



Center for Clinical Standards and Quality/Survey & Certification Group

Ref: QSO-20-08-CLIA

DATE: January 10, 2020

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Applicability of Proficiency Testing (PT) Referral to Cytology/Histopathology
Slide Staining by a Separate Entity

Memorandum Summary

- Staining of Cytology/Histopathology slides is considered part of specimen preparation and not part of the “examination” referenced in the CLIA definition of a laboratory. As such, entities that only conduct these preparatory steps to testing are not considered laboratories, and would not be subject to CLIA.
- For purposes of Proficiency Testing (PT) referral, if a laboratory merely sends PT slides to a separate entity for staining and the slides are returned to the original laboratory for examination, CMS would not consider this to be PT referral.

Background

There are instances when the staining of cytology/histopathology slides is performed by an entity other than the laboratory that ultimately examines (e.g., interprets) the slides. CMS is clarifying how Proficiency Testing (PT) referral applies to cytology/histopathology slide staining by a separate entity.

Cytology/Histopathology Slide Staining

CMS has stated in the State Operations Manual (SOM), Appendix C (Interpretive Guidelines) that tissue cassette embedding, paraffin block sectioning, and slide staining (e.g., for ultimate use in Pathology testing) are considered part of specimen preparation and are not part of the “examination” referenced in the CLIA definition of a laboratory. As such, entities that only conduct these preparatory steps to testing are not considered laboratories, and would not be subject to CLIA. *See IGs ppg. 44, 88 (D2006) and 162-163 (D5311)*

Applicability of PT Referral

Under 42 CFR §493.801(b), when testing PT samples, if the laboratory’s patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the PT sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. Based on this requirement, cytology/histopathology slide staining by a separate entity would not be considered “further” testing as it occurs prior to the actual testing of the sample.

In addition, “Distributive testing” is defined at 42 CFR §493.2 as laboratory testing performed on the same specimen, or an aliquot of it, that requires sharing it between two or more laboratories to obtain all data required to complete an interpretation or calculation necessary to provide a final reportable result for the originally ordered test. Based on this definition, cytology/histopathology slide staining by a separate entity is not considered distributive testing since, as noted above, slide staining is considered part of specimen preparation and is not part of the “examination” referenced in the CLIA definition of a laboratory.

For purposes of PT referral, if a laboratory merely sends PT slides to a separate entity for staining and the slides are returned to the original laboratory for examination, CMS would not consider this to be PT referral. If, however, the separate entity performs any activity other than staining, such activities may be part of the “examination” referenced in the CLIA definition of a laboratory, in which case, CLIA requirements, including those referencing PT referral, would apply. CLIA applicability would depend on the specific additional activities being performed by the separate entity.

Contact: Questions related to this memorandum may be submitted to: LabExcellence@cms.hhs.gov

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/
David R. Wright

cc: CLIA Branch Managers
CLIA Location Staff