BM2/22: Bone Markers

This EQA round was accomplished according to the document ***EQA Plan 2022***.

Note for the participants from the abroad
We are using comma as a decimal separator and dates in day.month.year format.

Samples
We used commercial samples in this round.

Supervisor's comment
There were 177 participants in this round, 29 of them from Slovakia, and 1 from Korea.
For the purposes of the evaluation, the participants' results were sorted into **groups according to the reagent manufacturers (code R)** and for each group the assigned value was determined as a robust mean. Only groups with the number of participants n $\geq$ 5 were assessed. Smaller groups were not evaluated (for tests that were not evaluated, participants will find the mark ± in the result sheet).
Possible exceptions are described below.

25-hydroxyvitamin D
Roche: The users of Roche kits must report the generation of the kit. Based on this data, their results were divided into 2 groups:

- R = 60 = Roche: 2nd + 3rd generation (any of these generations were reported by most participants)
- R = 256 = Roche (2): 1st generation (only 4 participants, thus not assessed)

The results provided by the 2nd and 3rd generations of the kits were comparable, the 1st generation provided approximately 50 % lower results.
Beckman Coulter: Similarly to the previous rounds the results measured by the participants who reported the use of Beckman Coulter kits (R = 12) were significantly higher (approximately 2 times compared to the total average). This phenomenon may be due to the matrix of EQA samples or the possible presence of 25(OH)vitamin D epimers in these samples. According to the available information, this effect does not appear when measuring patient samples.

Parathyrin intact (PTH)
Large differences persist between the averages of the results of the individual groups and thus the overall reproducibility remains unsatisfactory (average CV was 35 %).

Parathyrin biointact (PTH 1-84)
The results of PTH 1-84 have a higher clinical effectiveness than the results of intact PTH, especially in patients with chronic renal disease (especially in patients on haemodialysis). Namely in cases where the manufacturer offers both analytes, the transition to PTH 1-84 measurement is appropriate.
136 participants reported the results of parathyrin in this round this way:

Analyte	***Count***
Parathyrin intact (PTH)	87
Parathyrin biointact (PTH 1-84)	50
Both analytes	1

Collagen telopeptide CTx-beta, P1NP
The results obtained using the Snibe (R = 73) kits were significantly different from the numerically dominant group Roche (R = 60) and that is why these results are outside of the area of the Youden plots (but this fact has no influence to the assessment of the results).

Further information concerning the activities of the IFCC in the field of the standardisation of the bone metabolism parameters you can find here: https://www.ifcc.org/ifcc-scientific-division/sd-committees/c-bm

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 (0 % … no success; 50 % … success from 1 to 50 %; 75 % … success from 51 to 75 % etc.). Next 2 lines contain both absolute and relative number of participants that reached the success from the header.

	Success	***0 %***	***50 %***	***75 %***	***80 %***	***85 %***	***90 %***	***95 %***	***99 %***	***100 %***
Count	absolute	0	3	7	1	2	11	20	0	130
	relative	-	1,7 %	4 %	0,57 %	1,1 %	6,3 %	11 %	-	75 %
Note: You can find your individual success over last 2 years in your result sheet.										

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Overall success of most participants of this round over the last 2 years is higher than 80 %.
Success rates of 80 % or less should be considered to be an impulse to improve.

Educational part of the round – questionnaire (units)
After 4 years, we again included in this round a questionnaire mapping the units in which individual laboratories issue patient results. 66 laboratories responded to the questionnaire (i.e. 37 % of the participants), which is not a lot, and **we thank them very much**. You can find an overview of the answers in the following table (numbers of the participants who declare the use of the unit in accordance with the CSKB recommendation are framed in bold):

Analyte	Recommended unit	Number of the participants for particular units					
		µg/L	ng/L	µg/mL	ng/mL	pg/mL	pmol/L
Osteocalcin	µg/L	**55**		3	9		
P1NP	µg/L	**56**			6		
Parathyrin biointact (PTH 1-84)	pmol/L		1			2	**41**
Parathyrin intact (PTH)	pmol/L		19			11	**35**
Collagen telopeptide CTx-beta	ng/L	17	**44**		12	6	2

The table shows persisting large fragmentation in the expression of concentrations, despite the existence of CSKB recommendations (see https://www.cskb.cz/wp-content/uploads/2020/04/dop-jednotky.pdf and the *Recommended unit* column in the table).
Some laboratories use obscure notations of units (sometimes also referred to as "traditional") that contradict the IUPAC Silver Book recommendation (it is not correct to use prefixes in the denominator, so µg/mL is not correct, it should be mg/L instead of pg/ mL should be ng/L).
The harmonisation of units is one of the basic pillars of the harmonisation of laboratory results. The use of different units undoubtedly increases the risk of errors in patient care, especially in cases where the same result expressed in different units is numerically completely different, which is the case of a mixture of substance and mass concentrations.

We urgently recommend to all laboratories to harmonise the units in which they issue patient results with the current recommendation of the CSKB.

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Supplements

As a supplement to this report individual participants receive:

Name of the supplement	*Remark*
Confirmation of attendance	Issued only to those participants that fulfilled the criteria.
Result sheet (quantitative results)	Issued only to those participants that reported quantitative results.
Complex statistics	Only for tests with quantitative results and two samples.

The supplements are identified by their name, EQA round identification and participant code and are intended for the needs of the participant.

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 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.