2.6. Pathology

Important notice common to all pathology schemes
It is important that you perform sample processing as soon as possible after receiving the samples. If you start processing the samples just before the deadline and the slide is destroyed, you will not be able to get a replacement sample from SEKK in time and you will not be able to complete the round in due time.

Professional supervision: **European Society of Pathology (www.esp-pathology.org)**

CRC – Colorectal Carcinoma

Tests: detection of *KRAS, NRAS, BRAF* genes mutations

Samples: 1 set containing 30 unstained FFPE sections obtained from 10 primary samples (invasive colorectal adenocarcinomas, rarely a tissue without neoplastic cells should be used as a primary sample). Every participant receives 3 sections of each primary sample (6 µm thick). One section is to be used for hematoxylin-eosin (HE) staining and the remaining 2 sections for DNA isolation and mutation detection.

Reports for participants: confirmation of attendance, result sheet (qualitative results)

Supervision: Prof. Dr. med. Daniela Aust (Germany), Prof. Magali Svrcek, M.D., PhD. (France)

Participants: without limit **Minimum participation:** 1 round **Additional evaluation:** no

Further information: The participants should identify and describe gene mutations (the participant can choose any combination of *KRAS, NRAS, BRAF* testing) clinically relevant to anti-EGFR therapy. It is assumed that:

- If the participant tests KRAS or NRAS then in minimum: codons 12, 13 (exon 2)
  codons 59, 61 (exon 3)
  codons 117, 146 (exon 4)
- If the participant tests BRAF then in minimum: codon 600 (exon 15)
  codon 601 (exon 15)

The participant must (not later than on the day of deadline):

1. Process EQA samples received using the procedure routinely used in their laboratory.
2. Specify methods used, including analytical sensitivity (the term "method" refers to the reagents used; the measuring system/automat/instrument need not be specified).
3. For each sample, indicate whether it has been tested and, if so, add the additional information required, indicate the mutations found and indicate the methods used for individual genes.
4. Upload scans of their own laboratory reports (negative and positive results) of real patient samples (not bounded to EQA samples, with blacked-out patient/sample identification data, in participant's language).

Participants are not allowed to share EQA results with other participants or to enter the results into systems/databases that allow such sharing. Each participant must send their own results to SEKK without consulting other participants.

Performance evaluation

Each gene is evaluated separately.

Assigned values (AV), i.e. the mutations that the participants should find, are determined in the network of 3 expert laboratories in the Europe. From the point of view of the ISO 17043 it is CVE (consensus from experts) type of AV.

Detection of mutations: The participant's result (identified mutation) is compared to the AV for each sample and if it is identical to AV then it is considered correct, any other result is considered wrong (in this step the participant's method is taken into consideration).

Post analytical phase: The participant's laboratory reports represent educational part of the scheme and its content does not influence the performance of the participant – but upload of the reports is required. Possible recommendations and notes to the laboratory reports (after the comparison with the requirements of the ISO 15189) shall be sent to the particular participant in the form of the individual comment.

Summary: To be evaluated as successful in particular gene that the participant must correctly detect mutations of this gene in all samples and must upload their laboratory reports.

Schedule

EQA round	**CRC1/20**
Dispatch date	4.5.2020
Deadline	8.6.2020

Prices

Participation in the scheme: **490 EUR**. This price is final and includes both VAT and the samples, transport and evaluation costs. The participants will pay this amount to the bank account of the ESP Foundation (European Society of Pathology) on the basis of the document (payment note) issued by SEKK (SEKK will send this document to the e-mail of the participant).

Replacement samples: If the participant needs to obtain a replacement sample(s) (due to damage or deterioration of the original sample), the participant must order it by e-mail not later than 1 week after the delivery of the parcel with round (see the text box at the top of this page). SEKK will send replacement samples to the participant by the courier service and the price **10 EUR** (price without VAT) for each FFPE section plus the **price for the transport** of the parcel will be charged. Replacement samples shall be invoiced by SEKK directly to the participant.