AKS4/25: 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 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	2,086	0,059	0,846	0,023
ALP	µkat/L	1,382	0,039	1,239	0,035
ALT	µkat/L	3,239	0,072	0,923	0,023
AST	µkat/L	3,489	0,077	1,044	0,023
Bilirubin total	µmol/L	10,50	0,30	65,1	1,5
Total protein	g/L	89,1	1,9	55,8	1,2
CK	µkat/L	2,400	0,058	6,15	0,16
Potassium	mmol/L	6,087	0,099	3,823	0,060
GGT	µkat/L	1,922	0,048	0,829	0,021
Glucose	mmol/L	5,325	0,054	3,723	0,038
Magnesium	mmol/L	0,462	0,007	0,868	0,013
Chloride	mmol/L	123,3	1,8	113,8	1,7
Cholesterol	mmol/L	5,825	0,068	3,607	0,093
Creatinine	µmol/L	397,3	4,0	59,54	0,60
Uric acid	µmol/L	400,4	5,1	239,6	2,4
LD	µkat/L	4,228	0,094	2,582	0,058
Lithium	mmol/L	1,048	0,016	0,686	0,010
Urea	mmol/L	12,55	0,13	3,072	0,031
Sodium	mmol/L	128,9	2,0	124,8	1,9
Triacylglycerols	mmol/L	2,002	0,020	0,704	0,011
Calcium	mmol/L	2,759	0,041	2,503	0,038

Supervisor's comment

There were 413 participants in this round, 75 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 (only sporadic participants) and we do not evaluate their results. From 2026, we will no longer take this separate group into account in the evaluation, and we recommend that users of these kits not report the results of α-amylase and cholesterol within the EQA.

α-amylase pancreatic

In the group R = 162 = Siemens (Atellica), we noted a relatively large bias (approximately +15%, in the Youden plot these are the points on 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 and Beckman Coulter (AU) reagents 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.

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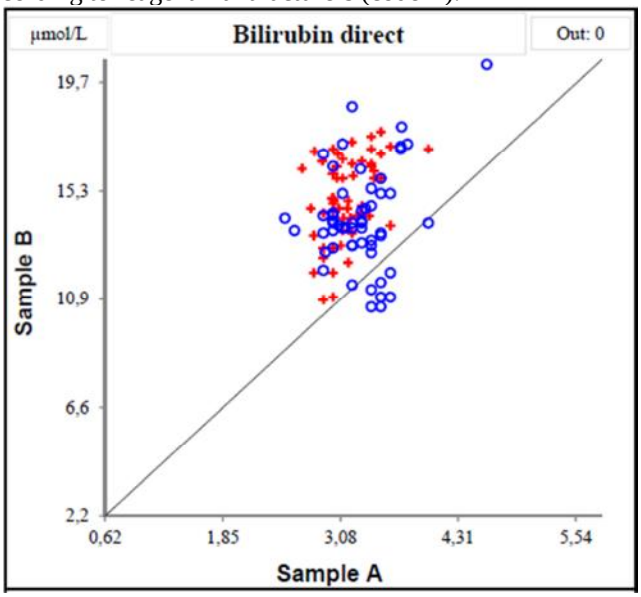
Bilirubin total
Problematic results for sample A (lower concentration) in the Beckman Coulter group (in the Youden plot, a cluster of points is visible on the right), where the bias reached +30 %, which had negative effect on the success rate. However, the results for sample B were completely fine.

Bilirubin direct
AVs were determined as robust means of groups arranged according to reagent manufacturers (code R).
For direct bilirubin, we asked users of **Roche** kits this question:
The manufacturer allows you to choose the Doumas or Jendrassik-Gróf method when applying it to the analyzer. Which one do you use?
The participants' answers were as follows:

18x Not specified
58x Jendrassik-Gróf
55x Doumas
4x I don't know, I don't have the information

The graph on the right shows the results of participants who reported a specific method. The means and variances of both groups are almost identical.
It turned out that a number of participants who report the measurement principle M = 2 = DCA, DPD, somewhat surprisingly use the standardization of the method according to Jendrassik-Gróf. This follows from the fact that Roche allows double standardization (Jendrassik-Gróf and Doumas) using the measurement principle of the method with stabilized diazonium salts. It is pleasing to find that both options lead to practically identical results.



+ ... Jendrassik-Gróf
o ... Doumas

CK
For both samples and all groups of results (according to the reagent manufacturer), there was a negative bias that was at the level of a half to two thirds of D_{max} compared to CRV. Therefore, we used robust averages of the results of all participants as reference values.

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 10 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 B. Laboratories using the enzyme assay achieved a success rate of 100 %. In the case of the Jaffé method, the success rate was only 94 %.
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
Here we observed a greater positive bias of the measurement results for sample B (lower concentration) in the Roche (b = +13%) and Siemens (Atellica) (b = +17%) groups. In the Roche group, the negative impact of this bias on success was small, in the Siemens (Atellica) group it was larger.

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.

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	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	1	3	16	26	288	79
	relative	-	0,24 %	0,73 %	3,9 %	6,3 %	70 %	19 %
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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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).

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.