

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D2170807	(X3) Date Survey Completed 02/24/2020
Name of Provider or Supplier Advanced Dermatology And Skin Cancer Center,Pa	Street Address, City, State 210 W 13th Street, Ottawa, 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
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on incomplete documentation, and interview, the laboratory failed to have and follow policies and procedures to monitor, assess, and when indicated correct problems in: confidentiality of patient information, positive identification and integrity of the patient's specimen from the time of collection through the completion of testing. Findings: 1. No quality assurance procedures for this location were available at the time of survey. 2. Form labeled "Histology Quality Control of MOHS Processing" had only dates listed at the top and no completed documentation for: a. Processing b. Sectioning c. Stain Quality H&E d. Mounted & Labeled e. Tech Initials 3. Interview with Histo Tech at 11:15 a.m. February 24, 2020 confirmed, the laboratory failed to have and follow policies and procedures to monitor, assess, and when indicated correct problems in: confidentiality of patient information, positive identification and integrity of the patient's specimen from the time of collection through the completion of testing.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p>

This STANDARD is not met as evidenced by:
Based on the lack of procedures for review and interview with staff revealed that the laboratory failed to have written, approved procedures. Findings: 1. No procedure manual for this facility was available for review at the time of survey. 2. The Histotech in interview stated that he thought bringing the procedure manual used at the Manhattan facility was sufficient. All signature dates in the Manhattan manual proceed the opening of this facility by more than a year. All procedures shown had only the Manhattan facility's address listed. On February 24, 2020 @ 11:15 a.m., the Histotech confirmed, laboratory failed to have written, approved procedures.

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 the thermometer. Findings: 1. Request was made for accuracy check records for temperature monitoring used in the laboratory. No documentation was made available at the time of survey. 2. Interview with the Histotech on February 24, 2020 at 10:45 a.m. confirmed, the laboratory failed to establish and follow a routine accuracy check for the thermometer.