Round: HR2/20 – Hormonal Receptors

This EQA round was accomplished according to the document **EQA Plan 2020**.

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

Samples

The samples (TMA) for this round were prepared at the sub-contractor's site. Participants received 2 histological slides made of the TMAs (each TMA consists of 10 samples of the tissue), one to determine the estrogen receptor (ER) and one for progesterone receptor (PgR).

Supervisor's comment

There were 61 participants in this round, 10 of them from Slovakia, and 1 from Hungary.
We asked the participants to report a qualitative result (negative / positive) for each sample and to supplement it with a quantitative estimate of the percentage of ER or PgR in the invasive carcinoma.
Each sample on each slide is processed as a separate test in the process of the EQA assessment.
In general, if a participant does not provide a result for the particular sample/test (e.g. sample lost during staining), then we do not process the relevant sample/test at all for that participant - it is not counted in the evaluation and statistics. Therefore, for all tests in the statistics, the total number of results may not be equal to the number of participants - those who have not reported the result are missing.

Assigned values (AV)
The AVs are determined as the consensus of the participants in this EQA scheme.

Qualitative results

In the case of qualitative results, the consensus is reached if at least 80 % of the participants agree on the result.

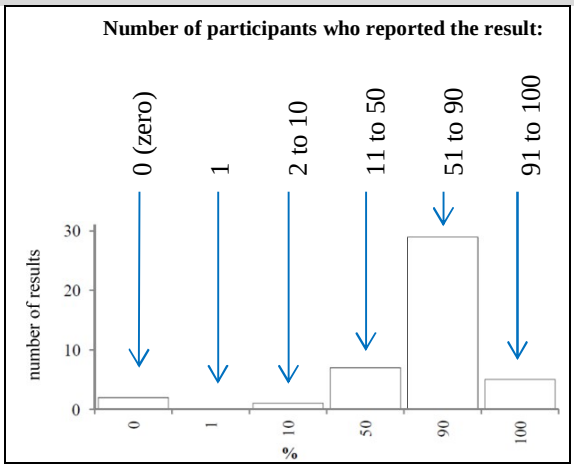
The **ER** staining was completely without problems, consensus of qualitative results was reached in all tests, we observed only sporadic errors.

In the case of **PgR**, the consensus of qualitative results was reached for all tests **except PgR at the position 10** (59 % negative, 41 % positive). I recommend to all participants the internal validation of their protocol on a TMA block containing cervical tissue (cylindrical epithelium, basal cells of the squamous epithelium and stromal cells should be moderately to strongly positive) and tonsils (completely negative).
A higher number of erroneous results (10 times negative) we observed at position 2.

Quantitative results

We do not determine AVs for **quantitative** results in this EQA scheme. Since these are only estimates with a large uncertainty, consistent determination of the AVs is not possible. Instead of evaluating, we send to the participants the histograms where the summary of all quantitative results and their location within the histogram should be found.

The figure on the right shows how the results of the participants are sorted (summarised) in the histograms, i.e. what results are summed in the individual columns.



The assessment of the test always depends on the qualitative results. Quantitative results do not affect the assessment of the test, but are an important guide to the staining sensitivity settings, and therefore histograms should be considered. If the individual position deviates systematically from most participants, this indicates a problem. Unfortunately, many participants did not provide quantitative results (no quantitative estimation was given for 15 % of the results).

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Cut-offs reported by the participants

Cut-off	*Number of the participants*	
	Estrogen receptor (ER)	***Progesterone receptor (PgR)***
1 %	45	45
2 %	1	-
5 %	4	4

According to the recent recommendation of the ASCO/CAP (Journal of Clinical Oncology, Vol 28, Issue 16 (June), 2010: 2784-2795) the **cut-off = 1 %**. The recommendation of the Czech Society of Pathology is identical. It is always true that low ER values are questionable in terms of clinical response to hormonal manipulation; therefore, a quantitative result in percent or as Allred score (as agreed with the clinical oncologist) must also be reported. It cannot be replaced by a cut-off of 5 % or 10 %. In this EQA scheme the cut-off is required also if the laboratory does not use it in the routine practice.

Antibodies and detection systems used according to the notes of the participants

The SP1 antibody from various suppliers dominates in the ER determination, closely followed by EP1 (DAKO-Agilent), older antibodies 1D5, 6F11 are used rarely.

The spectrum of antibodies against PgR is somewhat broader with the dominance of 1E2 (Roche) and PgR 636 (DAKO-Agilent), and clones SP42 (Zytomed), 16 (Leica) also appear.

The rule of thumb is the detection by sensitive polymer systems (mainly Roche and DAKO-Agilent, but also Leica, DCS, and BioSB).

There is no apparent correlation of discordant PgR results at position 10 with the antibodies used as shown in the table below.

Antibody	1E2	PgR636	SP42	16
	Number of the participants			
PgR10 positive	8	8	2	1
PgR10 negative	6	12	2	3

Long term success rate

You can find in the following table the overview of the total success of the participants of this round over last 2 years. Individual 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 rate specified in the header**.**

	Success	***0 %***	***50 %***	***75 %***	***80 %***	***85 %***	***90 %***	***95 %***	***99 %***	***100 %***
Count	absolute	0	0	0	0	0	1	6	28	26
	relative	-	-	-	-	-	1,6 %	9,8 %	46 %	43 %
Note: You can find your individual success over last 2 years in your result sheet.										

The table shows that almost all participants in this round show a long-term success rate of over 90 %.

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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 (qualitative results)	Issued only to those participants that reported qualitative results.
Histograms	Only for the quantitative results.

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

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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 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.