

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2022434	(X3) Date Survey Completed 11/26/2024
Name of Provider or Supplier Akron Dermatology, Inc	Street Address, City, State 566 White Pond Drive Suite E, Akron, OH	
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 and an interview with the Mohs Histology Technician (MHT), the laboratory failed to follow their "302 MC Scabies and Lice" policy and procedure. This deficient practice had the potential to affect 11 out of 200 patients tested in the subspecialty of Parasitology from 02/21/2024 through 10/28/2024. Findings Include: 1. Review of the policy and procedure titled "302 MC Scabies and Lice" approved and dated by the Laboratory Director on 01/02/2017 found the following statements: "If a positive and a negative control are not available, a second level of sample analysis will be provided by testing daily, the first specimen under each test regiment of Scabies and Lice using single slide reading by two providers." 2. Review of patient test logs titled "106.1 TQM KOH Chart Review & Quality Control" from 02/21/2024 through 10/28/2024 found 11 out of 29 patients tested for parasites were not read by two testing personnel. 3. The inspector requested the daily quality control for the microscopic examination of parasites. The MHT confirmed the laboratory did not conduct quality control each day of patient testing for the microscopic examination of parasites as stated in the policy and procedure and was unable to provide the requested information. The interview occurred on 11/26/2024 at 2:00 PM.</p>