AKS1/25: Basic Clinical Chemistry - Serum

This EQA round was accomplished according to the document ***EQA Plan 2025***.

Typing conventions: *We are using comma as a decimal separator and dates in day.month.year format.*

Samples

Commercial samples were used. For some tests, we had certified reference values (CRVs) available, which are listed in the following table, including expanded uncertainties (description from the protocol of the Referenzinstitut für Bioanalytik, Bonn, Germany). The uncertainties are given in units of measurement and must be converted to relative values (in percent) if necessary.

Analyte	Unit	Sample A		Sample B	
		CRV	Expanded uncertainty (k = 2)	CRV	Expanded uncertainty (k = 2)
α-amylase	µkat/L	5,98	0,16	4,79	0,13
ALP	µkat/L	0,828	0,035	1,987	0,058
ALT	µkat/L	1,702	0,045	0,827	0,022
AST	µkat/L	1,473	0,044	1,983	0,048
Bilirubin total	µmol/L	21,42	0,57	31,69	0,76
Total protein	g/L	69,9	1,5	61,1	1,4
CK	µkat/L	6,00	0,17	3,417	0,083
Potassium	mmol/L	5,621	0,084	3,619	0,064
GGT	µkat/L	1,053	0,027	2,052	0,053
Glucose	mmol/L	4,656	0,047	5,542	0,055
Magnesium	mmol/L	1,499	0,029	1,191	0,023
Chloride	mmol/L	121,2	1,8	108,1	1,6
Cholesterol	mmol/L	4,483	0,045	4,145	0,041
Creatinine	µmol/L	58,14	0,58	88,27	0,88
Uric acid	µmol/L	391,8	3,9	532,6	5,3
LD	µkat/L	3,368	0,086	4,87	0,11
Lithium	mmol/L	0,857	0,013	1,612	0,024
Urea	mmol/L	12,97	0,13	9,70	0,10
Sodium	mmol/L	138,3	2,1	123,3	1,8
Triacylglycerols	mmol/L	2,104	0,021	1,386	0,014
Calcium	mmol/L	2,076	0,031	2,441	0,037

Supervisor's comment

There were 216 participants in this round, 58 of them from Slovakia and 1 from Austria.

The CRV values above were used as assigned values (AV) and robust averages were used for the other tests. Any exceptions are described below.

α-amylase, cholesterol

For these analytes, we evaluate separately, using a narrower D_{max} (7,0 % for α-amylase and 6,0 % for cholesterol) and without issuing a certificate, the results of participants who indicated the code R = 149 = Siemens (Dade, BN, Dimension). In this case, the reason for the significant differences in the measurement results obtained on these systems and the CRV values appears to lie in the matrix of the samples used. However, in this round, the number of participants in this group was small, and therefore their results were not evaluated.

α-amylase pancreatic

In the group R = 162 = Siemens (Atellica), we observed a relatively large bias (approximately +15 %, in the Youden graph these are the points at the top right).

ALP

We evaluate ALP results in two ways:

- Traceability by comparison with CRV (D_{max} = 18 %).
- Comparability by comparison with a assigned value determined as a robust average of a group of participants who reported the same reagent manufacturer (code R) (D_{max} = 14 %).

This method of evaluation is a response to the long-term unsatisfactory state of implementation of traceability to the ALP IFCC 2011 reference method and thus the persistent bias in some groups of results.

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ALT
Sample A was without problems. For sample B (lower value), we noted a bias exceeding half of D_{max} in the groups R = 46 = Erba Lachema (bias +14 %) and R = 162 = Siemens (Atellica) (bias +11 %).

Bilirubin direct
AVs were determined as robust means of groups arranged according to reagent manufacturers (code R).

CK
For both samples and all groups of results (according to the reagent manufacturers), there was a negative bias that was at the level of a third to a half of D_{max}. We have observed a similar negative bias several times in recent rounds - this is therefore a repeated phenomenon, the cause of which is not obvious.

Glucose
For both samples, we noted a negative bias in participants' results at the level of half of D_{max}, with glucose concentrations in both samples within the reference interval.

Chloride
Robust averages of results from all participants were used as assigned values. This is due to the long-standing significant differences between results obtained by routine laboratory methods (mostly ISE) and the coulometric method used to determine CRV (the bias of routine methods is around -5 % for a long term).

Cholinesterase
The results of 5 participants obtained with Siemens Atellica sets (R = 162) were approximately 50 % higher than the overall consensus. We repeatedly observe a similar bias in the results of the Atellica group, we evaluated participants separately using a narrower D_{max} = 9,4 % and without issuing a certificate.

Creatinine
The concentration was relatively low in sample A. Laboratories using the enzyme assay achieved a success rate of 99 %. In the case of the Jaffé method, the success rate was only 74 %.
The reason for the lower success rate for samples with lower concentrations is the level of correction used to eliminate the influence of pseudo-creatinine chromogens. Usually, a constant value is read that is the same for all samples and for the entire concentration range, which does not fully correspond to reality.

Long term success rate
You can find the overview of the total success of the participants of this round over last 2 years in the following table. Particular ranges of success are defined in the column headers (percentage of the tests on which the participant reported the correct result). Next 2 lines contain both absolute and relative number of participants who reached the success from the header.

Success		***0 %***	***1 - 74 %***	***75 - 79 %***	***80 - 89 %***	***90 - 94 %***	***95 - 99 %***	***100 %***
Success in words		unsatisfactory		acceptable	good	very good	excellent	
Count	absolute	0	3	1	10	18	123	61
	relative	-	1,4 %	0,46 %	4,6 %	8,3 %	57 %	28 %
Note: You can find your individual success over last 2 years in your result sheet.								

The long-term success rate of most participants of this round over the past 2 years is 90 % or greater.
Lower success rates should be an impulse for improvement.

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Educational part of the round – uncertainties of measurement results

An overview of the relative combined expanded uncertainties (U_c) reported by the participants can be found in the table below.

Test	Minimum [%]	Average [%]	Maximum [%]	n	Minimum [%]	Average [%]	Maximum [%]	n
	Sample A				**Sample B**			
(22) α-amylase	0,30	4,1	18	79	0,30	4,1	18	79
(35) α-amylase pancreatic	1,8	5,0	9,3	25	1,8	5,1	9,3	25
(32) γ-globulin (elfo)	2,1	9,3	21	13	2,1	9,3	21	13
(10) Albumin	1,3	3,6	11	76	1,3	3,7	11	76
(31) Albumin (elpho)	1,8	4,5	12	13	1,8	4,5	12	13
(21) ALP	2,0	7,1	18	75	2,0	6,4	18	75
(24) ALT	0,57	5,3	15	89	0,85	5,7	15	89
(23) AST	0,60	4,9	17	89	0,29	4,7	17	89
(13) Bilirubin total	2,3	6,1	18	87	2,1	5,8	18	87
(14) Bilirubin direct	0,60	5,4	22	49	0,60	5,4	22	49
(9) Total protein	0,41	3,2	12	81	0,46	3,3	12	81
(26) CK	0,40	4,9	19	73	0,40	4,8	19	73
(2) Potassium	0,27	2,4	5,6	88	0,14	2,4	5,6	88
(5) Inorganic phosphate	1,4	3,8	9,9	70	1,2	3,7	9,9	70
(27) gamma-GT	0,54	4,8	10	85	0,44	4,7	10	85
(16) Glucose	1,0	3,0	9,6	89	0,90	3,0	9,6	89
(7) Magnesium	1,2	4,2	15	70	1,2	4,4	14	70
(3) Chloride	0,52	2,6	8,2	88	0,42	2,6	8,2	88
(15) Cholesterol	0,20	3,2	6,0	82	0,20	3,2	6,0	82
(30) Cholinesterase	1,9	5,1	12	25	1,9	5,0	11	25
(19) Creatinine	1,6	4,7	12	84	1,2	4,6	12	84
(17) Uric acid	0,30	3,3	9,6	87	0,33	3,3	9,6	87
(12) Lactate	0,40	4,0	14	42	0,40	4,0	14	42
(28) LD	1,6	5,0	14	62	1,6	5,0	14	62
(29) Lipase	1,0	7,2	15	44	1,0	7,2	14	44
(8) Lithium	1,6	6,4	15	9	1,6	5,9	15	9
(18) Urea	0,74	5,2	14	89	1,2	5,2	14	89
(11) Osmolality	0,60	1,8	5,4	26	0,60	1,8	5,4	26
(1) Sodium	0,28	2,0	5,6	88	0,18	2,0	5,6	88
(20) Triacylglycerols	0,25	3,8	10	81	0,50	3,9	10	81
(4) Calcium	0,87	2,9	7,2	75	0,87	2,9	7,2	75
(36) Calcium ionised	1,1	3,0	9,9	16	1,1	3,0	9,9	16
(6) Iron	1,7	3,9	11	61	1,8	3,9	11	61

90 participants, i.e. two fifths of the participants of the round, reported uncertainties of their results.

The average magnitudes of uncertainties are realistic. However, we still encounter cases where the differences between the minimum and maximum are orders of magnitude. In these cases in particular, we recommend checking whether participants have included all uncertainty components in the uncertainty calculation and whether they regularly revise (recalculate) their uncertainty estimates, or whether there has been no confusion of units and whether the expanded (k = 2) uncertainty has actually been reported.

Scientific supervision: Ing. Květa Pelinková, MBA
VFN a 1.LF UK, ÚLBLD - central laboratory
Praha
e-mail: Kveta.Pelinkova@vfn.cz

Supplements

As a supplement to this report individual participant who reported the results gain:

Name	***Description***
Confirmation of attendance Certificate Result sheet	The conditions for issuing the relevant document specified in the EQA Plan must be met.
Summary overviews of quantitative results	These documents include a graphical overview of the results in the form of the complex statistics (this includes for each test a Youden plot or histograms, an overview of the P-score for 2 years history, an overview of the results with uncertainties and summary statistics in graphical form).

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The supplements are identified by their name, EQA round identification and participant code and are intended for the needs of the participant.
If you reported the results in this round, you can find your individual evaluation (reports) in the **Cibule** application (https://www.eqa.cz/cibule). After login, select ***EQA Results - View*** in the menu and then click the ***Reports*** button for the particular round.

Additional information

The final report, with the exception of the supplements, is public. Further information is freely available to the participants and other professionals at www.sekk.cz, in particular:

- The summary of the results of this round, including this final report.
- The criteria (D_{max}) for a quantitative results assessment.
- The document ***EQA Plan*** (contains information that applies both to this round and also the EQA in general).
- Explanation of the content of the particular supplements mentioned above.
- Contact to the EQA provider and the EQA coordinator and the list of all supervisors, including contacts.