulnerable to preanalytical errors. To evaluate the rejection rates and causes of blood gas samples may help us to prevent prenalytical errors by educating hospital staff from physicians to nurses and transporters.

METHODS: This study evaluates the blood gas rejection rates in the emergency laboratory of Ankrra Numune Training and Research Hospital retrospectively for a six month period (June 2016- November 2016). Our laboratory accepts samples from emergency service, emergency operating rooms (ORs), emergency internal medicine and surgery services, and emergency intensive care units (ICUs).

RESULTS: Within this six month period, a total of 17865 blood gas samples were recieved to the laboratory. A total of 238 samples were rejected, which gives 1.3% rejection rate. The major reason for rejection was blood clots. 175 of 238 samples (73.5 %) were clotted samples. 51 samples (21.4%) was rejected because of inadequate volume.12 samples (5.1%) were rejected from other reasons such as mislabelling or false test orders. 125 of 238 (52%) samples rejected were from (ICUs), 72 samples (30 %) were from emergency service and remaining 41 (17%) were from inpatient services and ORs.

CONCLUSION: 1.3% total rejection rate seems to be acceptable but it is in our hands to improve healthcare provided. The collection of blood gas sample is of critical importance. İnadequate sample volumes may be reasonable from ICU patients, but blood clots can be provided with more careful usage of heparinized injectors and a quicker transportation of the sample to the laboratory.

ID: 12543

EVALUATION OF PREANALYTICAL ERRORS AND SAMPLE REJECTION RATES IN THE EMERGENCY LABORATORY IN A ONE YEAR PERIOD

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BACKGROUND-AIM: Emergency laboratories accept samples from emergency outpatient policlinics, intensive care units, inpatient clinics and emregency operation rooms (ORs). The most important burden over the emergency laboratories is to give the most accurate resuts in a very short time. Among laboratory errors, the most common one are the preanalytical errors, which in fact cause delays and misinterpretaitons in patient results.

METHODS: The study includes the samples accepted to the emergency laboratory of Ankara Numune Training and Research Hospital in the one year period between December 2015-December 2016. Accepted samples were evaluated according to the sample acceptance-rejection criteria of our laboratory and rejected samples were classified according to rejection reasons and services.

RESULTS: A total of 767,832 samples have been accepted to our emergency laboratory. 6732 samples were rejected which makes the total rejection rate of 0.8 %. 42.7% of the rejected samples were from intensive care units and inpatient clinics, while 35.2% were from emergency outpatient clinics and 22.1% were from emergency ORs. Most frequent rejection criteria among 6732 rejected samples was clotted samples (42.5%), inappropriate volume (36.6%) and hemolysis (12.2%). Lipemic samples were % 3. Other reasons such as incorrect test orders, contaminated samples, inaproppriate material, false tubes, icteric samples consisted 5.7% of preanalytical errors.

CONCLUSION: Preanalytical errors affect the laboratory results and test re-orders are needed. Especially in the emergency laboratory where timing is very important, least errors in a short time are desired. Preanalytical errors cover a wide range of processes including test orders, sample collection, transport and acceptance to the laboratories. Periodical education of hospital staff about controlling prenalaytical variables will be very useful in reducing error rates.

ID: 12556

THE COMPARISON OF KNOWLEDGE ABOUT PREANALYTICAL PHASE BETWEEN NURSES AND INTERNS AT ÇANAKKALE **ONSEKIZ MART UNIVERSITY SCHOOL OF MEDICINE**

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BACKGROUND-AIM: It has been shown that in clinical laboratory practise most mistakes are the result of human errors occurring before the blood sample reaches the laboratory. In this study, we aimed to assess the knowledge and awareness of medical school students -interns- and nurses on preanalytical phase.

METHODS: The questionnary was done by the nurses and interns at departments and policlinics of research hospital. Questionnary was composed of 25 statetements and contained questions about steps patient identification, sample collection, sample transport, and frequencies of error reporting. Descriptive analyses were presented using means, standard deviations, minimum, maximum for normally distributed variables. The Chi-square test was used to compare these proportions in different groups. Comparisons between the two groups were made using the two independent-sample t-test. The p value of less than 0.05 was considered statistically significant.

RESULTS: Study was included 92 nurses and 38 interns. Nurses had higher proportion of correct answer (%68.08) compared to interns %61.24, p=0.008. Nurses were found more informed than interns at impact of hemolysis (p<0.001), importance of sample mixing (p=0.012), proper anticoagulant choosing (p=0.012), proper choice of blood collection needle (p=0.024). In addition, nurses are significantly had wrong informations, but interns had not any information about blood sample transport from needle to tube(p<0.001) and the order of the transport to tubes(p = 0.035).

CONCLUSION: According to questionnary results, nurses are more conscious of the importantance of preanalytical phase compare to interns. In general practise, nurses are more knowledgeable about preanalytical phase than intern group. On the other hand, interns had no idea, nurses had wrong knowledges about some steps of preanalytical phase. Under these findings, we can say that nurses and interns need to take education about preanalytical phase, urgently.

ID: 12582

AUDITING PRE-ANALYTICAL PHASE – AN AUTOEVALUATION OF LABORATORIES

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BACKGROUND-AIM: Pre-analytical phase is more prone to errors due to non-automated activities such as collection, handling, transportation and preparation of specimens. Since 2007, PNAEQ provides a specific program on pre-analytical phase. In 2016, it was proposed to laboratories to audit their own pre-analytical phase. The aim is to involve laboratories in evaluation and monitoring process, giving those tools for their own evaluation of this important extra-analytical phase.

METHODS: The audits should be performed in two rounds by a laboratory element with competence and experience in these matters. In each round, the auditor should assist to 5 blood specimen collection for 8 phlebotomists. Audits should be performed in 1-2 days, in central laboratory and collection stations (private) or in outpatient consultation (public). The information should be collected concerning 3 main themes: patient/specimen identification, phlebotomy technique and biosafety, according to an audit form previously validated with a pilot study. Between 2 audits, laboratories should provide education in order to improve critical points.

RESULTS: Were received 12 and 9 results in the 1st and in the 2nd audits, respectively. Results are similar in the 2 rounds. Questions related to patient/specimen identification showed good practice. Questions related to phlebotomy technique must be improved with corrective and preventive actions. Questions related to biosafety should be reviewed. Only 3 laboratories have provided education in blood collection during 2016. CONCLUSION: The education of healthcare workers should be continuous in order to reach harmonization of collection procedures and to fulfill with current legislation. The implementation of auto evaluation schemes gives the laboratory the main role in evaluation of their performance, as well as in improving the service quality and client satisfaction.

ID: 12585

PNAEQ - 10 YEARS OF PRE-ANALYTICAL EQAS IN PORTUGAL

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BACKGROUND-AIM: In the last 10 years, PNAEQ provided a specific program on pre-analytical phase. Since 2014 were offered 5 more schemes in this area: phlebotomy and POCT units, blood gas analysis, clinical chemistry and microbiology in collaboration with Labquality Oy, and haemostasis in collaboration with ECAT Foundation. The main objective of implementing a specific program on pre-analytical phase is to evaluate the performance of laboratories nationwide on these matters in order to improve their quality service. To reach this goal PNAEQ provided various types of assays and collected information from questionnaires and meetings with participants, in order to find tools to facilitate the evaluation of this important extra analytical phase.

METHODS: This scheme comprised 2 rounds/year: 4 rounds for indicators monitorization, document evaluation and case simulation, 3 rounds for sample shipment and case study and 1 round for audits. In 2015 PNAEQ established a work group inviting participant's collaboration to select indicators and tools for monitoring quality in the pre-analytical phase.

RESULTS: In 10 years were enrolled 126 laboratories with a 46% average of participation. 52% signed up only once and 13% maintained their registration in 5 or more years. The highest percentage of answers received was those with an active role from PNAEQ such as mystery client (79%) [2015], audit (63%) [2016] and sample shipment with simulated clinical history (61% to 72%) [2008, 2009, 2011].

CONCLUSION: The first year of the scheme had a good reception but the number of registrations decreased 1/7 from 2007 to 2013, doubling in 2016. In work group meetings PNAEQ took note of participant's difficulties in data collection, so there is still a long way to go alongside laboratories. We are working on laboratories awareness trying to highlight the importance of monitoring pre-analytical phase with an important focus on education.

EXTERNAL QUALITY ASSESSMENT OF THE PREANALYTICAL PHASE OF BLOOD SAMPLE COLLECTION IN REGIONAL **GENERAL HOSPITAL**

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BACKGROUND-AIM: The process of blood testing can be subdivided into prenalytical, analytical and postanalytical phase. Most errors affecting laboratory test, occur in the preanalytical phase and can lead to a serious patient misdiagnosis and improper treatment. A pilot study was conducted using a structured observation scheme to assess compliance with the international and local phlebotomy guidelines and to identify necessary focus items.

METHODS: A pilot study of two days was conducted by external reviwers. The individual steps of the preanalytical phase were observed on five hospital departments including the processing of the samples in laboratory. Error frequencies were calculated by comparing results of our institution with a benchmark group of European hospitals in which same study has already been completed.

RESULTS: A total of 60 blood drawings by 20 nurses were observed in the pilot study. Major error items were hand hygiene (75% error), single use of tourniquet (92%), tourniquet application time (51%), mixing of samples (60%), collection, handling and transport of sample (38%) haemolysed samples), clotting time (12% fibrin strands present in chemistry tubes), adequate sample volume (13% of coagulation tubes observed were filled less than 90%) and order of draw (33%). Significant differences from guidelines and compliance with directives were found in: blood collection devices (4 different brands), internal standard blood collection procedure and in healthcare worker safety (use of non-safety engineered devices with 70 % needle recapping).

CONCLUSION: Corrective measures for these activities were established: educational program for nurses, selection of blood collection system in compliance with national guidelines, implementation of >30% safety devices to comply with the EU Directive 32/210 and increase the healthcare worker safety. Follow-up study is planned in future to investigate whether adherence to the phlebotomy guideline improved.

ID: 12609

DETERMINING THE QUALITY INDICATORS AND EVALUATING THE LABORATORY PERFORMANCE IN THE PREANALYTICAL **PHASE OF TESTING**

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BACKGROUND-AIM: Background: The clinical laboratories should decide which quality indicator to use while evaluating their performance in the preanalytical phase. In this study our aim was to determine the sample rejection rate, to choose the most appropriate quality indicators and to evaluate our laboratory performance in the preanalytical phase.

METHODS: Materials and Methods: The samples rejected during 1-year period from December 2015 to November 2016 were analysed according to our laboratory rejection criteria (n = 26). Data were retrieved from the laboratory information system. The percentage of rejected samples was calculated and the most frequent reasons of rejection were determined as the quality indicators.

RESULTS: Results:During the study period, a total of 1,924,876 samples were received. The number of samples collected with anticoagulant was 913,481. The total number of rejected samples was 18,871, accounting for 0.98% of the total number of samples received. Of the total rejected samples, 49.66% were samples clotted, 23.04% were samples with inappropriate sample-anticoagulant volume ratio, 13.01% were samples with insufficient sample volume and 2.87% were samples of wrong or inappropriate type. Among the samples with anticoagulant, 1.026% were clotted and 0.4859 % were not properly filled. Of the total samples, 0.1275 % was samples with insufficient sample volume and 0.0282 % was samples of wrong or inappropriate type. The highest percentage of rejected samples were from the Emergency Department (16%). 55% of the rejected samples from the Emergency Department were clotted samples.

CONCLUSION: Conclusions:The preanalytical performance of our laboratory needs to be improved in terms of some quality indicators. Staff training programs are planned for the Emergency Department.

SPECIMEN REJECTION RATES IN A CENTRAL UNIVERSITY LABORATORY: A NEED FOR EDUCATION

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BACKGROUND-AIM: The central laboratory of Celal Bayar University Hospital receives specimens from emergency department, inpatient and outpatient clinics. The samples are accepted or rejected according to the laboratory rejection criteria. In this study, we aimed to measure the sample rejection rates in concordance with established preanalytical errors and collection sites.

METHODS: In this study, the laboratory information system was reviewed for data concerning samples accepted at the laboratory during 12 months (between January 1st and December 29th 2016). The number and reasons for rejected samples were scrutinized. Rejection rates were calculated. RESULTS: In a total of 911,460 biological specimens, 11,801 (1,2 %) were rejected based on the laboratory rejection criteria. The specimen rejection rate was higher in the inpatient (66.1 %) than the outpatients clinics (18.2 %) and emergency department (15.7 %). Detailed analysis revealed the following rejection ratios; 22,9 % for biochemistry, 20,6 % for complete blood count (CBC), 15,3 % for blood gases, 4,6 % for sedimantation analyses, 0,94 % for urine analysis and 35,5 % for coagulation. The most frequent rejection reasons were inadequate volume (39 %), fibrin clots (29,4%) and hemolysis (13,4 %).

CONCLUSION: The highest rejection rate was found to be from the inpatient clinics with 66,1 %. These data suggest that training of the nurses working in the inpatient clinics is needed. As a part of our total quality management policy, we expect to decrease sample rejection rates by periodic education programmes.

ID: 12619

FREQUENCY OF ADULTERATED, SUBSTITUTED AND DILUTED SAMPLES: A 24-MONTH RETROSPECTIVE STUDY

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BACKGROUND-AIM: Drug abusers try to avoid detection by drug testing in many ways, including use of products designed to prevent detection of drugs present in a urine sample. Some products advertised to "beat a drug test" require ingestion prior to submission of a urine sample, whereas other products are to be added to or substituted for the urine sample itself. Collection procedures have been designed to prevent such substitution, dilution, or adulteration of the specimen. In the view of such information, we defined the proportion of adulterated, substituted and dilute specimen. METHODS: We retrospectively evaluated the patient's urine creatinine and specific gravity measurements whom had applied to Alcohol-Substance Addiction Research, Therapy and Education Centre (AMATEM) from 1 January 2014 to 31 December 2015. Beckman Coulter AU580 was used to measure urine creatinine and, iRICELL 3000 was used to measure specific gravity. Adulterated, substituted and diluted specimens were defined by criteria of National Laboratory Certification Program Manual for Laboratories and Inspectors guideline.

RESULTS: 61.177 patients were evaluated. 94.9% of patient group were male, 36874 patients (60.3%) were applied to the hospital with the diagnosis of opioid users. Number of adulterated, substituted and diluted samples were 186, 254 and 400 (0.3%,0.4% and 0,6%) respectively. There were no differences between adulterated, substituted and diluted samples in terms of age (p:0.000, p:0.01, p:0.00, respectively), year(p:0.00, for all), gender (p:0.000, p:0.02, p:0.03, respectively).

CONCLUSION: Taken into consideration of low frequency of adulterated, substituted and diluted sample; it can be said that policy of sample collection in Turkey works efficiently. However, our study should be expanded by the evaluation of pH values, in order to obtain higher level of evidence.

ID: 12622

THE SIGNIFICANCE OF PRE-ANALYTICAL QUALITY INDICATORS IN ACCREDITED MEDICAL-BIOCHEMISTRY LABORATORY

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BACKGROUND-AIM: The implementation of international harmonized Quality indicators (QIs) at the Department of Medical Biochemistry and Laboratory Medicine of the University Hospital Merkur in Zagreb, Croatia, accredited according to ISO15189 norm, made a great improvement in risk management and therefore presented a crucial step towards quality and patient safety.

METHODS: Seven quality indicators from Model of QIs, recommended by working group "Laboratory errors and patient safety", were introduced for evaluating pre-analytical phase of laboratory process. All unsuitable samples are organized in four groups due to: inadequate vacutainer, type of test error, specific department unit and patient individually.

RESULTS: There were 900 test errors (0,05%) in the period from April to October 2016. We analyzed and evaluated the performance of the emergency laboratory including admission unit and identified three QIs with the highest error rates: Pre-Hem (number of samples with free Hb>0,5 g/L (clinical chemistry)/total number of samples (clinical chemistry) (1,77%), Pre-Clot (number of samples clotted/total number of samples with an anticoagulant) (0,26%) and Pre-InsV (number of samples with insufficient sample volume/total number of samples) (0,13%). According to number of test errors that were calculated during six months most of them derived from the Emergency Department (21%), the Intensive Care Unit (13%) and the Department of Neonatology (8%). In all Units QIs with the highest error rate are Pre-Hem (22%) and Pre-Clot

CONCLUSION: Defining QIs as harmonized reporting system for clinical laboratory has important role in order to reduce errors in laboratory testing and improving its quality and effectiveness. With distinctly designed model it is possible not only to have a systematic overview, but also use it for better communication with clinicians and other medical employers in order to minimize risks that lead to errors resulting in patient harm.

ID: 12633

SIX SIGMA APPROACH IN CONDUCTING THE CLINICAL VERIFICATION OF PRE-ANALYTICAL VARIABLES FOR **HEMATOLOGICAL PARAMETERS IN A LABORATORY**

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BACKGROUND-AIM: The pre-analytical variables have played a crucial role in a clinical laboratory. Though the analytical goals in has attained a certain level of satisfaction in a hematology section, the pre-analytical phase is often neglected; probably with the pre-conceived notion that centrifugation is not a necessity. Often, laboratory technical managers are not aware of the need to perform verification of the pre-analytical parameters. The use of vacutainers has also contributed to the notion that pre-analytical variables are none. The aim of the study was the clinical verification of intra-brand as well as inter-brand verification of EDTA vacutainers as per the guidelines laid down by the WG-PRE of EFLM. The study was conducted to determine that different tube brands possibly with difference in additives may produce differences in CBC. The study has been done to fulfill the basic criteria of technical as well as clinical acceptability.

METHODS: The current study was conducted in the months of Sept 2016. 50 adult healthy volunteers, attending the OPD were evaluated. In both the type of verification, the 2 samples were collected from the same patient into 2 different K2 EDTA vacutainers as follows: Tube I-BD Vacutainer 3.0 ml (5.4 mg) ;Tube II-BD Vacutainer 4.0 ml (7.2 mg) and Tube III-Krivida Vacutainer 3.0 ml. Blood Collection was accurately standardized, including the use of needles and vacuum tubes of the same lot and by the same phlebotomist. Analysis of the samples were done immediately in the cell counter equipment simultaneously and in duplicates. The instrument was calibrated against appropriate reference standard material and verified with accepted IQC protocols. The parameters included Hemoglobin, RBC, Hematocrit, MCV, MCHC, RDW, TLC, Platelet count and DLC.

RESULTS: The significance of the differences between samples was assessed by repeated measures using paired Student's t- test after checking for normality (Anderson Darling Normality test) (Minitab®). The normality failed to reject the null hypothesis with p > 0.05 to concluded that the data for all the 3 tubes showed a normal distribution. With p value < 0.005 being considered statistically significant; student t test was analysed. Statistical analysis of the intra-brand verification indicated that the different BD vacutainers having different EDTA concentration; but of different volume have no significant impact on patient results (p > 0.005). Similarly, analysis of inter-brand data showed that the new vacuum tubes do not show a clinical relevant new source of error in the hematology parameters (p > .005). Finally the biases from the two studies were compared with the current desirable quality specifications for Bias (B), derived from biological variation. In view of both the criteria being fulfilled, the second vacutainer were deemed to be clinically verified for use in patient service.

CONCLUSION: The study showed that the clinical verification analysis of EDTA vacutainers is an important step in patient reporting. As per the ISO 15189:2012, verification of the procedures to ensure the acceptance testing of the consumables is a necessity. The differences observed during both the verification stages; though statistically insignificant, may be due to the concentration of the EDTA in the vacutainers. However, the process has ensured that the task of performing a clinical verification is the step ahead in ensuring quality of patient results and hence ensuring patient safety.

ACUTE EFFECT OF DARK CHOCOLATE ON LIVER FUNCTION ENZYMES

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BACKGROUND-AIM: Frequently, patients would claim to crave chocolate and enjoy the feeling that eating it induces. A chemical called anandamide - which is similar to the compounds released when cannabis is taken - could be responsible for this feeling. This study was aimed to evaluate the acute effect of dark chocolate intake on liver function enzymes.

METHODS: A blood sample was firstly collected from 17 fasting volunteers. Immediately after blood collection, volunteers ingested 50 g of 90% cocoa chocolate within 3-5 min. A second sample was collected 4h afterwards, for assessment of aspartate aminotransferase (AST), alanine aminotransferase (ALT), and gamma-glutamyl transferase (GGT) on Roche Cobas 6000 (c501) module. Differences between concentrations (U/L) were assessed by Wilcoxon ranked-pairs test. The level of statistical significance was set at P < 0.05.

RESULTS: Significant differences were observed at 4 h after dark chocolate ingest vs. baseline for AST (P = 0.006), and ALT (P = 0.026); whereas GGT was not influenced by dark chocolate (P = 0.160).

CONCLUSION: The significant variation in AST and ALT afterwards dark chocolate intake shows that could be better to avoid dark chocolate ingestion before blood collection when performing these tests. It could prevent laboratory variability and guarantee correct data interpretation.

ID: 12638

MONITORING OF ADVERSE EVENTS IN LABORATORY DIAGNOSTICS - OUR EXPERIENCE

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BACKGROUND-AIM: Management of adverse events in laboratory diagnostics is one of the most important procedure which is the foundation of "patient risk management" as well as the basis of risk for employees. The obligation of monitoring adverse events (AEs) is defined by the standard ISO 15189: 2014.

METHODS: Between 1st February 2013. to 15th December 2016, in the Policlinic Laboratory Diagnostics Department, Center of Medical Biochemistry, Clinical Center of Serbia, we gathered adverse events related to patients and staff. The total number of patients was 670,982.

RESULTS: The total number of adverse events was 168, of which 159 (94.64%) related to patients and 9 (5.35%) AEs related to employees engaged in preanalytical phase. 50 (29.76%) AEs were related to Department of reanimation assistance: 19 (11.31%) immediately before the blood sampling, 6 (3.57%) during the blood draw, and 25 (14.88%) after completion of phlebotomy. Six patients (3.57%) had severe complications like hematoma that required vascular surgeon assistance. With 10 (5.95%) patients there was an error in the process of identification. Other AEs in the preanalytical phase (14.29%) were related to: failure in sample collection, recollected sampling due to laboratory error, patient non-appearance. 69 (41.66%) AEs are related to laboratory information system (LIS) operation: total failure of LIS, failure in patient identification, missing data and missing results.

CONCLUSION: Laboratory personnel have to engage in continuous education and by professional commitment work on reducing adverse events with the aim of improving patient and staff safety.

ID: 12643

HUNGARIAN NATIONAL GUIDELINE FOR PREANALYTICAL-PHASE

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BACKGROUND-AIM: Development and implementation of an evidence-based national guideline for preanalytical (PA) phase was a strategic goal of the Hungarian Society of Laboratory Medicine (HSLM).

METHODS: The national PA guideline was developed by principles and methods of evidence-based guideline development in laboratory medicine (Oosterhuis WP et al, ClinChem 2004) in consensus of laboratory profession and general practitioners. Systematic overview of the literature focusing on PA practices and quality assurance in different routinely practiced fields of laboratory medicine was done for the period of 2002 - 2016. The overview was completed with a search for existing PA guidelines. Phlebotomy was not investigated. Main recommendations with indication of the level and strength of evidence according to New Zealand Guidelines Group were formulated.

RESULTS: 95 recommendations were phrased after considering reimbursement and infrastructural conditions of the national health care system for such steps of PA-phase as laboratory test requesting, patient identification, sample- preparation, transport, arrival and storage. Each recommendations were followed by short summary of the existing pieces of evidence as well as quality indicators recommended by EFLM Task and Finish Group on Performance specifications for the extraanalytical phases in the fields.

CONCLUSION: The first national multidisciplinary PA guideline was developed and introduced in Hungarian healthcare institutions very recently. HSLM will take active part in successful implementation of the PA guideline with establishing Working Group on PA-phase for coordination training courses and benchmark data collection in the field.

ID: 12644

IMPORTANCE OF AN ADEQUATE LABORATORY MATERIAL SELECTION IN NON-CHOLESTEROL STEROLS DETERMINATION BY GAS CHROMATOGRAPHY (GC) METHODS-OUR EXPERIENCE

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BACKGROUND-AIM: Non-cholesterol sterols determination provides the basis for the cholesterol homeostasis assessment. Multistep sample preparation and necessity of derivatization process introduces additional preanalytical sources of assay variability. These especially include labware selection and preparation.

METHODS: Human serum and plasma pools were used for method optimization. Gas chromatography-flame ionization detection (GC-FID) was used for NCSs quantitation, while GC- mass spectrometry (GC-MS) method was used for plasticizer identification.

RESULTS: During sample preparation there is a possibility of oxidative transformation of the analyte. It is acknowledged that this can be accelerated by the presence of metal ions originating from the various labware components, such as tube seals. In order to minimize the influence of oxidation during sample preparation, commonly used metal screw caps for reaction tubes were substituted with PTFE-lined screw caps. During method development, unidentified peaks emerged and the derivatization yield dropped to 60%, far below the cut off value for reliable quantification. After examining the overall preanalytical and analytical process we tracked the interference down to disposable plastic pipettes used during the extraction protocol. It has been shown that when using organic solvents, low density plastic laboratory dishes release certain plastic components, Plasticizers' retention time, relative retention time and mass spectrum were determined and specifically palmitamide, oleamide and stearamide were identified as plastic leachates. Current study represents, to the best of our knowledge, the first study focused on plastics' leachate interferences during NCSs analyses in plasma and serum samples.

CONCLUSION: All of the in-house sample preparation procedures regarding labware selection and preparation proved to be useful for minimizing the preanalytical and analytical variations.

ID: 12645

REDUCTION OF PREANALYTICAL ERRORS BY USING CYBERLAB WIRELESS BEDSIDESCANNING

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METHODS: statistical evaluation

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BACKGROUND-AIM: AZ Sint Jan Brugge - Oostende, campus Henri Serruys Oostende, is a hospital with 330 beds and has a routine laboratory, performing test in chemistry, hematology and microbiology (24h/24H). For the optimalisation of the pre-analytical phase for patient safety, we started In 2011 with the digitalisation of order entry (cyberlab - glims). Tubelabels were printed at the nurses station and we introduced wireless bedside scanning of prelabeled tubes together with the barcoded wristband of the patient. Nurses and doctors were trained to use the cyberlab-orderentry program. The implementation of the workflow of wireless bedside scanning at the nurse stations in the hospital and at the emergency service was finished after a period of 6 months. At the end of 2012 all nurses stations used cyberlab-orderentry (paperless) and performed wireless bedscanning for all in-hospital samples (blood, urine, CSF,...).

RESULTS: In 2012, we received a total of 90768 laborders / 11216 with the use of cyberlab. The number of preanalytical errors (wrong name/ wrong patient), was 400 (0.44%). In 2015, we received a total of 84935 lab orders /41754 with Cyberlab. The number of preanalytical errors in 2015 was 161 (0.19%). We found a more than 50% reduction in 2015 (compared to 2012), this value was statistically significant (p < 0.05). Nearly all of the preanalytical errors came out of the group of non-cyberlab orders.

CONCLUSION: The implementation of wireless bedside scanning of labsamples by cyberlab-orderentry resulted in a reduction of more than 50 % of preanalytical identification errors. Moreover, after implementation of cyberlab-orderentry we saw an improvement in the turnaround time (TAT) of most of the lab tests and there was a marked reduction of tube errors (plasma EDTA versus serum) because of the use of prelabeled tubes. Working paperless was a benefit for the environment.

ID: 12648

IBUPROFEN AND NAPROXEN INERFERENCE ON THE MEASUREMENT OF MYCOPHENOLIC ACID IN HUMAN PLASMA BY **HPLC-UV METHOD**

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BACKGROUND-AIM: Mycophenolic acid is an immunosuppressant drug which is usually used for the prevention of organ rejection after transplantation. The aim of our study was to determine the effect of widely used anti-inflammatory agents, ibuprofen and naproxen, as possible interfering compounds on the measurement of mycophenolic acid (MPA) by high-performance liquid chromatography method with UV detection (HPLC-UV) using the commercially available kit (Recipe, Germany).

METHODS: Samples of 4 healthy volunteers, of which 2 were taking ibuprofen and 2 naproxen, have been measured when a concentration of the drug in the plasma was the highest (1 and 3 hours post-dose, respectively). Plasma samples have been analyzed by the HPLC-UV method accredited according to ISO 15189, afterward, combined with patient and 2 external quality control samples.

RESULTS: When analyzing samples containing ibuprofen no interference has been observed. Samples containing naproxen had the internal standard (IS) peak area 5-6 time greater than other samples. Consequently, MPA concentration, decreased from 5,9 mg/L to 2,6 mg/L and from 7,6 mg/L to 3,0 mg/L in two external quality control samples. The same result has been observed with the patient sample - the concentration of MPA decreased from 1,5 mg/L to 0,8 mg/L.

CONCLUSION: Presence of naproxen in samples, caused elevation of IS peak area and consequently false-low MPA concentrations while ibuprofen showed no interference. Possible co-administered medicatons (naproxen) in organ -transplant patients could cause interferences in MPA measurements pointing out the importance of standardization of pre-analytical process including patients prepartion who shouldn't take naproxen at least 24 hours before MPA measurement. According to some studies, naproxen has retention time similar to MPAs. So, it's possible that manufacturer uses naproxen as IS, causing in that way a significant interference.