

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D1105247	(X3) Date Survey Completed 12/03/2019
Name of Provider or Supplier Pinnacle Dermatology - Plymouth	Street Address, City, State 3655 Plymouth Blvd, Suite 110, Plymouth, 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
D5435	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, document review and interview with laboratory personnel, the laboratory failed to document function checks on an integrated digital thermometer. Findings are as follows: 1. The laboratory performed Mohs Micrographic Surgery under the subspecialty Histopathology as confirmed by the Mohs Technician (MT) during a tour of the laboratory on 12/03/19 at 1:05 p.m. 2. An integrated digital thermometer was observed within the Thermo Scientific Microm HM 520 cryostat. The MT indicated this digital thermometer was used to monitor cryostat temperature each day of use. 3. Function check requirements to verify the accuracy of the digital thermometer were established in the CLIA Laboratory Manual; section 1) Quality Control; part a) Cryostat. 4. Digital thermometer function check documents for 2018 were not found during review of laboratory records. 5. In an interview on 12/03/19 at 3:00 p.m., the MT confirmed the above findings. NOTE: This is a repeat citation from the previous survey 12/5/17. .</p>
D5609	<p>HISTOPATHOLOGY CFR(s): 493.1273(e)(f)</p>

(e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

. Based on document review and interview with laboratory personnel, the laboratory failed to document all information required for Histopathology quality control records. Findings are as follows: 1. The laboratory performed Mohs Micrographic Surgery under the subspecialty Histopathology as confirmed by the Mohs Technician (MT) during a tour of the laboratory on 12/03/19 at 1:05 p.m. 2. Requirements for documentation of reagent lot numbers and expiration dates on the Receipt Log was established in the CLIA Laboratory Manual; section 1) Quality Control; part d) Reagents. 3. A reagent Receipt Log was found during review of laboratory records. Reagent lot number and expiration dates were not recorded since December, 2017. 4. In an interview on 12/03/19 at 3:20 p.m., the MT confirmed the above findings. NOTE: This is a repeat citation from the previous survey, 12/5/17. .