

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0915347	(X3) Date Survey Completed 10/22/2024
Name of Provider or Supplier Dermatology Ltd	Street Address, City, State 101 Chesley Dr Ste 100 Georgetown Bldg, Media, PA	
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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test 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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, and interviews with Laboratory Director (CMS 209 LD) and Testing Personnel #11 (CMS 209 TP #11), the laboratory failed to provide a complete procedural manual for quality control for the stain of Histopathology slides performed from 02/27/2023 to the date of survey. 1. On the day of the survey, 10/22/2024, review of the laboratory's Histopathology procedure manuals, the laboratory failed to include the following applicable requirements under 493.1251 (b) for Histopathology slides performed on 2 of 2</p>

microscopes from 02/27/2023 to 10/22/2024: - Control procedures. 2. LD and TP #11 confirmed in interview 10/22/2024 at 1:30 pm that the procedure manual did not contain: - Expected staining characteristics for quality control slides stained with Hemotoxylin and Eoxin. - Positive and negative reactivity control slides for slides stained with Immunohistochemical stains. - Reactions of the control slide for special stains and/or differential stains.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's temperature records, and interview with the laboratory director (LD), the laboratory failed to monitor and document room temperature (RT) and humidity to ensure operating conditions were met to ensure reliable test system operation and test result reporting of histopathology microscopic slide examinations performed from 02/27/2023 to the day of survey. Findings Include:
1. The instruction manual for the Leica DM LB series states for "General Specifications:" - "Ambient temperature: 10 - 36 C - Relative humidity: 0 - 80 % up to 30 C" 2. On the day of the survey, 10/22/2024, the laboratory failed to provide RT and humidity monitoring records to ensure reliable test system operation for 1 of 1 Leica DM LB microscope prior to reporting microscopic histopathology slide examinations from 02/27/2023 to 10/22/2024. 3. The LD confirmed the findings above on 10/22/2024 at 02:00 pm.

D5601

HISTOPATHOLOGY
CFR(s): 493.1273(a)(f)

(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's quality control (QC) staining records, and interview with the laboratory director (LD), the laboratory failed to check for intended staining activity each time of use for immunohistochemical (IHC) and special stains used for microscopic histopathology slide examinations performed from 02/27/2023 to the day of the survey. Findings Include: 1. On the day of the survey, 10/22/2024, review of the laboratory's QC records revealed the laboratory failed to for the

following from 02/27/2023 to 10/22/2024: - Postive and negative reactivity for 143 of 143 IHC stains. - Control slide of known reactivity for 22 of 22 special stains. 2. The LD confirmed the finding above on 10/22/2024 at 02:00 pm.