

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0687945	(X3) Date Survey Completed 04/28/2021
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For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Office Staff, the laboratory failed to follow procedures to assess testing personnel competency for 1 (Testing Personnel #2) of 2 testing personnel listed on the CMS-209 form. Findings include: 1. A record review of the laboratory's records revealed a lack of documentation of a competency assessment for Testing Personnel #2 performing histopathology testing in 2020. 2. A review of the laboratory's "Quality Assessment Policy" revealed a section stating, "The laboratory must establish and follow written policies and procedures for an on-going mechanism to monitor, assess and when indicated, correct problems identified in all four quality systems." Under "General Laboratory Systems" lists, "Personnel Competency Assessments." 3. An interview on 4/28/21 at 9:30 am with the Office Staff confirmed the laboratory did not have a competency assessment for Testing Personnel #2 performed in 2020.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Office Staff, the laboratory failed to</p>

verify the accuracy of its histopathology testing at least twice annually in 2019. Findings include: 1. A review of the laboratory's "Slide Review Log" revealed a lack of a second verification of accuracy testing event in 2019. 2. A review of the laboratory's "Policy for Quality Assessment of Analytic Systems" revealed a section stating, "Twice a year an analytic quality assessment will be performed by choosing at least 1 moha slide and chart to be reviewed by a physician to confirm the correct diagnosis." 3. An interview on 4/28/21 at 9:30 am with the Office Staff confirmed the laboratory did not have documentation available for the second verification of accuracy testing event in 2019.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:
. Based on observation and interview with the Office Staff, the laboratory failed to ensure histopathology inks were not used beyond the expiration date for 7 months (September 2020 to April 2021) since the inks had expired. Findings include: 1. The surveyor conducted a virtual tour of the laboratory on 4/26/21 at 9:37 am. During the tour, it was discovered the inks used in histopathology testing had an expiration date of 9/6/2020. 2. An interview on 4/26/21 at 9:45 am with the Office Staff confirmed the inks used in histopathology testing were expired.