Supplementary Table S3. Recommendation statements according to the validation of digital diagnostics from the Digital Pathology Guideline of the Federal Association of German Pathologist [5]

Recommendation statement
Recommendation 2_2: The validation SHOULD be suitable for the clinical aim (kind of diagnosis) which is addressed by the WSI implementation. The preparation of the material (formalin fixation, paraffin embedding, frozen sections, immunohistochemical stains, cytology smears, etc.) should be included in the study. A renewed validation study is necessary if a new preparation technique is inaugurated which differs from the already proven method.
Recommendation 2_3: The validation study SHOULD reproduce the reality of the clinical – pathological environment which will be used for the virtual technology.
Recommendation 2_4: The validation study SHOULD include the complete WSI-System and its archive. It is not necessary to validate individual components of the system.
Recommendation 2_5: The adequately trained pathologist, who will diagnose the WSI diagnostically in the routine, SHOULD be involved in the validation process.
Recommendation 2_6: The validation process SHOULD include a sample of at least 60 cases per application (Routine stains of fixed tissue), which are representative samples of the spectrum and complexity of routine diagnostics. The validation process SHOULD each have 20 cases for each additional Application (e.g. immunohistochemistry, special stains). The validation is done by the diagnosis comparison of the associated glass slide and of archived WSI, or of the actual WSI, if the manufacturer provides this procedure as fallback option.
Recommendation 2_7: WSI and glass slides MAY be evaluated at random or systematic order.
Recommendation 2_8: A waiting period of at least two weeks between the assessment of the WSI and glass slides SHOULD be arranged.
Recommendation 2_9: Revalidation MUST be performed as soon as a significant change to one components of the WSI system has occurred.
Recommendation 2_10: The validation MUST confirm the diagnostic concordance between WSI and glass slides, and document the accepted intra - observer reproducibility.
Recommendation 2_11: The validation SHOULD confirm that all material, which is present on the glass slide, will be also present in the WSI.

References

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