

AKS2/25: 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	0,846	0,023	1,332	0,036
ALP	μkat/L	1,239	0,035	4,21	0,12
ALT	μkat/L	0,923	0,023	2,755	0,062
AST	μkat/L	1,044	0,023	3,467	0,076
Bilirubin total	μmol/L	65,1	1,5	32,10	0,74
Total protein	g/L	55,8	1,2	61,3	1,6
CK	μkat/L	6,15	0,16	4,40	0,13
Potassium	mmol/L	3,823	0,060	3,655	0,056
GGT	μkat/L	0,829	0,021	6,25	0,15
Glucose	mmol/L	3,738	0,037	4,491	0,045
Magnesium	mmol/L	0,868	0,013	-	
Chloride	mmol/L	113,8	1,7	107,0	1,6
Cholesterol	mmol/L	3,607	0,093	3,94	0,11
Creatinine	μmol/L	59,54	0,60	40,23	0,40
Uric acid	μmol/L	239,6	2,4	483,3	4,8
LD	μkat/L	2,582	0,058	3,265	0,072
Lithium	mmol/L	0,686	0,010	1,579	0,024
Urea	mmol/L	3,072	0,031	15,20	0,15
Sodium	mmol/L	124,8	1,9	118,4	1,8
Triacylglycerols	mmol/L	0,704	0,011	1,354	0,014
Calcium	mmol/L	2,503	0,038	2,474	0,038

Supervisor's comment

There were 399 participants in this round, 76 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 have previously evaluated separately, using a narrower D_{max} and without issuing a certificate, the results of participants who indicated the reagent manufacturer R = 149 = Siemens (Dade, BN, Dimension). However, the number of users of these kits has decreased significantly over time (now units of participants) and their results are in good agreement with the CRV. Therefore, we evaluate this group as standard, like the results of all other participants.

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 ($D_{max} = 18 \%$). We observed an unsatisfactory bias, exceeding 10 %, in the Abbott, Erba Lachema, Beckman Coulter (AU) and Mindray groups.
- Comparability by comparison with an 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.

AKS2/25: Basic Clinical Chemistry - Serum**ALT**

For sample A (lower value), we noted a bias exceeding half of D_{\max} in the groups R = 46 = Erba Lachema (bias +7,9 %), R = 162 = Siemens (Atellica) (bias +9,8 %) and R = 179 = Siemens (Advia) (bias +8,7 %). Sample B was without problems.

Bilirubin direct

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

For sample A, we observed a greater dispersion of results (CV approximately 15 %) in the groups R = 60 = Roche and R = 162 = Siemens (Atellica), which led to a slight decrease in success rate.

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.

Inorganic phosphate

For the R = 177 = Mindray group, we observed a large negative bias in both samples with a negative impact on success.

Magnesium

We only had CRV available for sample A, for sample B the AV was determined as a robust average of all participants and overall comparability is assessed.

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

Here we observed 2 anomalies:

- The results of 6 participants, which cannot be overlooked in the Youden plot at the top right, were obtained with Abbott kits – however, another 29 participants, working with kits of the same manufacturer, showed results in good agreement with the consensus.
- The results of 7 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 both samples. Laboratories using the enzyme assay achieved a success rate of 97 %. In the case of the Jaffé method, the success rate was only 86 %.

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 the same for all samples and for the entire concentration range is subtracted, which does not fully correspond to reality.

Triacylglycerols

For sample A (lower concentration), we observed a relatively large positive bias (approximately +10 % to +15 %) in a number of groups, arranged according to reagent manufacturers, while for sample B the bias was usually within 5 %.

However, in the Siemens group (both Advia and Atellica), we observed a positive bias exceeding half of the D_{\max} for both samples, for sample A (lower concentration), the bias was highest in the Atellica group (+18 %, with a negative impact on success).

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.

<i>Success</i>		<i>0 %</i>	<i>1 - 74 %</i>	<i>75 - 79 %</i>	<i>80 - 89 %</i>	<i>90 - 94 %</i>	<i>95 - 99 %</i>	<i>100 %</i>
Success in words		unsatisfactory		acceptable	good	very good	excellent	
Count	absolute	0	2	0	16	29	248	104
	relative	-	0,5 %	-	4 %	7,3 %	62 %	26 %

Note: You can find your individual success over last 2 years in your result sheet.

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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.

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	0,95	4,0	12	105	0,95	4,0	12	105
(35) α-amylase pancreatic	1,4	5,1	9,3	43	0,35	4,8	8,7	43
(32) γ-globulin (elfo)	1,4	9,4	19	18	1,5	9,9	19	18
(10) Albumin	0,66	3,7	11	112	0,66	3,7	11	112
(31) Albumin (elpho)	1,6	4,8	12	18	1,6	4,6	12	18
(21) ALP	0,63	6,6	18	120	0,63	6,0	18	120
(24) ALT	0,87	5,3	15	126	0,87	4,9	15	126
(23) AST	1,1	4,9	17	126	1,2	4,4	17	126
(13) Bilirubin total	1,4	5,3	18	123	1,4	5,4	18	123
(14) Bilirubin direct	1,3	6,7	22	86	1,6	6,7	22	86
(9) Total protein	0,90	3,4	12	121	0,91	3,4	12	121
(26) CK	1,1	4,4	13	107	1,1	4,3	13	107
(2) Potassium	0,89	2,5	14	125	0,89	2,5	14	125
(5) Inorganic phosphate	0,81	3,7	11	114	0,81	3,6	9,9	114
(27) gamma-GT	0,90	4,6	12	124	0,90	4,1	12	124
(16) Glucose	1,3	3,2	10	126	1,3	3,2	7,4	126
(7) Magnesium	1,0	4,4	11	113	1,0	4,1	11	113
(3) Chloride	0,50	2,7	44	125	0,50	2,6	9,5	125
(15) Cholesterol	0,69	3,5	8,7	118	0,69	3,5	8,7	118
(30) Cholinesterase	1,0	4,0	11	46	1,0	4,0	12	46
(19) Creatinine	1,0	4,9	15	122	1,0	4,8	15	122
(17) Uric acid	0,39	3,4	9,6	124	0,39	3,3	11	124
(12) Lactate	1,0	3,9	8,4	64	1,0	3,6	8,4	64
(28) LD	0,89	5,2	16	100	0,89	5,2	16	100
(29) Lipase	1,9	6,6	14	72	1,9	6,6	14	72
(8) Lithium	1,6	6,2	15	14	1,6	4,9	13	14
(18) Urea	1,2	5,5	14	125	1,6	5,2	14	125
(11) Osmolality	0,50	1,6	4,0	43	0,50	1,7	4,0	43
(1) Sodium	0,73	2,1	6,2	125	0,73	2,1	10	125
(20) Triacylglycerols	1,2	4,4	10	117	0,63	4,1	10	117
(4) Calcium	0,89	3,1	9,7	118	0,89	3,1	9,7	118
(36) Calcium ionised	1,4	3,0	9,9	20	1,4	3,1	9,9	20
(6) Iron	1,7	4,4	12	101	1,4	4,2	12	101

127 participants, i.e. one third 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.

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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

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	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.