

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0684091	(X3) Date Survey Completed 03/27/2023
Name of Provider or Supplier Skin Specialists Of The Capital Region Pllc	Street Address, City, State 264 Washington Extension, Suite 201, Albany, NY	
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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of 2-year verification records for the calendar year 2022 and an interview with the clinical manager, the laboratory failed to perform 2-year verification for KOH slides in the calendar year 2022 for the three providers who perform PPMP testing. FINDINGS: 1. The clinical manager confirmed on March 27, 2023, at approximately 2:00 P.M. that the laboratory failed to verify and document the accuracy of interpretation of KOH slides at least twice per year in calendar year 2022. a. Approximately ten patient samples were tested for KOH for the calendar year 2022.</p>
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</p>

(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:

Based on review of the KOH procedure manual, lack of a 2-year verification procedure for the KOH slides, and an interview with the clinical manager, the laboratory failed to establish a written policy to verify the accuracy of the KOH slides at least twice per year. FINDINGS: The clinical manager confirmed on March 27, 2023, at approximately 2:00 P.M. that the laboratory did not establish a written policy for the twice per year verification and remediation of any discrepant results found during the twice-yearly verification of KOH.

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 the lack of room temperature logs, the Microbiologic's reagent manufacturer required room temperatures for both the 10% KOH and Mart-1 pHRP stain in 1/1/2021 for melanoma, and an interview with the clinical manager, the laboratory failed to implement the manufacturer's requirements for storage and testing of the 10% KOH reagent and the manufacturer's requirements for Mart-1 pHRP stain utilized for detection of melanoma and melanocytes in skin. FINDINGS: 1. The Microbiologic's manufacturer required a room temperature of 15 - 30 C or 68 - 72 F for the 10% KOH reagent. 2. No thermometers were present to monitor the room temperatures of the storage areas and testing areas. a. The KOH and mineral oil reagents were stored in a locked cabinet located in the Dermatology office. Also, the microscope utilized for KOH testing is located in an exterior room proximal to the emergency exit. Surveyors observed two 2.5 mL bottles of 10% KOH lot number 224105 and 9F44736 with expiration dates 8/28/2023. 3. The Novodiox manufacturer required storage of reagents at 2 - 8 C or 36 - 46 F. The documented refrigerator temps at 2 - 8 C were reviewed. It was noted that the laboratory did record the room temperatures 21 - 30 C or 70 - 86 F from 1/1/2021 through survey date, when preparing the stain.

D5473

CONTROL PROCEDURES
CFR(s): 493.1256(e)(2)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The

laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the Mohs procedure manual, lack of quality control records, and an interview with the Histotechnologist #2, the three Mohs surgeons evaluated their findings for the H & E, Toluidine Blue stain's quality each day of testing, using the slides from the first case. However, this was not documented from 1/2021 through the survey date. FINDINGS Histotechnologist #2 confirmed on March 27, 2023, at approximately 2:30 P.M. that the three Mohs surgeons evaluated the H & E, Toluidine Blue stain's quality each day of testing, using the slides from the first case. However, the facility did not document their evaluations of the stain's quality from 1/2021 through the survey date. a. It was noted that Histotechnologist #2 stated, "that when the stains and/or reagents are changed or filtered in the stainer, that they are checked for their quality."