

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0383358	(X3) Date Survey Completed 07/30/2024
Name of Provider or Supplier Dermatology, Pc	Street Address, City, State 6000 University Avenue Suite 450, West Des Moines, IA	
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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on lack of laboratory documentation records from March 2024 and confirmed by laboratory personnel identifier #1 at 10:37 am on 07/30/2024, the laboratory failed to retain daily, weekly, and monthly laboratory records for one out of three months from February 2024- April 2024. The findings include: 1. The laboratory records the following documentation on paper log sheets each month: daily, weekly, monthly, and as needed maintenance records for the Tissue- TEK VIP processor, Tissue- TEK TEC embedder, 2 Leica Autostainers, 2 microtomes, and 3 cryostats; Mohs Hematoxylin & Eosin (H & E) stain quality records; temperature records for the tissue preparation room, 2 waterbaths, 2 slide dryers, an embedding pot, and 3 cryostats; and records of stain changes and/or filtration for the 2 Leica Autostainers. 2. Personnel identifier #1 stated that the paper logs are scanned into electronic files at the end of the month and the paper copies are subsequently destroyed. 3. Review of the laboratory's electronic files did not include those from March 2024. In addition, personnel identifier #1 stated that the laboratory overwrote the March 2024 electronic files with those from February 2024. 4. At the time of the survey, the laboratory did not have additional documentation from March 2024 for the records listed above.</p>
D6128	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)</p> <p>The technical supervisor is responsible for evaluating and documenting the</p>

performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:

Based on review of personnel records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at 9:50 am on 07/30/2024, the technical supervisor failed to assess and document the competency of individuals performing gross examination of tissue specimens at least annually for one out of eight testing personnel (laboratory personnel identifier #1) in 2023.