SEKK EQA Division

IHC1/24: Immunohistochemistry - Detection of HER-2/neu

This EQA round was accomplished according to the document *EQA Plan 2024*. *Typing conventions: We are using comma as a decimal separator and dates in day.month.year format.*

Samples

Each participant received one histological glass (TMA). All slides contained identically arranged samples from identical source tissue blocks. The TMA	A B C D E \bigcirc \bigcirc \longleftarrow Liver tissue for a block orientation
block map is displayed on the right.	100000
The samples were prepared by the subcontractor.	200000
	30000

Assigned values (AV)

The results of **HER-2/neu expression** reported by the participants for individual TMA positions are evaluated in this programme.

AVs are determined as the consensus of the expert laboratories. The list of the expert laboratories for the IHC programme is available at the <u>www.sekk.cz</u> (EQA button and the link Expert laboratories). In fact this is a group of so called Reference laboratories for Her-2 diagnostics.

The consensus of expert laboratories that participated in the round is reached if at least 80 % of the experts agree on the result. The agreement of the experts is examined over the following groups of results:

- negative (0) and negative (1+)
- positive (2+) and positive (3+)

These rules are applied:

- If the experts agree on one particular result then this result is marked as the expected result and complementary result from appropriate pair (0/1+ and 2+/3+) is marked as the acceptable value.
- If the results of the experts are spread inside the pair the way in which 80 % of the experts conclude on whole pair but not on one value from the pair, then both values are marked as expected results.
- If there is not consensus of the experts then the particular TMA position is not assessed (AV is missing).
- The consensus cannot be reached "across" the pair 0/1+ and other results. For example the consensus on the results 1+ and 2+ together is not possible.

This procedure of the AV determination eliminates cases in which the samples could be labelled as "inconclusive" or "questionable".

		Numbe	Number of the results from the expert laboratories				
#	TMA position	Negative (0)	Negative (1+)	Weak positive (2+)	Strong positive (3+)	AV	
601	A1				10	3+	
602	A2	9	1			neg	
603	A3		3	7		consensus not reached	
606	B1		2	8		2+	
607	B2			10		2+	
608	B3		4	6		consensus not reached	
611	C1			10		2+	
612	C2	6	4			neg	
613	C3			10		2+	
616	D1	6	4			neg	
617	D2		3	7		consensus not reached	
618	D3	2	8			neg	
621	E1	10				neg	
622	E2	9	1			neg	
623	E3	10				neg	

Overview of the AVs in this round

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Supervisor's comment

SEKK

There were 47 participants in this round, 1 of them from Poland, 1 from Romania and 15 from Slovakia.

As follows from the description of AVs above, **10 samples** (positions in the TMA block) were assessed in this round. Positions A3, B3, D2 were not assessed because the consensus was not reached among the expert laboratories. Other participants reported for these samples the results with a distribution similar to the experts.

Problematic samples

Problematic samples (meaning: erroneous results are not sporadic to them) are usually found among those where expert laboratories have agreed on the AVs of 1+ or 2+. However, it cannot be said that all of these samples are problematic. Problematic samples are listed the following table:

Position	AV	Note
B1	2+	But 26 % of the participants classified it as negative.

The problematic differentiation of the samples 1+ and 2+ may be influenced by the inhomogeneous distribution of a positivity in the sample (60 sections are cut from one TMA block for EQA, so this phenomenon cannot be completely ruled out), as well as by demonstrable interpersonal variability in physician evaluation. The deviation 1+ versus 2+ in an individual case can therefore be caused by these phenomena and does not necessarily indicate a reason to change the setting of the IHC methodology. In the case of a systematic phenomenon, on the other hand, it is recommended to adjust the staining methodology. In this round the B2, C1 and C3 positions have been classified by the clear consensus as 2+ and if your results in these positions are different (often it was "overestimated" at 3+), please consider this as a reason for reflection.

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	exce	llent
Count	absolute	0	0	1	3	12	22	9
	relative	-	-	2,1 %	6,4 %	26 %	47 %	19 %

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

Overall success of most participants of this round over the last 2 years is 90 % or higher. Success rates below 90 % should be considered to 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 the results.					

The supplements are identified with a 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 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.