

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D1103873	(X3) Date Survey Completed 02/01/2018
Name of Provider or Supplier Dermatology Specialists Pa	Street Address, City, State 3316 W 66th St Suite 200, Edina, MN	
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
D5431	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, record review and interview with laboratory personnel, the laboratory failed to establish and follow a procedure for maintenance and function checks of general laboratory equipment. Findings are as follows: 1. A tour of the laboratory on 2/1/18 at 12:05 a.m. revealed the presence of the following laboratory equipment: - TSP Waterbath with Cardinal Health Digital Thermometer (S/N = 61933003, Manufacturer Calibration Expiration Date = 10/30/08) - Leica Model EG1150H Embedder with Taylor 9940N Digital Thermometer (S/N = 4915 V3043, No Manufacturer Calibration Expiration Date seen) - Leica Model ASP 300 Tissue Processor with Interval Temperature sensor 2. A procedure that defines the maintenance and function check tasks, frequency, acceptable outcomes, and responsible persons could not be located in the Dermatology Specialists Equipment Maintenance and History Binder. 3. Thermometer function checks records from 2016 and 2017 for the equipment noted above could not be located in the laboratory's files. 4. The laboratory was unable to provide the missing procedure or records upon request. 5. In an interview on 2/1/18 at 3:30 p.m., the General Supervisor confirmed the above findings. .</p>
D6120	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8)</p> <p>(7) The technical supervisor is responsible for identifying training needs and assuring</p>

that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

. Based on document review and interview with laboratory personnel, the Technical Supervisor failed to evaluate the competency of 1 of 3 testing personnel at least annually in 2016. Findings are as follows: 1. A review of patient records located in the Special Stains & Immunohistochemical Orders Binder indicated that Testing Personnel 2 (TP2) had performed patient testing on the following dates in 2016: - June 8, 10, 11, 12, 15, & 17 - August 4, 5, 8, & 9, - December 15, 16, 19, 20, 21, 22, 26, 27, & 28 2. 2016 Competency Assessment records for TP2 were not found during review of laboratory documents. 3. The laboratory was unable to provide any competency assessment records for TP2 upon request. 4. In an interview on 2/1/18 at 1:30 PM, the General Supervisor confirmed the above findings. .