Test Item Information Sheet (TIIS)

“Tissue Histology” 2019_R1 Scheme

This sheet contains all the information on Tissue Test Items that you should be aware of to conduct the above mentioned Scheme. Please read carefully before performing any operation and/or test on the provided samples.

Test Item Description

- Source material: Colorectal adenocarcinoma.
- Material support: 3 pictures.
- Biological hazard: Not applicable.
- Biosafety level: Not applicable.
- Method used for value assignment: Consensus by ISO17025/CLIA accredited laboratories, according to The International harmonized protocol for the proficiency testing of analytical chemistry laboratories, IUPAC technical report.
- Homogeneity and Stability information: Not applicable.

Instructions to Prepare Test Item for Testing

- No preparation required (Pictures).
- Test Items (3 pictures – Test Item A, Test Item B, Test Item C) are accessible electronically.

Particular Handling/Safety Requirements

- No handling/safety requirements.

Schemes Specifications

- How to access Test Items (pictures): You will access the Test Items through the digital biopsy platform. Follow the attached instructions on how to access the pictures.
- For Test Item A: Tissue Characterization/Mapping: please indicate the percentage of uninvolved tissue area and the percentage of the following categories for information (as applicable): Viable tumour tissue, and tumour stroma and/or mucin and/or necrosis areas.
- For Test Item B: Tissue Characterization/Mapping: please indicate the percentage of uninvolved tissue area of viable tumour tissue area and of the following categories for information (as applicable): tumour stroma and/or mucin and/or necrosis areas.
- For Test Item C: Tissue Characterization/Mapping: please indicate the percentage of viable tumour tissue area and of the following categories for information (as applicable): uninvolved tissue, tumour stroma and/or mucin and/or necrosis areas.
What and How to Submit

- For each Test Item, you can perform the evaluation more than once, and submit more than one test result. If you decide to submit several results for the same Test Item, it is recommended that either one pathologist performs the tissue characterization on different days, or that different pathologists perform the tissue characterization on the same day.
- Your results must be submitted online to the PT website http://biospecimenpt.ibbl.lu using the login information (Laboratory Number and Password) provided to you via email after the registration to the “Tissue Histology” Scheme.
- Please complete the questionnaire as accurately as possible, adding any relevant detail and comment in the appropriate comment section.

Timelines

<table>
<thead>
<tr>
<th>Results submission</th>
<th>Data analysis &amp; Report preparation</th>
<th>Reports available</th>
</tr>
</thead>
<tbody>
<tr>
<td>15 NOV 2019, latest</td>
<td>15 NOV 2019– 17 JAN 2020</td>
<td>28 FEB 2020</td>
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</tbody>
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In case of doubts in the completion phase, please contact IBBL at ISBERPT@ibbl.lu