

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D2116123	(X3) Date Survey Completed 10/05/2018
Name of Provider or Supplier Dr Anderson - Foot And Ankle Specialists Of Ut	Street Address, City, State 596 W 750 S, Suite 105, Bountiful, UT	
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 lack of documentation and interview with staff, the laboratory failed to establish and follow a written procedure to assess employee competency for 1 of 2 test specialties reviewed, histopathology. The testing person performed approximately 1800 tests per year. Findings include: 1. The laboratory lacked a procedure to assess gross analysis testing personnel competency. 2. The laboratory lacked documentation gross analysis testing personnel were evaluated for competency between 03/2017 and 10/2018. 3. In an interview with staff on 10/05/2018 at approximately 2:00 P.M. staff confirmed the laboratory lacked a procedure to follow for assessment of gross analysis testing personnel competency.</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 lack of documentation, procedure manual review and interview with staff, the laboratory failed to verify Epidermal Nerve Fiber Density (ENFD) test accuracy at least twice annually in 2017. Findings include: 1. The laboratory failed to document they verified the accuracy of ENFD testing twice annually in 2017. 2. Procedure</p>

manual review included the quality assessment policy stating twice annual test verification for ENFD testing would be performed in February and August annually. 3. In an interview with staff on 10/05/2018 at approximately 2:00 P.M. staff confirmed the laboratory failed to document twice annual ENFD test accuracy twice annually in 2017.

D5435

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(b)(2)

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: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

Based on maintenance records review, lack of documentation, patient test records review, and interview with staff, the laboratory failed to follow the laboratory procedure to document the cryostat instrument was operating within the range of -20 to -30 degrees Centigrade for 5 of 19 months of testing reviewed (May through September 2018). Findings include: 1. Maintenance records review failed to include the cryostat operating temperature from May 1, 2018 to October 5, 2018. 2. Patient test records reviewed for frozen section testing performed on 08/30/2018 for EN-18-20, and on 09/28/2018 for EN18-37 included test records the cryostat was used for specimen preparation on 08/30/2018 and 09/28/2018. 3. In an interview conducted on 10/05/2018 at approximately 12:30 P.M. staff confirmed the laboratory changed maintenance chart formats and cryostat temperature was left off since April 30 2018.