LABQUALITY

External Quality Assessment Scheme

Preanalytics, Pneumatic Sample Transport, Round 1, 2022

Shipping of the VitalVials for round 1, 2022 will be carried out in batches during September-November.

Content
Please find enclosed 1 transportation case including 2 VitalVials with magnetic clips attached and 2 additional magnetic clips. NOTE! Removing the white magnetic clip from the VitalVial will start the recording. The clip is only removed when the VitalVials are placed in the pneumatic transport system carrier.

Examinations
Vibration, acceleration and speed will be recorded during the transportation of the VitalVials when transported in the pneumatic transport system. No other tests are performed by the laboratory.

Use
A Step-by-step Guide for using VitalVials is included. Please read the guide carefully before performing the measurements. It is possible to perform recordings on three different lines from the same PTS manufacturer. In the report, the lines will only appear as “Line 1”, “Line 2” and “Line 3”. Please name the lines so that you can identify the lines from each other. You should save the completed paper result sheet for interpretation of the report. Note! It is important for the reliability of the results that the vials have been run twice successfully through each line to be monitored. If you have problems during transportation, you can perform more than two runs.

Return instructions
Return all items after inserting all needed information to LabScala (www.labscala.com) within 7 days to your local distributor. The data of the PTS (length, manufacturer) as well as the chemistry analyzer in use and the HIL cut-off limits are mandatory info for analyzing the results. If you don`t know your client code and/or password to LabScala, please contact info@labquality.fi.

For non-returned tubes we charge 250 € / per tube.

If you have any questions, please contact the EQA Coordinator.

2022-09-26

INSTRUCTIONS

Product no. 7807

If the kit is incomplete or damaged, please report immediately to info@labquality.fi.

These items should be returned to your local distributor no later than **7 days after** receiving.

Inquiries
EQA Coordinator
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iida.silvo@labquality.fi

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www.labquality.fi

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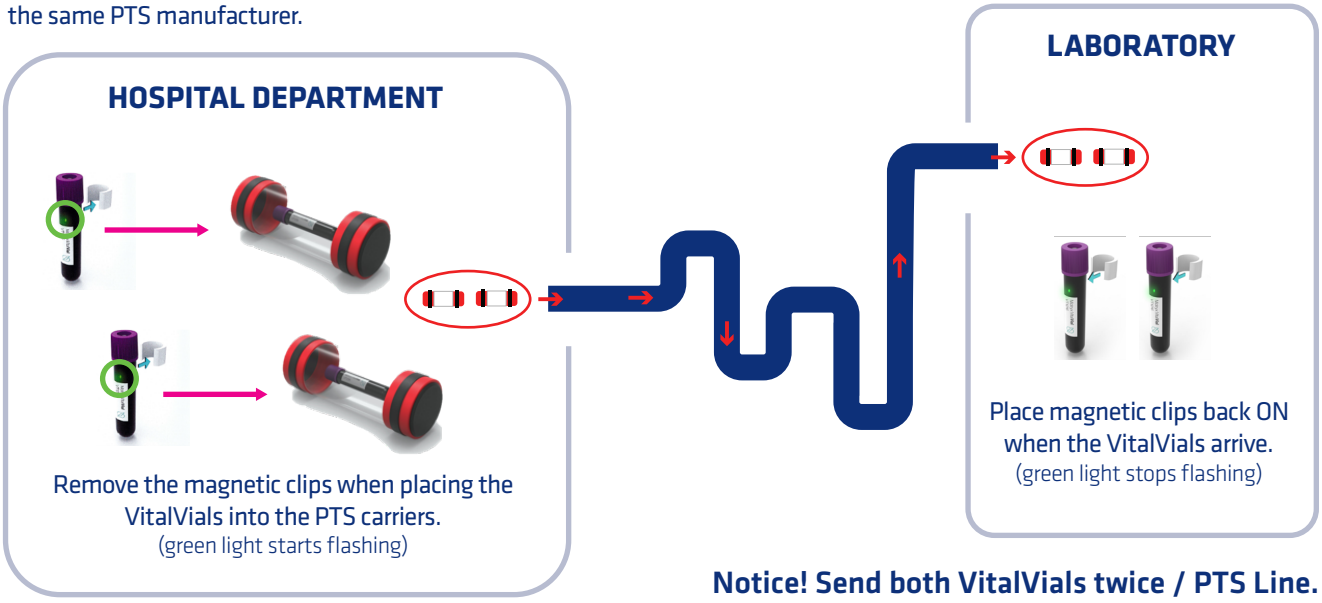
Preanalytics, Pneumatic Sample Transport 1, 2022

Participant Step-by-step Guide. Please complete the scheme within 7 days.

In the shipment:

General workflow

Up to three Pneumatic Tube System (PTS) lines can be monitored in this EQA round. Send 2 VitalVials from Department to Laboratory via the Pneumatic Tube System. Collect the VitalVials from the laboratory and repeat the sending process from the same department. The process may be repeated from two additional departmens. Note! All three lines must be from the same PTS manufacturer.



Notice! Send both VitalVials twice / PTS Line.

Notice!

1) Removing the magnetic clips from the VitalVials will activate the measurement. Remove the clips just before you place the VitalVials in the PTS carriers.

2) Before starting, make sure that the two extra magnetic clips are available in the laboratory when the VitalVials are received after transportation. Instruct the recepient of the PTS carriers to place the clips on the VitalVials when they arrive in the laboratory to stop the measurement.

Step 1

Take the case containing the VitalVials to the department of choice and there remove the VitalVials from the case.

Step 2

Remove the magnetic clip from the VitalVial and check that the green light in the VitalVial starts flashing.

Step 3

Start filling in the information to the table on the result sheet. Write down the Line name, the VitalVial number and the time of removing the magnetic clip as in the example below. This information is required to assign VitalVial Data from the correct line to the EQA scheme. The result sheet is for your internal use only and the data should be reported in LabScala after all measurements are done.

Line 1: *ED to LAB*		
PTS manuf: *Aerocom*		
Lenght of Line 1 (m): *250m*		
Date of measurement: *Oct 14th*		
	VitalVial number	Time (hh:mm)
1	*VT1243*	*09:28*
2	*VT1285*	*09:30*
3	*VT1243*	*09:42*
4	*VT1285*	*09:44*

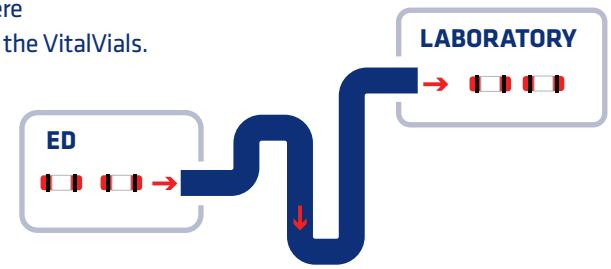
Step 4

Pack the two VitalVials as if they were regular blood samples in PTS carriers. Pack only one VitalVial per PTS carrier. Place the magnetic clips in your pocket, not inside the PTS carriers.

The VitalVials can also be used e.g. for the Tempus system where no separate carrier/canister is used.

Step 5

Send both PTS carriers to the Laboratory and go there to retrieve the VitalVials.



Step 6

The two extra clips should be placed on the VitalVials once they arrive to the laboratory. The green light should NOT be flashing when the clips are placed on the VitalVials. Place the VitalVials in their storage case.

Step 7

Hand the two extra magnetic clips from your pocket to the PTS recepient in the laboratory and take the case with the VitalVials first back to the same department to repeat the measurement a second time. When two measurement rounds are performed, move to a new department.

Step 8

Repeat steps 2-7

Step 9

Up to three PTS lines (Line 1-3) may be monitored in this EQA round. Both VitalVials should be sent twice in separate carriers through each line. After performing two measurements of Line 1, repeat the process for Line 2 and Line 3. Please pay attention when adding the data for each line to the Results Sheet.

Step 10

After the last measurements, please make sure that the magnetic clips are attached to the VitalVials and no light is flashing. Place the VitalVials in their case. Report the results from the Results Sheet to the eform in LabScala. Please log in at www.labscala.com.

Step 11

Return the VitalVial case with magnetic clips attached to the vials, the two extra magnetic clips and the Result sheet to your local distributor/Labquality as instructed within 7 days after receiving the shipment. The package material can be reused for the return shipment.

Result sheet for internal use - data should be reported in LabScala

This information is required to assign VitalVial Data from the correct Line to the EQA scheme and for analyzing the data retrieved from the VitalVial recordings. Please pay attention when adding the data for each PTS line. In the report, the lines will be named Line 1, Line 2, Line 3 only.

Log in to LabScala (www.labscala.com) and fill all information to the eForm. If you do not know your client code and/or password, please contact info@labquality.fi. The data of the PTS (length, manufacturer) as well as the chemistry analyzer in use and the HIL cut-off limits are necessary info for analyzing the results. This Result sheet is for your internal use only.

Labquality client code:	Laboratory name:
Date of receiving the shipment:	Date of return shipment:
Clinical chemistry analyzer manufacturer and model:	

Line 1:		
PTS manuf:		
Length of Line 1 (m):		
Date of measurement:		
	VitalVial number	Time (hh:mm)
1		
2		
3		
4		

Line 2:		
PTS manuf:		
Length of Line 2 (m):		
Date of measurement:		
	VitalVial number	Time (hh:mm)
1		
2		
3		
4		

Line 3:		
PTS manuf:		
Length of Line 3 (m):		
Date of measurement:		
	VitalVial number	Time (hh:mm)
1		
2		
3		
4		

Hemolysis index cutoffs (mg/dL) used in the laboratory

LDH: **ASAT:** **K:**

Hemolysis index cutoffs (mg/dL) recommended by the manufacturer

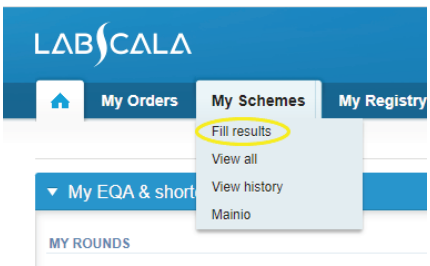
LDH: **ASAT:** **K:**

Please respond to the preanalytical questions in LabScala. The multiple choise answers are found in a drop down menu.

1. How many tests do you perform per year in total (estimated)?
2. Do you know the layout of your PTS*?
(Number of distribution centers, length from the departments, priority rules in case of high throughout, etc.)
3. Which insert do you use for PTS transport?
4. Patient samples should be labeled...

Return shipment to Labquality within 7 days

1. Go to LabScala (www.labscala.com) and fill in all the information needed.



2. VitalVials with magnetic clips attached in the storage case + 2 extra clips.

The VitalVials are off when the clips are on and NO LIGHTS are flashing.

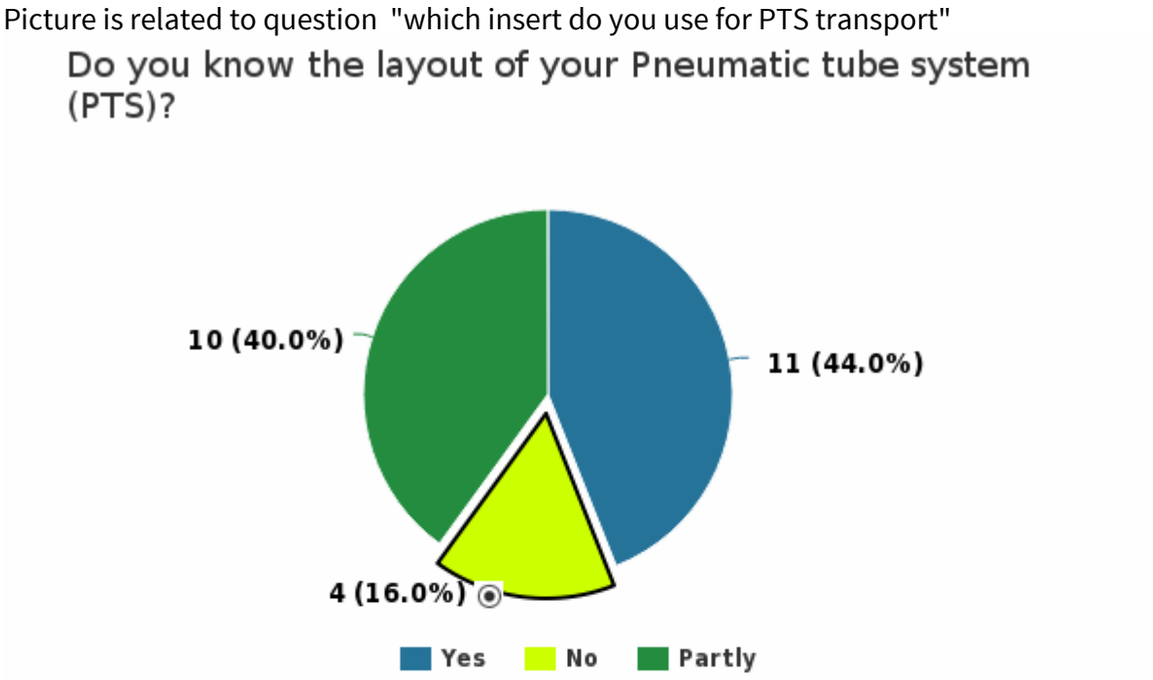
3. Please see detailed shipping instructions in the instruction letter.

If you have any questions, please contact the EQA coordinator **iida.silvo@labquality.fi**
If you do not know your client code and/or password for LabScala, please contact **info@labquality.fi**

Preanalytical questions | 1

Please respond to the preanalytical questions below

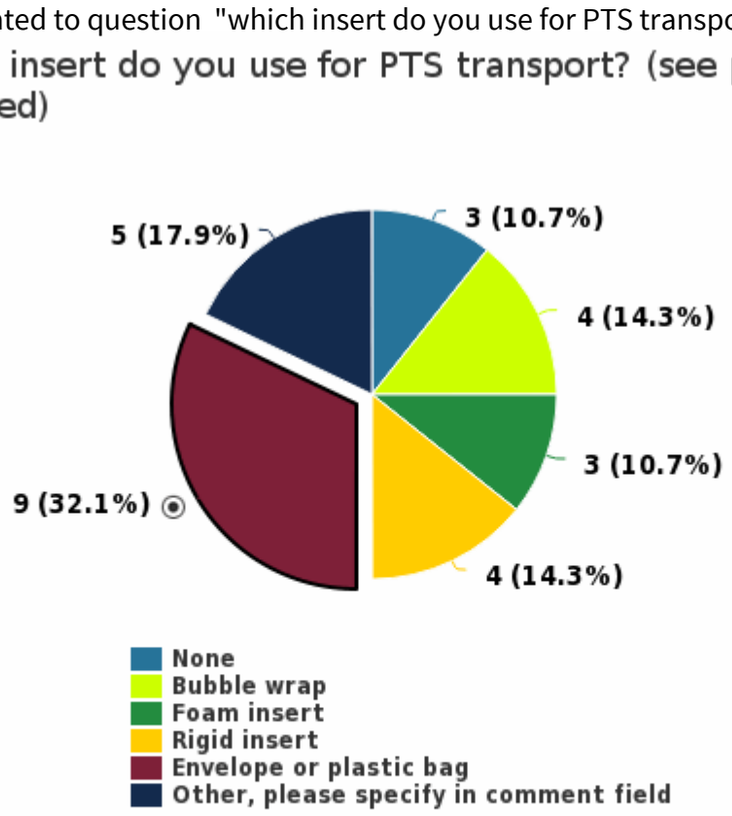
Picture is related to question "which insert do you use for PTS transport"



Preanalytical questions | 1

Please respond to the preanalytical questions below

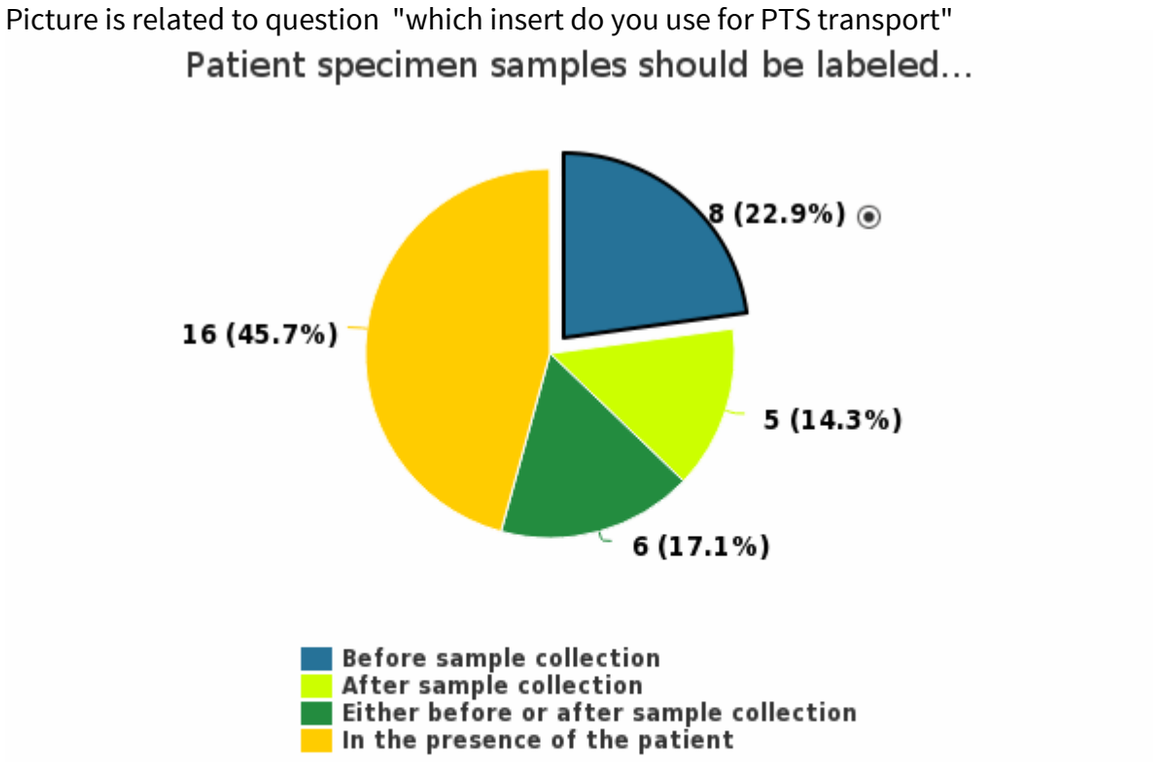
Picture is related to question "which insert do you use for PTS transport"



Preanalytical questions | 1

Please respond to the preanalytical questions below

Picture is related to question "which insert do you use for PTS transport"



LABQUALITY motryx

7807 Preanalytics, Pneumatic Sample Transport

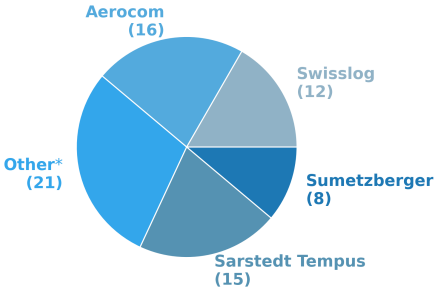
Round: 1, 2022

Client ID:xxxxxx | Report Date: **2023-01-03** | Sample Date: **2022-10-05**

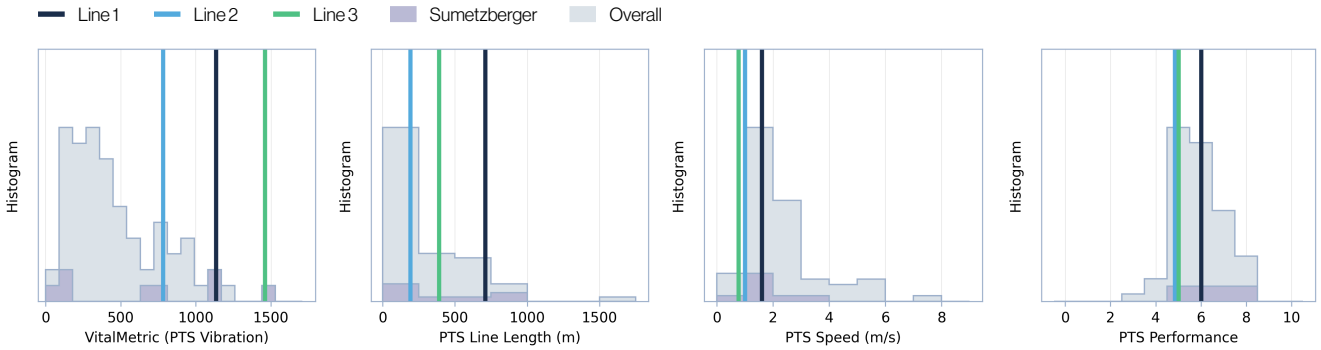
PTS: **Sumetzberger** | Analyzer: **Siemens**

Pneumatic Tube System

PTS Details	VitalMetric	Length	Speed	Performance
Line 1	**1133**	710 m	1.6 m/s	6
Line 2	**782**	190 m	1 m/s	5
Line 3	**1459**	390 m	0.9 m/s	5
Sumetzberger Median	**747.5**	290 m	1.6 m/s	6.5
Overall Median	**381**	200 m	1.7 m/s	6

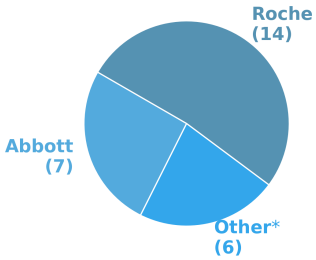


*Other: Instalis Elektroinstalacija, Oppent, Tehotekniikka, Custom, Rofa GmbH Rohrpostanlagen, JSN Techniek, Systik, Hansab, Quirepace, Telecom

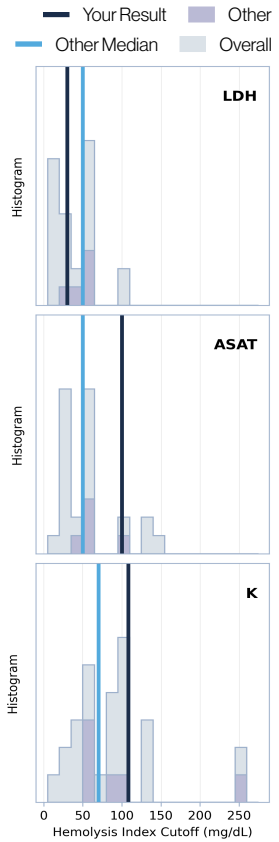


Analyzer

Analyzer Cutoffs (mg/dL)	Your Result	Other Median	Overall Median
LDH	30	50	35
ASAT	100	50	50
K	108	70	90

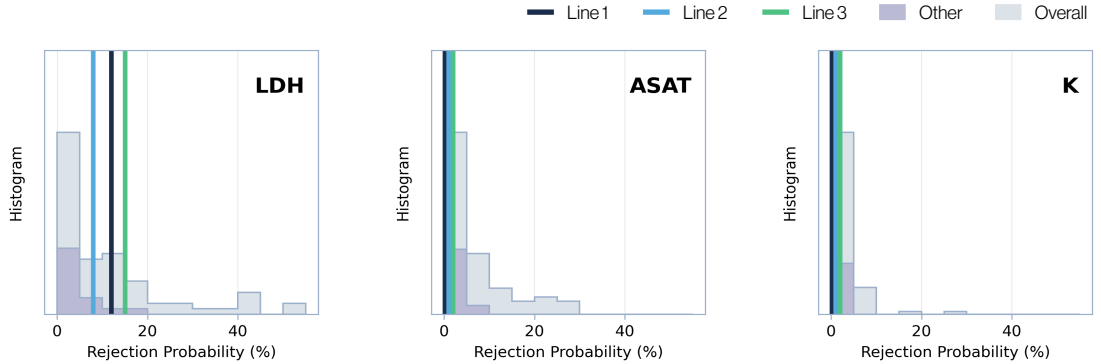


*Other: OrthoDiagnostics, Beckman, Siemens



Rejection

Rejection Probability	LDH	ASAT	K
Line 1	**12 %**	**1 %**	**1 %**
Line 2	**8 %**	**1 %**	**1 %**
Line 3	**15 %**	**2 %**	**2 %**
Other Median	1%	1%	1%
Overall Median	6 %	1.5 %	1%



Pneumatic Tube System

This section of the report compares your PTS with the systems used by the other participants of this study. The results are broken down into peer group (other participants who use the same manufacturer) and all participants.

Definitions

VitalMetric – The cumulative vibration level measured in your PTS line.

Length – Approximate length of the tested line (provided by the lab).

Speed – Calculated average speed while canisters moved through the PTS.

Performance – Rating where higher performance means less vibration per meter of PTS line. Performance is an indicator on a scale of 1-10 of how well the system mechanically runs relative to peers.

Figures

Pie Chart – Breakdown of PTS manufacturers for all participants in the study.

Histograms – The distribution of each of the variables length, speed, performance, and vibration seen among study participants. The shaded histogram is the distribution among your peer group.

Analyzer

This section compares your analyzer cutoffs with those of other participants who use the same make of analyzer that you do.

Figures

Pie Chart – Breakdown of analyzer makes for participants in the study

Histograms – The distribution of values for each analyte cutoff. The shaded histogram is the distribution among your peer group.

Rejection

Rejection Probability is the probability of exceeding the lab-specific hemolysis cutoffs, given the cutoffs from the Analyzer section and the vibration levels from the PTS section.

This section of the report compares your probability of rejecting samples with that of other participants. The analyzer cutoff is a large factor in rejection probability. Lower probability is better.

Observed clinical hemolysis rates may differ from values shown here.

motryx.com
info@motryx.com

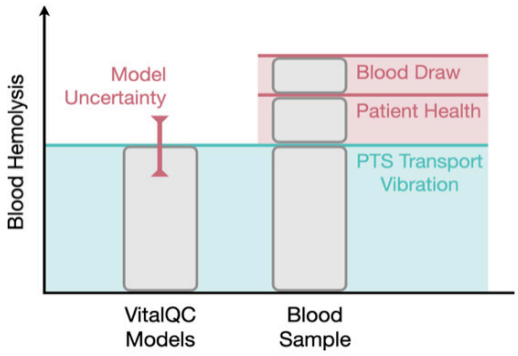
Vital**QC** Clinical Impact Prediction Model: **A Primer**

Introduction

To reduce the likelihood of hemolysis in the laboratory, hospitals are advised to validate their pneumatic tube system (PTS) to ensure the safe and efficient transport of blood specimens. Motryx's Vital**QC** uses a rigorously tested clinical impact prediction model based on thousands of clinical and PTS measurements to provide laboratories with hemolysis related rejection probabilities. This provides high statistical power to measure the impact of PTS's and eliminates the need for donor blood samples during validation.

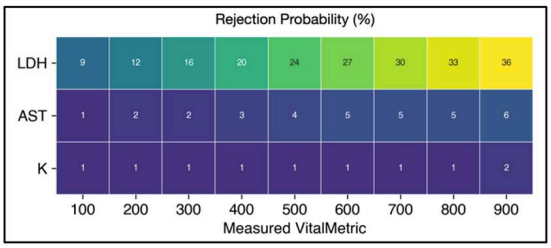
Rejection Probability

Surrogate blood vials (VitalVials) are sent though a PTS line to collect data pertaining to the conditions samples experience in that line (i.e., speed, temperature, vibration). Vital**QC** uses VitalVial measurements to calculate the statistical probability of a sample being rejected based on the lab's pre-defined hemolysis cut-off for a given analyte.



Natural & Preanalytical Variability

A variety of factors may induce hemolysis during the preanalytical phase (i.e., patient health, blood draw, transportation, pipetting, etc.). Vital**QC** separates natural and preanalytical variability from the hemolysis caused by the PTS and benchmarks these results to clinical data. This provides estimates of hemolysis independent confounding preanalytical variables.



Visualization of rejection probability model using common hemolysis cut-off thresholds (LDH: 15, ASAT: 40; K: 90)

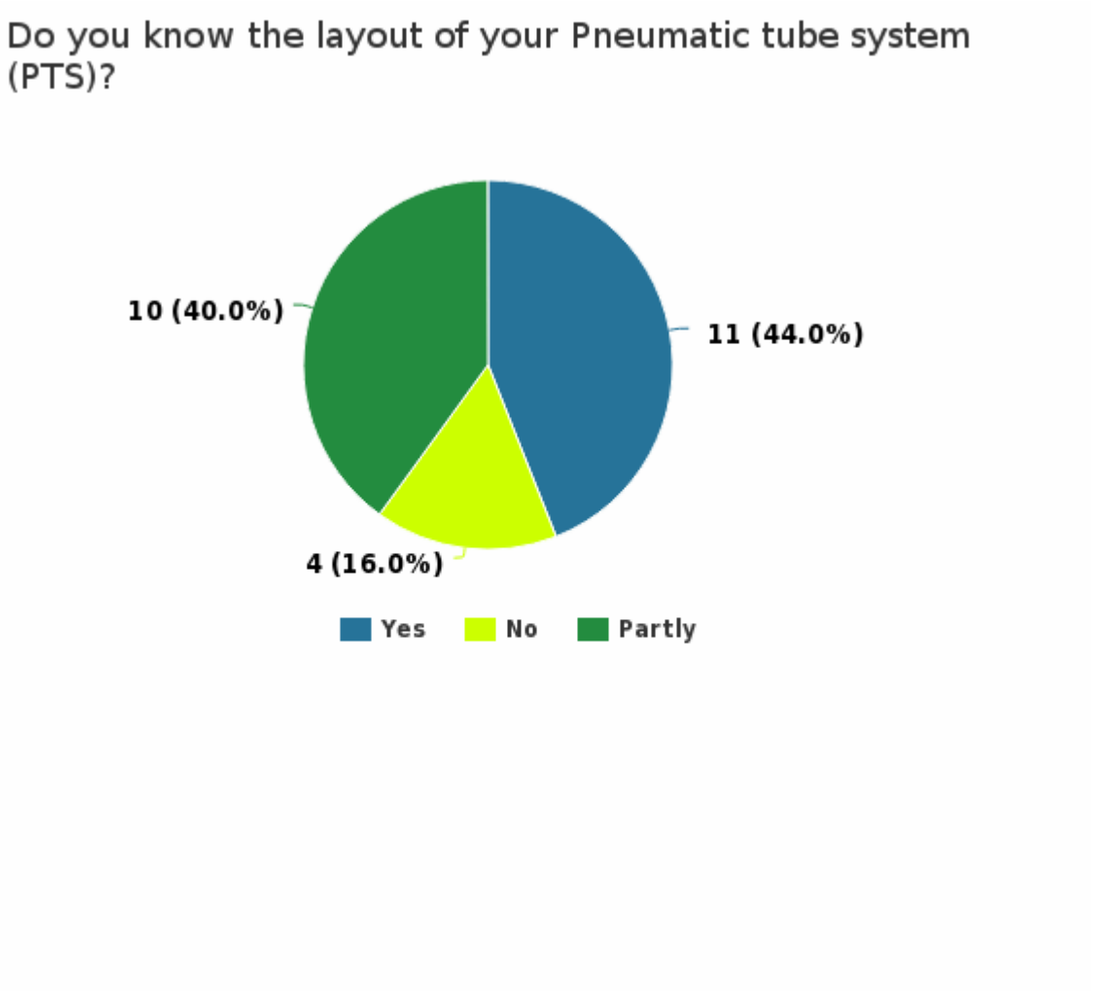
Data & Statistical Modelling

The Vital**QC** prediction model draws on a database of thousands of donor and patient data points collected from more than 70 lines in hospitals around the world. Vital**QC** benchmarks hemolysis index data from your lab against data from other lines (similar to your own) and any common clinical analyzers (i.e., Roche, Abbott, Siemens) to predict hemolysis.

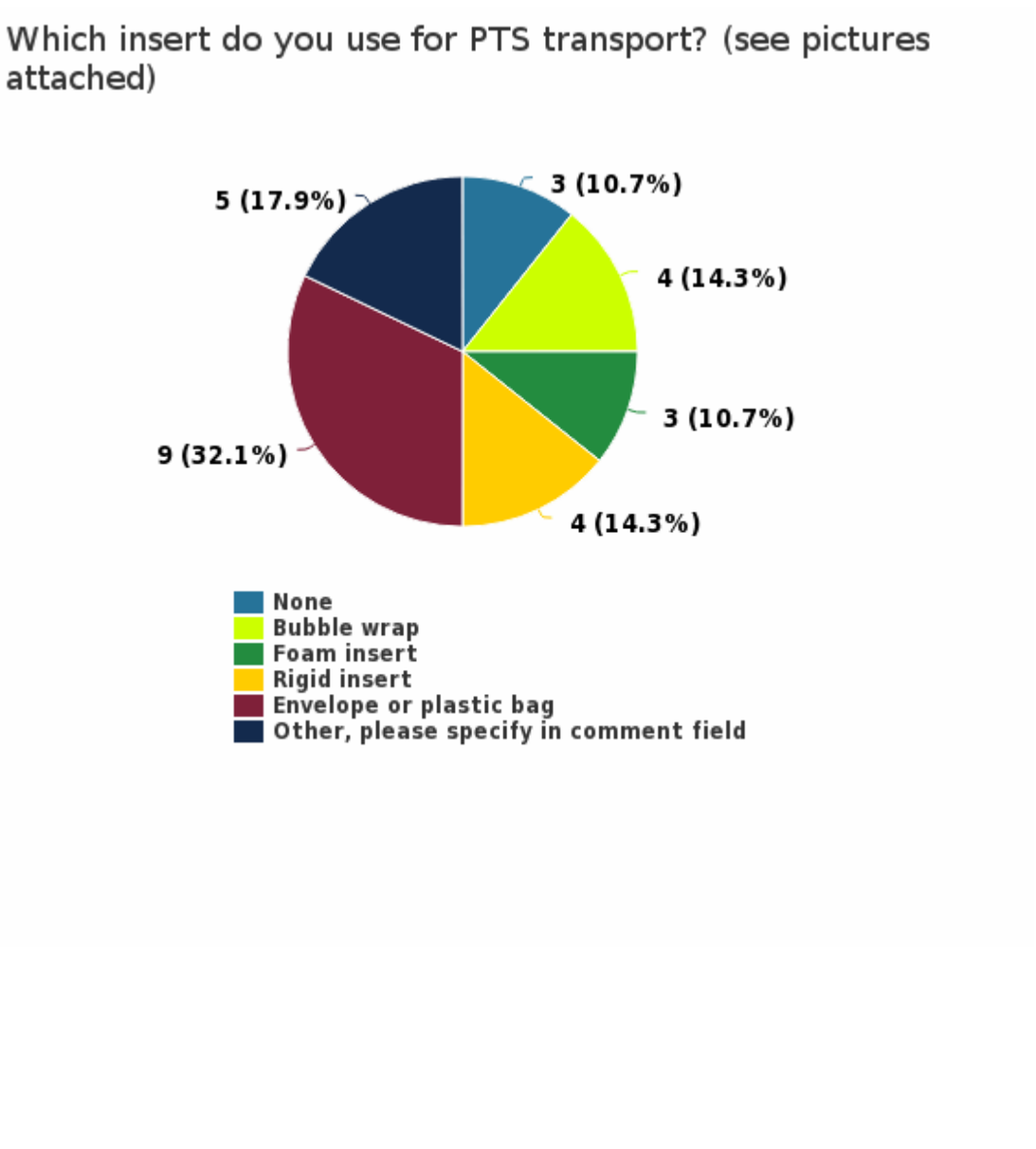
Limitations

Consistency of PTS transport can impact the reliability of the Vital**QC** model. It is not uncommon for vibration measurements to vary by up to 20%; however, even with this variability the sample rejection probability can still be predicted with up to 99% certainty. The model is most susceptible preanalytical hemolysis prior to transport. Since the model assumes that that most samples have no preanalytical hemolysis prior to transport, any discrepancies may yield underestimated rejection probabilities.

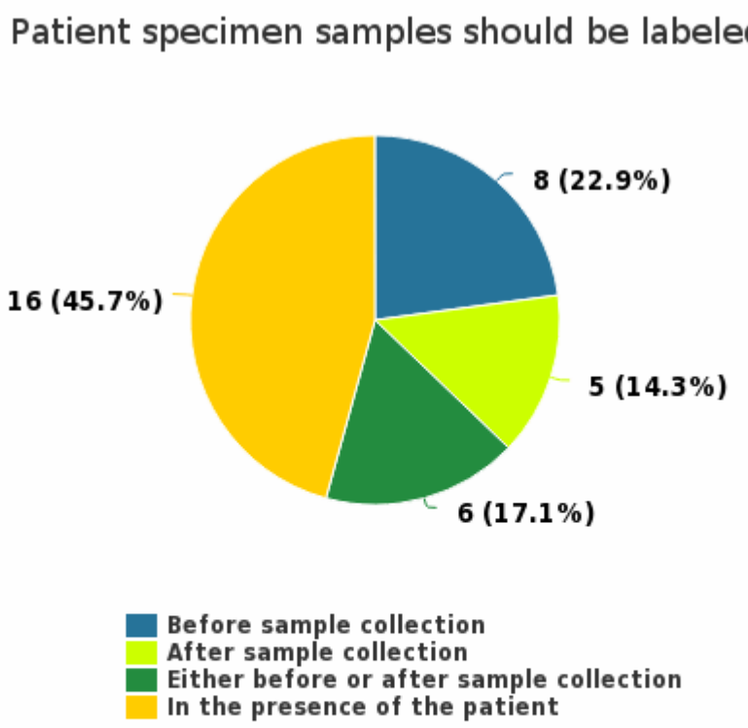
Preanalytical questions|Do you know the layout of your Pneumatic tube system (PTS)?



Preanalytical questions|Which insert do you use for PTS transport? (see pictures attached)



Preanalytical questions|Patient specimen samples should be labeled...



LABQUALITY

External Quality Assessment Scheme

Preanalytics, Pneumatic Sample Transport Round 1, 2022

The round was carried out during September-December 2022 as a cooperation between Labquality and Motryx Inc. Two VitaVial surrogate blood samples, i.e. measurement devices for recording 3-axis acceleration during pneumatic tube system (PTS) transport, were sent to the participating laboratories. Participants were asked to perform recordings of up to three different PTS lines by sending the vials through the PTS according to the same procedure as regular patient samples. The vials were then returned to Labquality for data upload and measurement data analysis was performed by Motryx Inc.

Report info
It is important to read this Final Report first. It contains important facts and information regarding results of each round. The data analysis report contains laboratory-specific numerical data and histograms (p.1/3), a description on how to interpret the results (p.2/3), and a technical page describing the background of the clinical impact prediction model used for calculations (p.3/3). Please read all information carefully when interpreting your results.
A summary of the preananlytical questions is included at the end of this final report.

Comments – EQA Coordinator
There were 28 participating laboratories from 16 countries in the round using PTS systems of 14 manufacturers and clinical chemistry analyzers of 5 manufacturers.

In the laboratory-specific report, your PTS is compared to those of other participants, and your reported analyte-specific hemolysis index (HI) cutoffs are compared to those of other participants using analyzers of the same manufacturer. Please note that if you have not filled out all required details in the LabScala, your report will be partially inadequate or deleted.

The VitalMetric is a measure of cumulative vibration measured by the VitalVial during transport. A high VitalMetric is not necessarily an indication of poor performance. Longer lines typically have higher vibration. High VitalMetric is only an issue when the probability of rejection is also high. This is also highly dependent on the clinical chemistry analyzer and HI cutoffs used.

Performance is an indicator of the vibration compared to the length of the line, where higher performance indicates less vibration per meter of a PTS line.
Lower performance means that the system has more vibration than typical for systems of that length. This may indicate a problem with the system or that maintenance is required.

Rejection probability for LDH, ASAT and K were calculated using the cumulative vibration level measured, analyte-specific HI cutoffs reported by the laboratory and a hemolysis model developed by Motryx Inc. The rejection probability value is the probability of exceeding the HI cutoffs set by the laboratory. Results are compared to the median value of the same analyzer group and to the median value of all participants.

Lower sample rejection probability as compared to other participants indicates a better relative performance of the PTS system, however, rejection probability is a reliable quality indicator of the PTS system only when HI cutoffs recommended by the manufacturer are used.

2023-01-13

FINAL REPORT

Product no. 7807

Samples sent	2022-9/12
Final report	2023-01-13

Request for correction
Requests must be notified in writing within three weeks from the date of this letter.

Authorized by
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Comments – Expert

This is an EQA scheme, evaluating and ensuring quality of sample transportation by pneumatic tube systems (PTS). It is significant to remember that the laboratory is responsible for upholding high standards throughout the preanalytical phase, including sample transit, in accordance with the EN ISO 15189 regulation.

Data from the participating laboratories, once again show the large heterogeneity between facilities when it comes to preanalytical topics and defining according quality acceptance thresholds. After exclusion of outliers, hemolysis thresholds for LDH, ASAT and potassium ranged from 9 to 100, 12 to 100 and 19 to 125, respectively. As a result, there were corresponding differences in the probability of sample rejection. In this context, we want to refer to a proposal made by the European Federation of Clinical Chemistry and Laboratory Medicine Working Group[1] in order to ensure patient safety while considering whether to reject haemolysed samples. Additionally incorporating clinically significant deviation thresholds, it provides an alternative to strictly using analytical haemolysis cut-offs, provided by the manufacturer.

According to the guidelines (RiliBäK) of the German Federal Medical Council guidelines[2] (similar to the CLSI guidelines used in the US) the root mean square deviation must not exceed 4.5% for potassium, 9% for phosphate, 11.5% for ASAT, and 9% for LDH. Streichert et al. showed that these thresholds may be surpassed already at transportation speeds as low as 1.5 m/s[3]. Most participants reported transportation speeds above this value, ranging up to 7.5 m/s. Additionally, there were partly substantial differences between the tested lines within the same facility.

In our previous rounds in 2021, about half of the participants stated using the manufacturer's hemolysis cut-offs. Of the remaining participants, the main reason for using other cut-offs was based on local verification data, among those who responded to the question. Most participants correctly used higher hemolysis thresholds for potassium than for ASAT or LDH according to results in the current and previous rounds. This heterogeneity of thresholds is reflecting similar data published on scientific journals[4]. It is recommended that cut-offs for interfering substances, provided by the manufacturer should be verified locally, using standardised methodology[5,6]. In any case when defining the former specifications, the according consensus guideline should be followed[7].

More than half of the respondents reported to be only partially of not aware of the layout of their PTS and answering the question on PTS validation in 2021, the majority reported that this was done upon installation but only a few laboratories had a possibility to monitor the system thereafter. Those centres who regularly control quality of PTS transportation, do this either by using data log errors or blood samples.

Regarding tub inserts for sample protection, responders (32%) stated to use envelopes or plastic bags. In this regard we want to refer to an evaluation of inserts and their impact on sample protection[8]. Especially for those using the foam inserts provided by the PTS manufacturer, this read will surely be interesting.

Overall, the results show the need of the following:

1) Recommendations on sample transportation via PTS regarding speed, tube inserts, thresholds.
2) Continuous monitoring of local PTS systems on various lines within one hospital.

References

[1] Lippi G. et al. Practical recommendations for managing hemolyzed samples in clinical chemistry testing. Clin Chem Lab Med. 2018;56(5):718-27.

[2] Bundesärztekammer. Richtlinie der Bundesärztekammer zur Qualitätssicherung laboratoriumsmedizinischer Untersuchungen. http:// www.bundesaerztekammer.de/downloads/ Rili-BAeK-Labor.pdf

[3] Streichert T, Otto B, Schnabel C, Nordholt G, Haddad M, Maric M, et al. Determination of hemolysis thresholds by the use of data loggers in pneumatic tube systems. Clin Chem. 2011;57(10):1390-7.

[4] Cadamuro J, Lippi G, von Meyer A, Ibarz M, van Dongen-Lases E, Cornes M, et al. European survey on preanalytical sample handling – Part 2: Practices of European laboratories on monitoring and processing haemolytic, icteric and lipemic samples. On behalf of the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) Working Group for the Preanalytical Phase (WG-PRE). Biochem Med (Zagreb). 2019;29(2):020705.

[5] Dimeski G. Interference testing. Clin Biochem Rev. 2008;29 Suppl 1:S43-8.

[6] Clinical and Laboratory Standards Institute. EP7-A2: Interference Testing in Clinical Chemistry; Approved Guideline - Second Edition. Wayne, PA: Clinical and Laboratory Standards Institute; 2005.

[7] Sandberg S, Fraser CG, Horvath AR, Jansen R, Jones G, Oosterhuis W, et al. Defining analytical performance specifications: Consensus Statement from the 1st Strategic Conference of the European Federation of Clinical Chemistry and Laboratory Medicine. Clin Chem Lab Med. 2015;53(6):833-5.

[8] 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 multicentre evaluation. Clin Chem Lab Med. 2021;59(8):e313-e6.

End of report