

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0948005	(X3) Date Survey Completed 02/12/2024
Name of Provider or Supplier Southwest Michigan Dermatology	Street Address, City, State 3000 Old Centre Road, Portage, 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:</p> <p>. A. Based on record review and interview with the Mohs Technician, the laboratory failed to establish written procedures for its Scabies preparation testing for 2 (February 2022 to February 2024) of 2 years. Findings include: 1. A review of the laboratory's test menu revealed the laboratory performs Scabies preparation testing. 2. A review of the laboratory's test procedures revealed a lack of procedure to perform Scabies preparation testing. 3. An interview on 2/12/24 at 10:47 am with the Mohs Technician confirmed a procedure was not present. B. Based on observation, record review, and interview with the Mohs Technician, the laboratory failed to follow written procedures for its Tzanck smear preparations for 2 (February 2022 to February 2024) of 2 years. Findings include: 1. The surveyor observed a "Tzanck Fungal Stain" bottle in the cabinet of the laboratory on 2/12/24 at 9:08 am. 2. A review of the laboratory's "Tzanck Prep" test procedure revealed a section stating, "The slide will then be taken to the lab for routine Hematoxylin and Eosin staining, and reviewed by the physician." 3. An interview on 2/12/24 at 10:50 am with the Mohs Technician confirmed the laboratory used the Tzanck Fungal Stain for its Tzanck smears and did not use routine Hematoxylin and Eosin staining according to the procedure.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test</p>

procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

. A. Based on record review and interview with the Mohs Technician, the laboratory failed to include the reportable range for test results for its Potassium Hydroxide (KOH) preparation testing for 2 (February 2022 to February 2024) of 2 years findings include: 1. A review of the laboratory's "KOH Examination" test procedure revealed a lack of reportable range. 2. A review of two patient KOH test reports revealed Patient #11 performed on 10/5/23 had the result of "+/-." 3. An interview on 2/12/24 at 11:11 am with the Mohs Technician confirmed the laboratory had not included the reportable range for test results in its test procedure. B. Based on record review and interview with the Mohs Technician, the laboratory failed to include the step-by-step performance of the procedure, the process for microscopic examination to include the detection of inadequate slides, and the reportable range for test results for its Tzanck smear preparations for 2 (February 2022 to February 2024) of 2 years reviewed. Findings include: 1. A review of the laboratory's "Tzanck Prep" test procedure revealed a lack of the step-by-step performance of the procedure, the process for microscopic examination to include the detection of inadequate slides, and the reportable range for test results. 2. An interview on 2/12/24 at 10:50 am with the Mohs Technician confirmed the laboratory did not include the step-by-step performance of the procedure, the process for microscopic examination to include the detection of inadequate slides, and the reportable range for test results.