## EQA Division BM1/21: Bone Markers

This EQA round was accomplished according to the document EQA Plan 2021.

## Note for the participants from the abroad

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

# Samples

SEKK

We used lyophilised commercial samples in this round.

# Supervisor's comment

There were 158 participants in this round, 29 of them from Slovakia, and 1 from Korea.

For the purposes of the evaluation, the participants' results were divided into **groups according to the reagent manufacturers** (code R) and for each group the assigned value was determined as a robust average. Only groups with the number of participants  $n \ge 5$  were evaluated. Smaller groups were not evaluated (for tests that were not evaluated, participants will find the mark  $\pm$  in the result sheet).

Possible exceptions are described below.

### Parathyrin intact (PTH)

The overall reproducibility is comparable to previous rounds (CV almost 30 %) and large differences persist between the averages of the results of the individual groups.

### Parathyrin biointact (PTH 1-84)

The overall reproducibility is significantly better than that of PTH ( $CV_A = 9,4\%$ ,  $CV_B = 5,6\%$ ), approximately three quarters of the participants use Roche reagents and a quarter DiaSorin.

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). Especially in cases where the manufacturer offers both analytes, the transition to PTH 1-84 measurement is appropriate. The portion of the more progressive PTH 1-84 method within the BM programme is not growing significantly (approximately 40 participants for many years).

# Collagen telopeptide CTx-beta, P1NP

The overall reproducibility (CV) of these parameters was comparable to the previous rounds. The use of "harmonized" units of measurement is recommended: ng/L for CTx and  $\mu$ g/L for P1NP (Morris HA et al.: Clin Chim Acta 2017,464: 34-41).

#### Osteocalcin

We observed problematic results for sample A measured using DiaSorin kits (R = 164; 5 results; lowest 8,1 and highest 16,6 µg/L). Because the uncertainty of the assigned value was unacceptably high, we did not evaluate this group.

#### 25-hydroxyvitamin D

For groups with the number of participants  $n \ge 10$  the reproducibility (CV) values ranged over a wide interval from 5 to 20 %.

**Roche:** Users of Roche kits must also report the generation of the kit. Based on this data, their results were divided into 2 groups ( $1^{st}$  generation as group R = 60 and  $2^{nd}$  generation as R = 256), because the results provided by individual generations of kits differ significantly ( $2^{nd}$  generation provides approximately 80 % higher results).

**Beckman Coulter:** Traditionally, vitamin D results measured by the participants who reported the use of Beckman Coulter kits (R = 12) were significantly higher (approximately 3 times). This positive bias 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.

#### 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  $(0 \% \dots$  no success;  $50 \% \dots$  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 %	<b>99</b> %	100 %
Count	absolute	0	0	9	2	2	4	22	1	116
	relative	-	-	5,8 %	1,3 %	1,3 %	2,6 %	14 %	0,64 %	74 %
Note: You can find your individual success over last 2 years in your result sheet										

Overall success of most participants of this round over last 2 years is higher than 80 %.

Success rates of 80 % or less were achieved by 11 participants (7,0 %) for whom it should be an impulse to improve.

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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	Issued only to those participants that reported quantitative results.
(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 <u>www.sekk.cz</u>, 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.