IVDCheckR

Project title

Quantum Transferase Activity Assay in Serum

Date

2024-01-01 - 2024-03-31

Analyte Description

Quantum transferase activity assay (QTA)

Intended use of the analyte

The Quantum Transferase Activity Assay (QTA) is a CE marked assay and measures the activity of a specific enzyme known as “Quantum Transferase”. The current QTA assay is measured in Quantum Plasma which is rarely available. The measurement in Serum is preferable. The performance of the assay will be compared between Quantum Plasma and Serum.

Indication

The primary purpose of the QTA is to diagnose Quantum Disease (QD).

Scientific validity

The scientific validity of the QTA can be reviewed in Qupaz et al., J Quant Lab 2023;11(14):128-36

Measurement scale

Quantitative

Sample material

Other

Other sample material

Quantum Plasma

Risk class

B

Risk class details

The measurement of QTA in Serum assay is categorized Risk class B as the original assay defined by the manufacturer. The risk class remains according to classification rules 4 and 6.

Modification of a existing CE marked product

Different sample material

Other Modification Reason

SOP

See attached PDF file

Justification for use of the LDT

See attached PDF file

Declaration of Conformity

See attached PDF file

Risk management

See attached PDF file

Monitoring and review activities

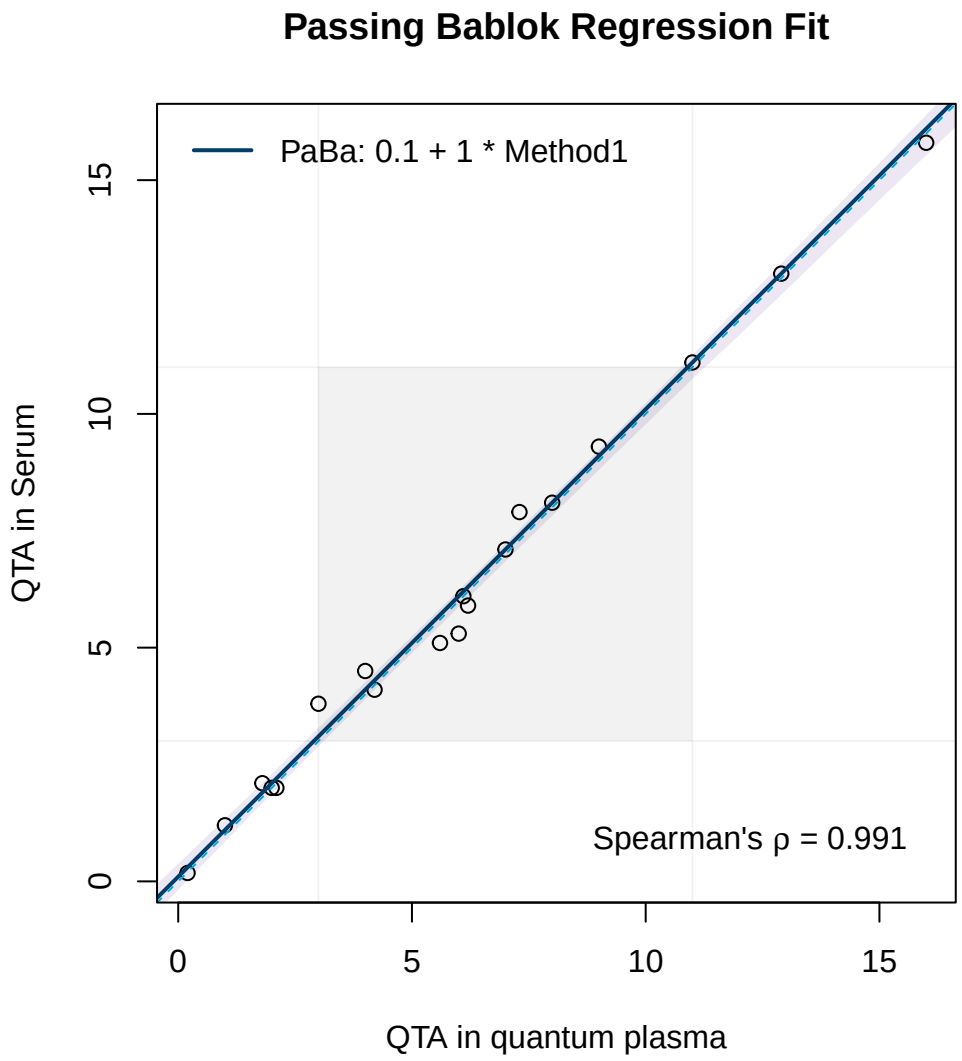
See attached PDF file

Analytical performance

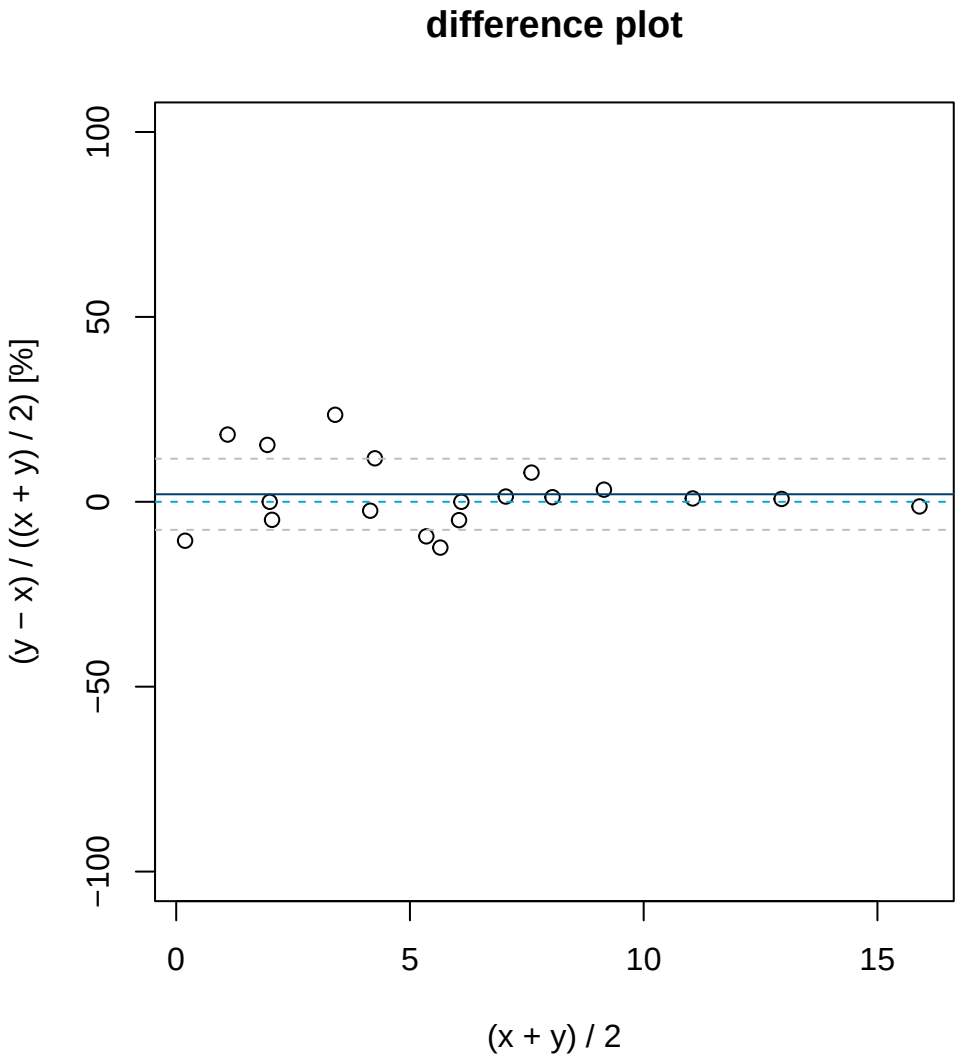
Clinical performance

Further comments

Method Comparison




```
Passing Bablok regression function: y = 0.1 + 1 * xSpearman coefficient of correlation: 0.99
```



Raw data entered for method comparison

	x	y
1	1.0	1.20
2	2.1	2.00
3	1.8	2.10
4	3.0	3.80
5	4.2	4.10
6	5.6	5.10
7	6.1	6.10
8	7.0	7.10
9	7.3	7.90
10	8.0	8.10
11	9.0	9.30
12	6.0	5.30
13	6.2	5.90
14	11.0	11.10
15	12.9	13.00

```
16  4.0  4.50
17  2.0  2.00
18 16.0 15.80
19  0.2  0.18
```

Quality control

```
[1] "QTA"
[1] "QC from Quantum Transferase Activity Assay"
[1] "withinrun"
```

	QC1	QC2	QC3
Mean	4.09	11.93	NaN
Target value	4.30	11.80	0
CV [%]	12.61	5.17	NA
Bias [%]	-4.96	1.07	NaN
RMSD [%]	12.60	5.16	NaN

qc1	qc2	qc3
4.0	11.6	NA
4.3	12.0	NA
3.0	11.1	NA
4.7	11.1	NA
4.5	11.9	NA
3.8	12.6	NA
4.9	12.4	NA
4.6	12.7	NA
4.0	11.8	NA
3.3	12.5	NA
4.2	11.0	NA
4.1	12.0	NA
3.6	12.2	NA
4.0	12.8	NA
4.3	11.2	NA
NA	NA	NA
NA	NA	NA
NA	NA	NA
NA	NA	NA
NA	NA	NA
NA	NA	NA

List of used chemicals and software

Product/Instrument/Software	Manufacturer	Product Number	Use Case	Referred Document
QTA Assay	B	QTA123456	Assay in Serum	SOP, Scientific validity

Example Document: SOP

SOP for process on which a different sample material is used.

Project title: *Quantum Transferase Activity Assay in Serum*

Measurement parameter: *Quantum Transferase activity*

Responsible Person(s):

Name and contact of Person(s) responsible for the IVD in laboratory

Material:

Detailed List of all Material necessary to use the IVD

Implementation:

Detailed description of the method (including hazards and protections, waste management), sample handling, pre-analytics, post-analytics

Example Document

Justification for use of the LDT for process on which a different sample material is used.

Project title: *Quantum Transferase Activity Assay in Serum*

Measurement parameter: *Quantum transferase activity*

Intended use and explanation of changes:

Description of what has been altered from the original, commercially available product

Literature research:

Literature research of this altered device not being commercially available or only being available in a way which is e.g. not suitable for the specific target group.

Evaluation of risk of changes of the original performance:

Influence of the alteration on the original performance and inherent risk

Clinical and analytical Perfarmance:

Reference to clinical and analytical performance evaluation etc.

Example Document: Declaration of conformity

Public declaration regarding the manufacture and use of laboratory developed tests by health institutions

as per Art. 5.5(f), Art. 17, Ann. IV of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017

Document No.: ***123456***
Health institution: ***Hospital hospital***
Address: ***Hospitalstreet 1, 12345 Hospitaltown, Germany***

-the health institution- declares that the devices or tests described in the accompanying table are only manufactured and used in -the health institution- and do meet the applicable general safety and performance requirements (GSPR) of the in vitro diagnostic medical devices Regulation (EU 2017/746). A reasoned justification is provided in case applicable general safety and performance requirements are not fully met.

Table of laboratory developed tests:

Device identification (e.g. name, description, reference number)	***Risk class of the device***	***Intended purpose***	***Applicable GSPR fully met? (Y/N)***	***Information on and justification for applicable GSPR that are not fully met (using the numbering as in Annex I of the IVDR/MDR)***
Using Quantum Plasma instead of serum for Quantum transferase activity assay (QTA) *(ID 654321)*	*B*	*Quantification of* Quantum transferase activity	*Y*	-

Date and location:
01.01.24, Hospitaltown

Name, function and signature of responsible person(s):
Hospital member 1
Hospital member 2
Hospital member 3

Example Document

Risk management plan for process on which extension of a different sample material used.

Project title: *Quantum Transferase Activity Assay in Serum*

Measurement parameter: *Quantum transferase activity*

Based on the general risk management plan of the laboratory and the risk management carried out by the original manufacturer, potential new risks arising from the modification of the IVD must be identified and controlled. Risks to the patient, the user and third parties/the environment must be considered.

Identify new hazards:

Newly occurring hazards due to device modification.

Risk evaluation:

Evaluate possible risks.

Control risks as best as possible

Control measures:

Adapt control measures, if necessary.

Description of remaining risks and risk-benefit balance:

Describe the remaining risks and how they can be controlled. Justify residuals risks considering the clinical benefits.

Example Document

Monitoring and review activities for process on which a different sample material is used

Project title: *Quantum Transferase Activity Assay in Quantum Plasma*

Measurement parameter: *Quantum transferase activity*

Performance and Safty:

Monitor performance and safety after device is put into use.

Documentation:

Document occurring incidents.

Risk-management report:

Write risk-management report (review production and post-production information).

Reassessment:

Reassess and update IVD in a specific time interval during whole life cycle.