

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D0682067	<b>(X3) Date Survey Completed</b>  02/10/2021
<b>Name of Provider or Supplier</b>  Pinnacle Dermatology	<b>Street Address, City, State</b>  4040 Medical Park Drive, Odessa, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5433</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(b)(1)</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 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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory policy and procedure, temperature log and interview, the laboratory failed to provide documentation of maintenance performed as defined by the manufacturer and their own policy using the 2 Leica CM1520 Cryostats used to cut frozen sections for Mohs testing. Findings follow. A. Review of the Leica CM1520 Cryostat Instructions for Use, V1.3 - 10 /2012, stated under Chapter 9 Cleaning, Disinfection, Maintenance, 9.3.1 General Maintenance Instructions, "Clean the instrument every day. Weekly: Oil the plastic coupling with a drop of cryostat oil (Type 407); Lubricate the specimen cylinder... Occasionally, or when required: Apply a drop of cryostat oil to the clamping piece on the microtome base plate and the clamping lever Oiling the slot cover... In case of visible pollution (such as dust), clean the air inlet opening of the condenser on the bottom right-hand side of the instrument using a brush, broom or extraction cleaner in the direction of the louvers." B. Review of the laboratory's Quality Control Policies and Documentation stated under Cryostat, "4. Defrost of machine is done every night. 5. Interior is cleaned each day after use using absolute alcohol...The surface is decontaminated [each] day of use using TBQ or equivalent. The microtome/chamber every month using TBQ, or equivalent. 6. Cryostat knives are changed as needed.... 7. Air filter is cleaned as part of the maintenance every 2 months... 9. The fly wheel and</p>

moving components on the cryostat are oiled, as recommended by the manufacturer, daily or when in use." C. Review of the 2021 Cryostat temperature log form stated at the bottom of the form, "4. The machines are wiped out daily with gauze, to collect waste material. Then wiped with gauze containing 100% isopropyl alcohol to disinfect. Wiped again with a dry gauze and ready for the next day. 5. The defrost cycle is done every night at 2300 hours. 6. According to manufacturer's instructions, lab personnel should oil weekly, grease monthly and/or perform necessary maintenance... 8. Disposable blades are used and disposed of properly in a sharp's container. 9. Preventive maintenance and grounding checks are done a documented monthly." D. Surveyor observation on February 10, 2021 at 1025 in the laboratory the air filters on the cryostat were visibly dirty. D. Interview with the histotechnologist on February 10, 2021 at 1015 in the office confirmed they don't have a form to document maintenance like oiled cryostat and will grease when it starts to give her problems. Interview with the histotechnologist on February 10, 2021 at 1025 in the laboratory confirmed she does not clean the air filters.