

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 20D0678000	<b>(X3) Date Survey Completed</b> 06/30/2022
<b>Name of Provider or Supplier</b> Penobscot Valley Dermatology, Pa	<b>Street Address, City, State</b> 381 Main Street, Orono, ME	
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>D5429</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with testing personnel #1 (TP1), the laboratory failed to document maintenance per the manufacturer and the laboratory's quality assurance policy. Findings include: 1. Record review of the cryostat maintenance manual on 6/30/2022 revealed the statement: "Have the instrument inspected by a qualified service engineer authorized by us once a year." 2. Record review of the laboratory's procedure manual on 6/30/2022 revealed the following statements: " The cryostat is checked every 6 months for proper functioning", "Preventative maintenance and grounding checks are done and documented annually", and "Preventative maintenance and grounding checks are done at 6 months." 3. Staff interview with TP1 on 6/30/2022 at 9:30 AM confirmed conflicting procedure manual policies and no documentation of the maintenance as noted above. 4. The laboratory performs 1800 compliance level tests per year.</p>
<b>D6106</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(14)</p> <p>The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with testing personnel #1 (TP1), the laboratory</p>

director failed to document approval of the procedure manual prior to testing patient samples. Findings include: 1. Record review of the laboratory's procedure manual on 6/30/2022 revealed the statement: "The manual must be reviewed / updated annually. The lab director must document and review / updates." 2. Staff interview with TP1 on 6/30/2022 at 9:00 AM confirmed the LD did document approval of the laboratory manual. 3. The laboratory performs 1800 compliance level tests per year under the specialties of Microbiology and Pathology.