

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2108488	(X3) Date Survey Completed 10/28/2019
Name of Provider or Supplier Stat Laboratory	Street Address, City, State 5115 El Paso Drive Suite B, El Paso, TX	
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 review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have assessed the competency of the Technical Consultant. The findings included: 1. A review of the laboratory's submitted CMS form 209 found that the laboratory identified 1 individual as a technical consultant. 2. A review of the laboratory's personnel records found no competency assessments performed for the Technical consultant hired October 2017. 3. Interview of the Technical Consultant conducted on October 28, 2019 at 11:12 AM confirmed that there was no documentation of competency assessment of the Technical Consultant performed by the previous laboratory director (exit date of April 2019), or the current laboratory director (hired April 2019), available for review</p>
D5219	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing records, patient test records and staff</p>

interview, it was revealed the laboratory failed to have documentation of performing twice annual accuracy assessment for KOH testing at least twice annually in 2018 and 2019. Findings included: 1. Review of the proficiency testing records found the laboratory was not enrolled in a proficiency testing program for clinical microscopy and did not have evidence of using another means to verify the accuracy of results for KOH wet mounts. 2. Review of patient test records found the laboratory reported performing 889 KOH wet mounts annually. 3. Interview of the Technical Consultant listed on the CMS report 209 Laboratory Personnel report conducted on October 28, 2019 at 11:36 AM confirmed that no records for KOH wet mount accuracy assessments in 2018 or 2019 were available for review.

D5415

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

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Observations, and interview of facility personnel found that the laboratory failed to ensure that all reagents and solutions were labeled with the contents, preparation expiration dates, lot numbers and storage requirements for all reagents and controls stored in the laboratory. Findings included: 1. Observations made during the survey conducted on October 28, 2019 found 36 unlabeled glass tubes in a tube storage rack located in the refrigerator. The tubes contained aliquots of a colorless liquid and were not labeled with the contents, preparation expiration dates, lot numbers and storage requirements. 2. Interview of testing person one on the CMS report 209 Laboratory Personnel report conducted on October 28, 2019 at 11:29 AM found that the liquid in the unlabeled tubes were aliquots of 0.85% saline to be used for wet mount preparations.