

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0969601	(X3) Date Survey Completed 08/19/2021
Name of Provider or Supplier Advanced Dermatology Of Michigan	Street Address, City, State 4170 Cedar Bluff Drive, Petoskey, MI	
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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview, the laboratory failed to follow their procedure for recording the cryostat temperature and/or maintenance each day of use for 22 out of 25 months reviewed. Findings: 1. Procedure "Quality Control Maintenance" states under section "B. Cryostat Temperature" that "1. The temperature of the cryostat must be recorded and initialed each day of use." Under section "C. Cryostat Maintenance Record." the procedure states "1. The cryostat must be cleaned after each use and the initials of the histologist recorded of the appropriate date." 2. Review of the patient log determine patient testing was performed 03/17/2021 and 03/18/2021. 3. Review of the "Cryostat Temperature Log" for March 2021 revealed no temperature documented on 03/17/2021 and 03/18/2021. 4. Review of "Monthly Quality Assurance Checklist" for March 2021 indicated "YES" for "All required temperatures were recorded." 5. No records of cryostat maintenance were found for January - August 2021, February 2020, and April - December 2020 when patient testing was performed. 6. No records of cryostat temperatures were found for August - November 2019 when patient testing was performed. 7. Testing personnel (TP#1) stated during phone interview on August 19, 2021 at approximately 12:55 PM that the cryostat maintenance and temperatures were located in the binder. 8. The records were not found during the survey.</p>