

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0450089	(X3) Date Survey Completed 12/19/2019
Name of Provider or Supplier Dermatology Pa	Street Address, City, State 1706 Sw 10th Ave, Topeka, KS	
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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) during calendar year 2018 and 2019 from the PT provider American Proficiency Institute (API) and interview, the laboratory failed to attest on two of four reviewed events that proficiency testing samples were handled in the same manner as patient samples. Findings: 1. A review of proficiency testing events during 2018, Microbiology 3rd Event and 2019 Microbiology 1st Event revealed that attestation statement did not contain the signature of the laboratory director (LD) or designee, and the signature of the testing personnel, attesting that the laboratory handled proficiency testing samples in the same manner as patients. 2. Interview with the Laboratory Director on December 19, 2019 at 10:45 a.m. confirmed, the laboratory failed to attest on two of four reviewed events that proficiency testing samples were handled in the same manner as patient samples.</p>
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's 2018 and 2019 API PT documentation, and interview, the laboratory failed to document all proficiency testing evaluation and</p>

verification activities for the specialty of microbiology for the 3rd Event of 2018 and all (3) Events of 2019. Findings Include: 1. Review of the laboratory's 2018 and 2019 APT PT documentation for microbiology had no documentation for evaluation and verification activities (4 of 4 events) occurring after the date of last survey August 23, 2018. 2. The LD stated the laboratory does perform an evaluation but did not document the review. 3. The LD in interview on December 19, 2019 at 11:00 a.m. confirmed, the laboratory failed to document all proficiency testing evaluation and verification activities for the specialty of microbiology for the 3rd Event of 2018 and all (3) Events of 2019.

D5293

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1239(b)(c)

(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.

This STANDARD is not met as evidenced by:

Based on a lack of current review documentation, procedures and interview, the laboratory failed to document that quality assessment reviews are done to ensure continuous improvement or prevent recurrence of problems. Findings: 1. Review of quality assessment (QA) activities revealed that no patient report review had occurred since August 1, 2018. 2. Review of thermometer records and maintenance records showed no documented review by the LD for 11 of 11 months of 2019. 3. No procedure, policy or guidelines concerning quality assessment processes were made available at the time of survey. 4. Interview with the LD on December 19, 2019 at 10:25 a.m. confirmed, that the laboratory failed to document that quality assessment reviews are done to ensure continuous improvement or prevent recurrence of problems.

D5433

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

Based on lack of documents and interview, the laboratory failed to establish and follow a routine accuracy check for their thermometers and maintenance protocol for their microscope. Findings: 1. Request was made for accuracy check records for the 3 thermometers used in the laboratory for 2018 and 2019. No documents were made available at the time of survey. 2. Request was made for maintenance records for the microscope used in the laboratory for 2018 and 2019. No documents were made available at the time of survey. 3. Interview with LD on December 19, 2019 at 11:20 a.

m. confirmed, the laboratory failed to establish and follow a routine accuracy check for their thermometers and maintenance protocol for their microscope.