

Letter to the Editor

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Hemolysis detection using the GEM 7000 at the point of care in a pediatric hospital setting: does it affect outcomes?

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To the Editor,

Point-of-care testing (POCT) unlike diagnostic testing performed in the core laboratory, is typically performed near patient's bedside which has proven to be valuable in clinical settings where rapid diagnostics are required for patient care such as emergency departments, critical care units, physician's office etc [1].

Despite these advantages and the continuous evolution of POCT technologies, some quality challenges associated with POCT remain [2] making it require constant training of POCT personnel and vigilant oversight to be performed properly to minimize erroneous sample handling or error rates [3]. Hemolysis caused by the disruption of red cell membrane and subsequent release of intracellular component into the surrounding fluid is a notable concern in whole blood POC testing [2, 4]. *in vitro* hemolysis can interfere with certain testing method and falsely increase the concentration of several analytes like potassium, aspartate aminotransferase etc. [2, 5] which can mislead physicians [6, 7]. The reported rate for hemolysis across different care setting and collection method range between 3 and 77 % with pediatric

rates on the high side of this range most likely due to their small veins and the blood collection techniques mostly utilized in pediatric settings [7, 8]. Overall, hemolysis affect patient management by causing repeated blood draws which has been associated with patient discomfort and linked to impaired behavioral outcomes in neonates [2, 7, 9].

Although most automated chemistry analyzers can detect hemolysis and other common endogenous interfering substances spectrophotometrically, most POCT devices cannot [4, 10]. Recently, Werfen launched the GEM Premier 7,000 with IQM3 blood gas analyzer (GEM 7000), which is the first POCT device that detects hemolysis as part of its analysis workflow [10]. It flags whole blood potassium results impacted by hemolysis [10]. Recently, Pighi et al. validated the analytical performance of the GEM 7000 hemolysis detection module using heparinized plasma and whole blood samples in an adult population, confirming its high agreement with central chemistry analyzers with minimal bias [11]. Our study complements this by providing the first pediatric implementation analysis in clinical practice. This study evaluated the performance of the GEM 7000 analyzer in detecting hemolysis in a pediatric hospital's Emergency Center (EC) and Neonatal Intensive Care Unit (NICU) settings. Specifically, we assess its concordance with central laboratory analyzers and examine the prevalence and clinical implications of flagged hemolysis in POC blood gas testing. This real-world analysis is the first pediatric-focused experience with this technology.

For hemolysis index (H-index) agreement comparison, the GEM 7000 hemolysis performance was assessed against two laboratory systems, Hemocue (HemoCue America) and VITROS XT 7600 (Vitros; QuidelOrtho). Hemolysis agreement across platforms was assessed using 31 residual heparinized whole blood samples, each analyzed on the GEM 7000, Hemocue, and Vitros to enable direct comparison on the same specimen. The VITROS H indices were aligned with the GEM 7000 index levels based on corresponding hemoglobin concentration ranges (e.g., 101–250 mg/dL=GEM index level 3), while the raw plasma free hemoglobin concentration

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measured by the Hemocue were converted to the GEM 7000's semi-quantitative hemolysis indice as shown in Supplementary Table 1. We also compared the potassium results between the GEM 7000 and Vitros.

Following conversion of Hemocue value to the GEM 7000's hemolysis indices, 90.3 % (28/31) of samples match consistently between the three analyzers (Table 1). The three discrepant results were all within one scoring level difference on the GEM 7000 H-index (Table 1). The potassium levels of these samples between the GEM 7000 and Vitros match within a total allowable error of 0.2 (Figure 1A and B). These potassium results on the GEM 7000 shows excellent agreement with the Vitros with a Pearson's correlation coefficient (R) of 0.989.

We also conducted a retrospective cohort study for blood gas analysis reports from January to April 2025 of

pediatric patients who visited our EC and NICU to calculate the aggregated hemolysis rate of our runs for the different unit focusing on mild and moderate hemolysis (GEM H-indices level 3, 4 and 5). Following this we compared the hemolysis indices agreement between the potassium results flagged by GEM 7000 and the results obtained from a repeat analysis on the Vitros within 2 h. Within this period, 8,032 specimens for blood gas testing were ordered and resulted from our EC and NICU. Majority of our run (88.1 %; 7,079/8,032) were from the NICU while 11.9 % (953/8,032) were from the EC. The distribution of the hemolysis flag for all the runs in these units are shown in Supplementary Table 2. From these runs, about 1 % (81/8,032) have hemolysis indices between 3, 4 and 5 corresponding to slight and moderate hemolysis on our Vitros. The EC had the highest hemolysis rate of 8.2 % (78/953) while the NICU recorded 0.04 % (3/7,079) for

Table 1: Hemolysis detection concordance between the GEM 7000 blood gas analyzer, Hemocue and Vitros XT 7600 chemistry analyzer.

Specimen	GEM 7000		Hemocue			Vitros		Agreement
	Hemolysis index	Hemolysis degree	Hemocue hemolysis value, mg/dL	Hemolysis index	Hemolysis degree	Hemolysis index	Hemolysis degree	
1	1	None	10	1	None	1	None	Yes
2	3	Mild	190	3	Mild	4	Mild	Yes
3	5	Moderate	390	5	Moderate	6	Gross	No
4	6	Gross	620	6	Gross	6	Gross	Yes
5	1	None	10	1	None	1	None	Yes
6	1	None	0	1	None	1	None	Yes
7	1	None	0	1	None	1	None	Yes
8	1	None	50	1	None	1	None	Yes
9	1	None	10	1	None	1	None	Yes
10	1	None	20	1	None	1	None	Yes
11	3	Mild	180	3	Mild	4	Mild	Yes
12	5	Moderate	360	5	Moderate	5	Moderate	Yes
13	6	Gross	600	6	Gross	6	Gross	Yes
14	5	Moderate	400	5	Moderate	5	Moderate	Yes
15	6	Gross	680	6	Gross	6	Gross	Yes
16	3	Mild	160	3	Mild	4	Mild	Yes
17	4	Mild	330	5	Moderate	5	Moderate	No
18	6	Gross	610	6	Gross	6	Gross	Yes
19	3	Mild	190	3	Mild	4	Mild	Yes
20	4	Mild	340	5	Moderate	5	Moderate	No
21	6	Gross	640	6	Gross	6	Gross	Yes
22	5	Moderate	370	5	Moderate	5	Moderate	Yes
23	6	Gross	620	6	Gross	6	Gross	Yes
24	3	Mild	200	3	Mild	4	Mild	Yes
25	4	Mild	370	5	Moderate	5	Moderate	No
26	6	Gross	660	6	Gross	6	Gross	Yes
27	3	Mild	230	4	Mild	3	Mild	Yes
28	3	Mild	170	3	Mild	3	Mild	Yes
29	5	Moderate	330	5	Moderate	4	Mild	Yes
30	5	Moderate	350	5	Moderate	4	Mild	Yes
31	6	Gross	480	6	Gross	6	Gross	Yes

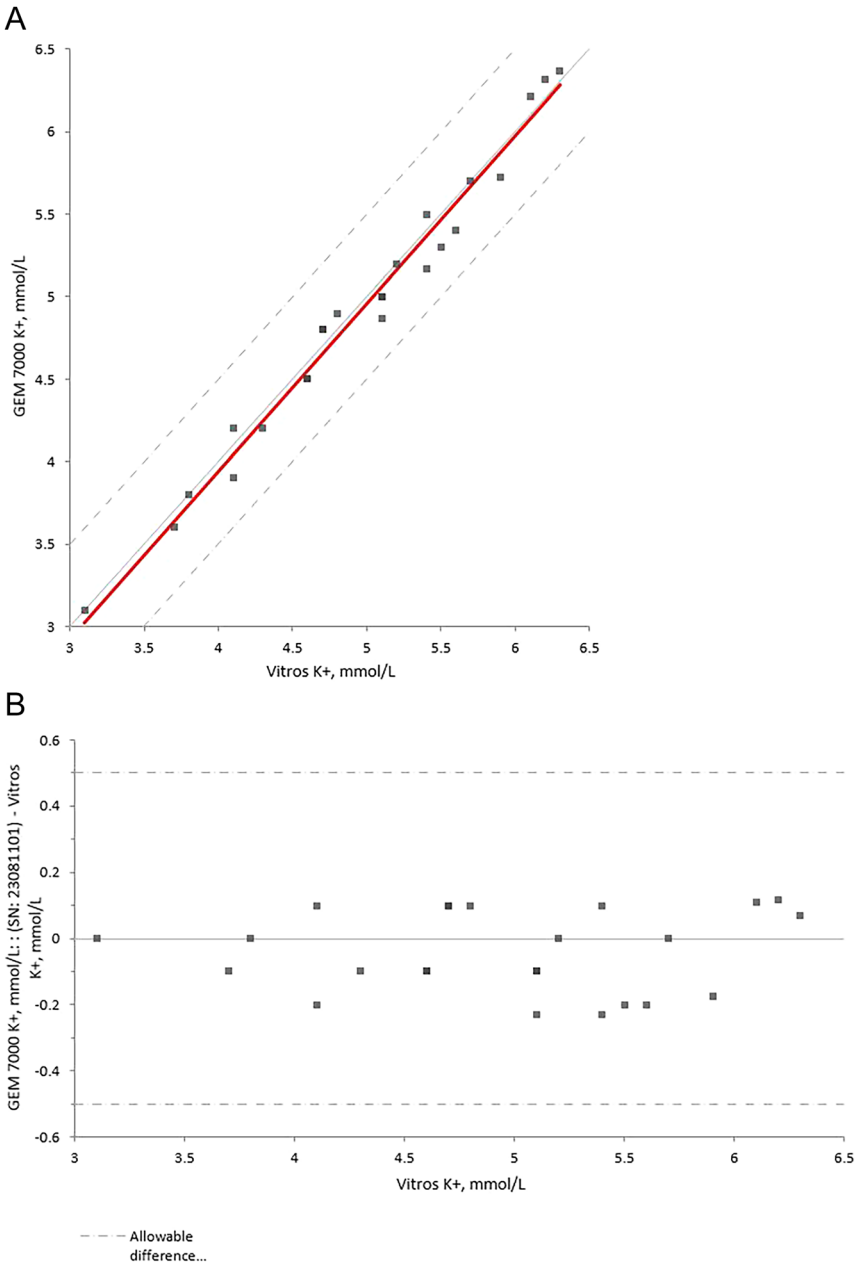


Figure 1: (A) GEM 7000 potassium levels correlates well with Vitros XT 7600 measurements. (B) Difference plot comparing potassium results from GEM 7000 and Vitros XT 7600.

Table 2: Hemolysis index rate across different hospital units.

		Hemolysis index (%)						
	Total	1	2	3	4	5	6	(4 & 5)
EC	953	750 (78.7)	97 (10.2)	48 (5.0)	23 (2.4)	7 (0.7)	28 (2.9)	30 (3.1)
NICU	7,079	7,066 (99.8)	9 (0.1)	2 (0.03)	1 (0.01)	0	1 (0.01)	1 (0.01)
Total	8,032			81 (1 %)				

Table 3: Concordance of hemolysis indices for flagged potassium results between the GEM 7000 and Vitros XT 7600.

GEM 7000 vs. Vitros H-indices for flagged potassium results for slight and moderate hemolysis (%)	
Match	50 (61.7)
Unmatched	29 (35.8)
Unmeasured	2 (2.5)
Total	81 (100)

samples with potassium results flagged at hemolysis level 3, 4 and 5. Of these, 3.1 and 0.01 % were moderately hemolyzed at both the EC and NICU respectively (Tables 2 and 3).

Following this, we compared the potassium rerun for samples flagged by the GEM 7000 for these H-indices on the Vitros and compared how it matches with our Vitros H-indices 4 and 5 for slight and moderate hemolysis within 2 h. Of these, 60.5 % match the Vitros for both slight and moderate hemolysis, 37 % did not match while 2.5 % did not have a potassium result rerun within 2 h of the GEM 7000 run (Supplementary Table 3). Of the 29 unmatched samples, 5 were grossly hemolyzed on the Vitros (>500 mg/dL).

The whole blood is a convenient sample of choice to assess electrolyte and metabolite concentration in the pediatric population where their small total body blood volume limits the amount of blood that can be drawn [7]. The risk of hyperkalemia due to hemolysis comes with the use of whole blood samples which may go unnoticed as most POC testing devices are not able to detect the presence of hemolysis [2]. Identifying hemolysis can help minimize inappropriate treatment in both pediatrics and adults. The new GEM 7000 blood gas analyzer is equipped with in-line detection of hemolysis via photometry principle similar to most chemistry analyzers [4, 10]. To our knowledge this is the first study to assess its real-time experience in a pediatric hospital.

In this study, the GEM 7000 showed high concordance with the Hemocue and Vitros chemistry analyzer in detecting hemolysis in both neat and spiked samples as previously reported [4, 10]. We also identified excellent correlation of the potassium results in these samples on both the GEM 7000 and the Vitros. Our EC samples showed the highest hemolysis rate of 8.2 % compared to our NICU rate of 0.04 %. This is consistent with previous reports of about 8–14 % hemolysis rate in ED specimens compared to other units [4]. To rule out pseudohyperkalemia, remnant blood samples are usually sent to the central laboratories for potassium measurements. In our study, 61.7 % of samples match the hemolysis index of the GEM 7000 when potassium results was rerun on the Vitros chemistry analyzer within 2 h of the GEM run while 35.8 % did not. Of these unmatched specimens, 17.2 % (5/28) were grossly hemolyzed. This discrepancy is mostly due to the fact that the repeat testing was not done using the original GEM 7000 sample. Our study demonstrates that in-line hemolysis detection on the GEM 7000 shows strong concordance with central laboratory analyzers, reducing the risk of pseudohyperkalemia and unnecessary potassium-related interventions. This is particularly valuable in neonatal settings, where sample volume and venous access are limited. The high rate of concordance we observed aligns with the adult validation study by Pighi et al. [11], further supporting the GEM 7000's accuracy in real-world clinical use. Early identification

of hemolyzed samples may reduce unnecessary redraws and improve turnaround time for actionable results.

Studies have linked the 7.4 % hemolysis rate for blood gas analysis done in the ED to factors like diverse professionals working in the ED compared to trained phlebotomists at other locations [2]. In our hospital, we recorded a 3.1 % rate of moderately hemolyzed specimens from our EC which is lower than previous reports. This lower rate may be directly linked to our POCT team's effort in continuously training our POC nurses to ensure they are well equipped with skills to reduce pre-analytical errors alongside the stability of our POCT device operators which minimizes frequent hiring of POCT device operators.

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