

Appendix of guideline for validation of (new) testing methods**Validated configuration: Pneumatic dispatch system and Tempus 600****Research or validation number:** (By coordinator)**Method of determination:** n/a**Objective:**

Validation of transport of blood sample tubes via the UMCG pneumatic dispatch system and the Tempus 600.

Analyst(s) in charge:

Martine Zuidema (test team leader)

Analysts AHC

Test period: 05/02/2016**Details:**

This report describes the validation of transport via the pneumatic dispatch system and the Tempus 600 system. The configuration of this validation differs from the normal situation when a validation consists of an equipment test. The validation configuration is described in the validation plan.

As a transport reference sample we made use of the mail service.

Method comparison

Table 1 shows the averages for the different determinations. The 4th, 5th and 6th columns show the absolute differences between these averages in case of transport by different systems. The 7th and 8th column show differences in percentages. The last column lists the CV's (analytical variation) for the different results, as determined during validations of additional experiments (L, H and I-index).

Table 1

Result	Mail Service	Tempus	Pneum. Disp.	Tempus Difference vs. Mail Service	Pneum. Disp. Difference vs. Mail Service	Tempus vs Pneum. Disp.	Tempus % Difference vs Mail Service	Pneum. Disp. % Difference vs. Mail Service	CV (QC today)
PT	10.3	10.3	10.3	0.0	0.0	0.0	-0.4	-0.5	0.86%
aPTT	25.7	25.4	25.5	-0.3	-0.3	0.0	-1.2	-1.1	1.4%
Hb	8.4	8.4	8.4	0.0	0.0	0.0	0.2	-0.4	0.58%
Leuco	6.0	6.1	6.1	0.1	0.0	0.0	1.0	0.8	1.40%
Trombo	281.3	277.1	277.0	-4.2	-4.3	-0.1	-1.5	-1.6	2.21%
K	4.1	4.1	4.2	0.0	0.0	0.0	-0.7	0.4	1.4%
LDH	188.5	172.8	187.7	-15.7	-0.8	14.9	-8.3	-0.5	2%
AF	62.2	61.7	61.8	-0.5	-0.4	0.1	-0.8	-0.6	2.5%
H-index	1.9	3.1	3.6	1.2	1.7	0.5	63.2	54.8	0.35%
L-index	19.5	11.4	15.2	-8.1	-4.3	3.8	-41.5	-37.7	0.14%
I-index	12.6	13.0	12.8	0.4	0.2	-0.2	3.2	1.5	0.03%

LDH results are particularly striking. LDH results with the Tempus are consistently lower, with an average deviation of 15.7%. These lower results are not explained by hemolysis, which should lead to higher results. There is no difference between pneumatic dispatch and mail service.

A second test was carried out to study this deviation. Again, blood samples were taken from 10 volunteers (in this case only a lithium heparin tube) and the K, LDH, AF and LHI index were determined. The results are included in table 2.

Table 2

Result	Mail Service	Tempus	Pneum. Disp.	Tempus Difference vs. Mail Service	Pneum. Disp. Difference vs. Mail Service	Tempus vs Pneum. Disp.	Tempus % Difference vs Mail Service	Pneum. Disp. % Difference vs. Mail Service	CV (QC today)
K	3.8	3.7	3.8	0.0	0.0	0.1	-0.4	1.0	1.4%
LDH	161.8	166.6	172.0	4.8	10.2	5.4	3.0	6.1	2%
AF	57.2	56.8	56.4	-0.4	-0.8	-0.4	-0.7	-1.4	2.5%
H-index	0.2	1.8	3.2	1.6	3.0	1.4	800.0	1667	0.35%
L-index	25.4	26.2	28.2	0.8	2.8	2.0	3.1	10.7	0.14%
I-index	9.0	9.6	9.4	0.6	0.4	-0.2	6.7	4.2	0.03%

Verification of the ICT system

This is momentarily non-applicable. A future design may contain a link with GLIMS for track&trace.

General findings / experiences

For determined test values, the differences between the methods of transport fall within the analytical variation, with the exception of the H and L index and the determined value of LDH.

H-index:

The H-index shows a slight increase with transport via pneumatic dispatch or Tempus. There is no difference between these two systems in the H index. The increase is explicable: It is probably the result of increased hemolysis. The same finding was observed in the validation of the Tempus 600 in Danish Aarhus. Yet the increase is so minimal that clinically it does not have any consequences. The majority of the determinations is only affected when the H index is over 100.

L-index:

In the first test the L-index drops slightly in case of the use of Tempus or pneumatic delivery. The second test shows a slight increase in case of transport with pneumatic dispatch/Tempus. The deviations are so minimal that these are also not clinically relevant.

LDH determination:

In the first test, the determined LDH value shows a slight but significant reduction in the Tempus system ($p < 0.05$) vs. the mail service as well as the pneumatic dispatch. There is no difference between pneumatic dispatch and mail service. This reduction cannot be explained on the basis of accelerated hemolysis, since this would result in an increase of the LDH. In the second test, LDH slightly increased upon transport with pneumatic dispatch (6.1%) as well as with Tempus (3%) vs. transport by mail service. This increase might be caused by a (slight) increase in hemolysis. In view of the results of the first test, the differences might be caused by analytical variation. The individual differences in the determined LDH values (maximum difference = 14.8%) are all within the limits of the clinically relevant difference (24.9%)*.

* The value for the clinically relevant LDH difference is calculated as follows: $2V_2 * (\sqrt{CV_a^2 + CV^2})$, with CV_a the analytical variation (2%) and CV ; the intra- individual biological variation (8.6%).

General conclusion (WLM worker)

Both the pneumatic dispatch system as well as the Tempus 600 are approved for transport of vacuum tubes.

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Validation final report (new) testing methods

Business Management - Policy

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- Appendices:
- Validation report Tempus 600, Aarhus
 - Rough data
 - Result processing: Excel file on G: drive. Location: