

Preanalytical EQA for PTS: A Modern Pneumatic Tube System Monitoring Tool for Clinical Laboratories

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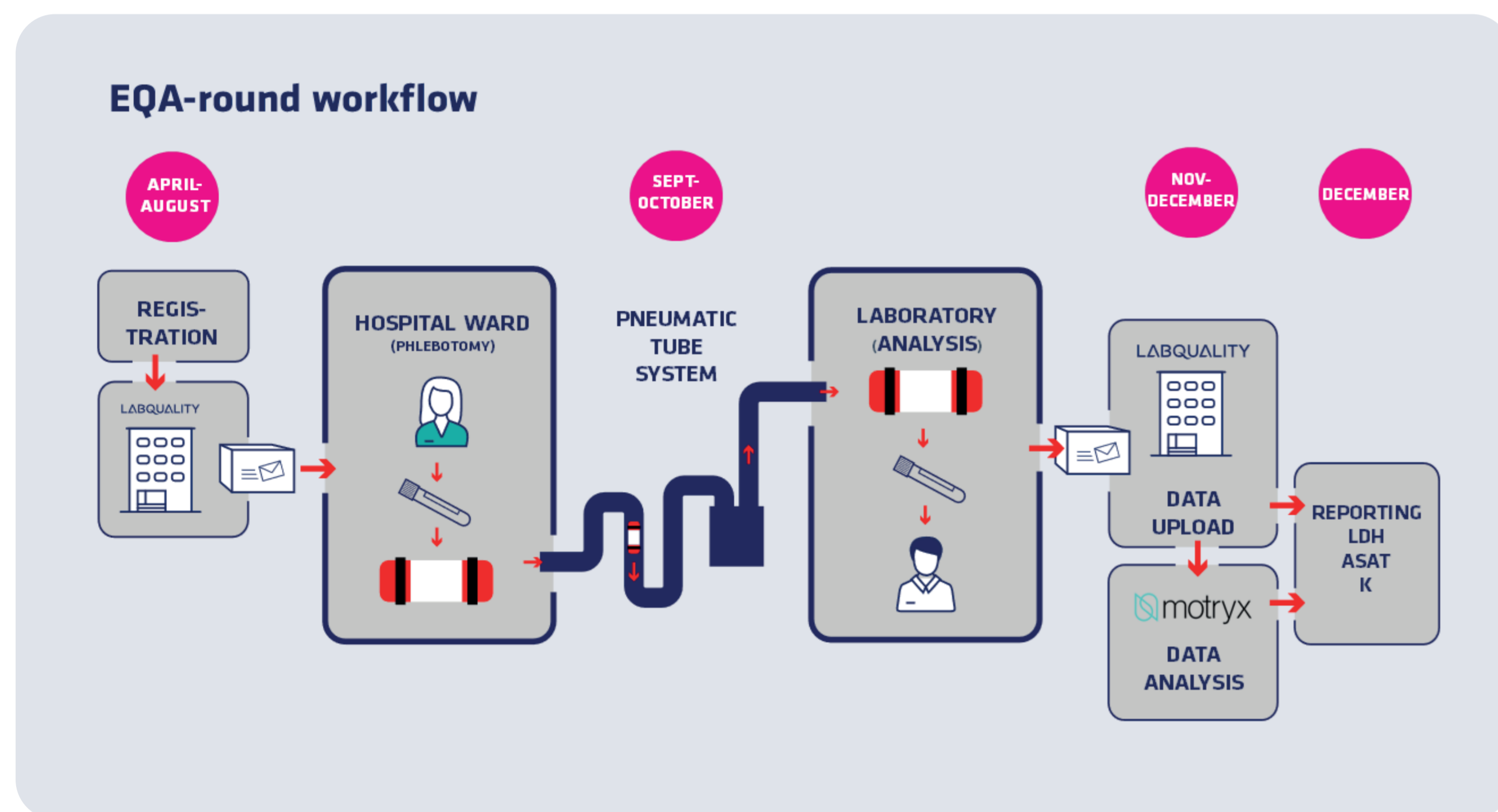
Introduction

Labquality is a Finnish independent EQA provider focused on producing clinically relevant external quality assessment (EQA) schemes that cover the whole laboratory process from pre- to postanalytics, in addition to the analytical phase. According to the ISO 15189 standard, laboratories should choose EQA programs that cover the total testing process and the EFLM Working Group for Pre-analytical Phase recommends that laboratories should evaluate and monitor impacts of transport and its effects on e.g. hemolysis when using pneumatic tube systems (PTS) for transporting blood samples. (1,2)

Labquality has introduced a new EQA scheme for PTS, using a solution developed by Motryx Inc, where sample rejection probability due to transport induced hemolysis is modelled based on laboratory set analyte-specific hemolysis index (HI) cutoffs and force measurements in the PTS. Based on the results and experiences of our pilot study performed in the spring of 2021, we conducted a first EQA round during the fall of 2021 of which results are presented here.

Keywords: External quality assessment (EQA), Pneumatic Tube System (PTS), hemolysis

Materials and Methods



Laboratories received two surrogate blood samples, i.e. VitalVial measurement devices that record 3-axis acceleration during PTS transport for calculation of a cumulative vibration level reported as a VitalMetric value, together with detailed step-by-step instructions on how to use the vials. The vials were sent through up to three PTS lines from hospital wards to the laboratory as regular patient samples and then returned to Labquality for data upload. Data analysis was performed by Motryx. Rejection probability for LDH, ASAT and K was calculated using a hemolysis model, analyte-specific hemolysis index cutoffs set by the laboratory, and the measured cumulative vibration level. A set of preanalytical questions regarding the PTS process was included.

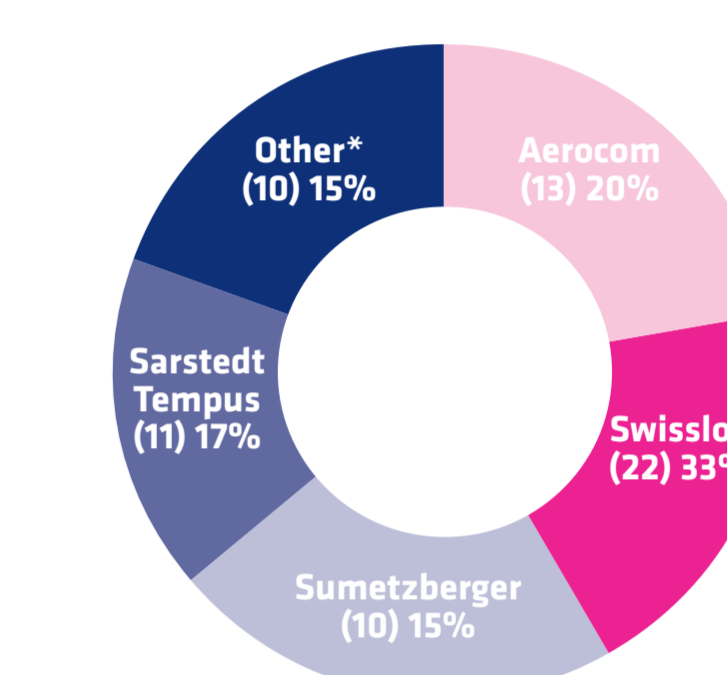


Results

32 Participating laboratories | **14** Countries | **66** PTS lines | **9** PTS manufacturers | **5** Clinical chemistry analyzer brands

PTS details

	Aerocom	Swisslog	Sumet zberger	Sarstedt Tempus	Other	Overall Median
VITAL METRIC	572 (216-1218)	415 (91-764)	995 (111-1540)	335 (257-677)	174 (95-568)	371 (91-1540)
LENGTH* (m)	375m (40-600)	290m (25-530)	768m (117-1426)	246m (100-1700)	99m (40-2050)	270m (25-2050)
SPEED (m/s)	2.2m/s (0.4-4.3)	1.5m/s (0.6-2.8)	2.5m/s (1.5-3.3)	4.8m/s (3.1-6.9)	2m/s (0.9-4.4)	2.2m/s (0.4-6.9)
PERFORMANCE (1-10)	6 (4-7)	6 (5-8)	6 (6-7)	6 (5-8)	6 (5-9)	6 (4-9)



*Other: Instals, Oppent, Tehotekniikka, Rofa Rohrpostanlagen, Custom

*Approx. length provided by participants

PTS system medians and distribution of PTS systems represented in the EQA round. A longer PTS line typically has a higher VitalMetric value which does not necessarily reflect on total performance. In the final reports, client specific results were compared to median of the other participants in the same group and to overall median results.

Analyzer HI cutoffs (mg/dL)

	Roche Median (n=20)	Abbott Median (n=7)	Other* Median (n=5)	Overall Median (n=32)
LDH	15 (10-60)	30 (10-33)	35 (30-50)	15 (10-60)
ASAT	25 (20-100)	92 (60-125)	65 (50-100)	40 (20-125)
K	60 (20-200)	100 (50-110)	75 (50-108)	80 (20-200)

Hemolysis cutoffs provided by participants

*Other: OrthoDiagnostics, Beckman, Siemens

Rejection probability (%)

	Roche Median	Abbott Median	Other* Median	Overall Median
LDH	17% (1-41)	5% (3-36)	10% (1-12)	12% (1-41)
ASAT	8% (1-16)	1%	1% (1-3)	3% (1-16)
K	2% (1-12)	1%	1% (1-3)	1% (1-12)

Hemolysis index cutoffs used presented as medians and distribution of clinical chemistry analyzers represented in the EQA round. The significant variation in hemolysis index HI cutoffs within the same manufacturer group should be noted.

VitalMetric values, i.e. the cumulative vibration level, and laboratory set HI cutoffs were used to calculate the sample rejection probability for the three analytes. The rejection rate medians are shown here.

32 laboratories from 14 countries using 9 different PTS and 5 different clinical chemistry analyzers participated. There was a large variation in length (25-2050 m) and speed (0.4-6.9 m/s) of the PTS's, which affect the PTS performance (median 6, scale 0-10). These impact the sample rejection probability together with used HI cutoffs. The impact of the PTS systems on vibration and mechanical stress causing hemolysis of the samples can be reduced by using appropriate tube carrier inserts to reduce the vibration levels (3). According to the answers on the preanalytical questions, using other than manufacturer recommended HI cutoffs was mostly verified by own studies or based on literature. 13 of the 32 laboratories had rejection probabilities below the overall round median for all three analytes (LDH 12%, ASAT 3%, K 1%).

REFERENCES

- ISO15189:2012 Medical laboratories - requirements for quality and competence.
- Vermeersch P, Frans G, von Meyer A, Costelloe S, Lippi G, Simundic A-M. How to meet ISO15189:2012 pre-analytical requirements in clinical laboratories? A consensus document by the EFLM WG-PRE. Clin Chem Lab Med 2020; 59(6): 1047-1061.
- Cadamuro J, von Meyer A, Johannis W, Haschke-Becher E, Keppel MH, Streichert T. Effect of five different pneumatic tube carrier inserts on mechanical sample stress: a multi-centre evaluation. Clin Chem Med Lab 2020; 59(8): 313-316.

Conclusions

- Lower sample rejection probability as compared to other participants indicates a better relative performance of the PTS system, however, rejection probability is also highly influenced by the HI cutoffs used in the laboratory. Therefore, laboratories should evaluate the PTS and clinical chemistry analyzer together.
- This EQA scheme shows that manufacturer recommended HI cutoffs are not always used, making result comparison challenging and supports a need for harmonization of preanalytical settings in clinical chemistry.
- Laboratories should set acceptable sample rejection levels based on PTS, analyzer performance and defined HI cutoffs. Some laboratories accept only very low rejection probability rates whereas others accept somewhat higher rates taking in consideration the convenience and benefits of using a PTS.
- Rejection probability exceeding acceptable levels according to the laboratory's standards might suggest a need for PTS maintenance or re-evaluation of the sending process including evaluation of the carrier inserts. Adjusting the process can help to reduce the risk of hemolysis of blood samples.
- This preanalytical EQA scheme is a convenient tool for clinical laboratories to monitor the PTS on a regular basis. It supports laboratories in managing the impact of the PTS on hemolysis and the quality of their extra-analytical process.