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Clinical Laboratory Improvement Advisory Committee
Centers for Disease Control and Prevention
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RE: Virtual Comments for April 10, 2024 Spring Virtual Clinical Laboratory Improvement Advisory Committee Meeting, the Role of Artificial Intelligence and Machine Learning in the Clinical Laboratory

The National Society for Histotechnology (NSH) appreciates the opportunity to provide comments concerning the Role of Artificial Intelligence and Machine Learning in the Clinical Laboratory on behalf of its membership. The National Society for Histotechnology is a non-profit member organization that supports histotechnicians and histotechnologists worldwide through education, collaboration and innovation.

When CMS last revisited the CLIA regulations in 1992, it excluded from oversight many histological pre-analytic, analytical, and post-analytical processes because they were deemed relatively simple, minimal risk procedures that did not require a Histotechnologist to produce an independent result. As NSH has commented in previous letters to CLIAC much has changed in the last 30 years, and an educated, well-trained Histotechnician and Histotechnologist is essential to arrive at an accurate diagnosis of anatomic pathology samples. The field of histotechnology has witnessed unprecedented technical advances over the last two decades, including innovative approaches, methodologies, and automation in traditional areas (tissue processing, histochemistry) as well as in the fields of immunohistochemistry, molecular diagnostics, and computerized assisted digital analysis (artificial intelligence and machine learning) all critical to patient diagnosis and treatment.

The medical profession continues to expand and utilize artificial intelligence and machine learning to aid patient diagnosis and treatment by extracting quantitative data from digitized whole slide images. The accuracy of this data is dependent upon the quality of the histology preparations. To achieve accurate and reproducible results from whole slide imaging to routine image analysis solutions to those that utilize artificial intelligence and machine learning, high quality histology is a necessity playing a significant role in the *Total Test* approach (1-4).

There are numerous challenges to applying current CLIA regulations to the technologies using artificial intelligence and machine learning. Histotechnicians and Histotechnologists perform a critical role in the process and are not currently under CLIA's oversight nor meet CLIA's high complexity personnel requirements. The National Society for Histotechnology advocates that the CLIA recommendations be amended to include Histotechnicians and Histotechnologists under CLIA's oversight therefore requiring histology laboratory personnel to meet CLIA's high complexity personal requirements.



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As technology continues to advance at a rapid pace, NSH strongly recommends that a CLIAC workgroup be formed to discuss the requirements that should be added or revised in CLIA to ensure the quality of testing when artificial intelligence and machine learning are a part of the total testing process. Furthermore, NSH strongly recommends that a histology professional be included on that workgroup.

The National Society for Histotechnology is the largest a non-profit member organization, representing histotechnicians and histotechnologists worldwide. NSH is the leading provider of histotechnology education designed to demonstrate continuing competence in an increasingly complex laboratory-testing environment. We look forward to CLIAC's response to these issues and continued discussion in order to advance the histotechnology profession and provide the highest quality care to the patients we serve. We thank the committee for the prior work, ongoing efforts, and consideration.

1. Keisuke Nakagawa, Lama Moukheiber, Leo A. Celi, Malhar Patel, Faisal Mahmood, Dibson Gondim, Michael Hogarth, Richard Levenson, AI in Pathology: What could possibly go wrong?, *Seminars in Diagnostic Pathology*, Volume 40, Issue 2, 2023, Pages 100-108,
2. Dunn, C., Brettle, D., Cockroft, M. *et al.* Quantitative assessment of H&E staining for pathology: development and clinical evaluation of a novel system. *Diagn Pathol* **19**, 42 (2024)
3. Schömig-Markiefka B, Pryalukhin A, Hulla W, Bychkov A, Fukuoka J, Madabhushi A, Achter V, Nieroda L, Büttner R, Quaas A, Tolkach Y. Quality control stress test for deep learning-based diagnostic model in digital pathology. *Mod Pathol*. 2021 Dec;34(12):2098-2108. doi: 10.1038/s41379-021-00859-x. Epub 2021 Jun 24. PMID: 34168282; PMCID: PMC8592835.
4. Haghighat, M., Browning, L., Sirinukunwattana, K. *et al.* Automated quality assessment of large digitised histology cohorts by artificial intelligence. *Sci Rep* **12**, 5002 (2022).