

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0673352	(X3) Date Survey Completed 07/16/2024
Name of Provider or Supplier Dermatology Specialists Pa	Street Address, City, State 4527 Jessup Grove Road, Greensboro, NC	
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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on review of 2023 and 2024 API (American Proficiency Institute) proficiency testing records and interview with the Clinical Compliance Coordinator 7/16/24, the laboratory failed to retain all proficiency testing records for 2 of 2 test events for at least two years from the date of the event. Findings: Review of 2023 and 2024 API proficiency testing records revealed the laboratory was enrolled for the 2023 Microbiology 3rd event and for 3 Microbiology events in 2024. The only records available were the graded results from the 2024 Microbiology 1st event. Graded results from the 2023 Microbiology 3rd event were printed by the Clinical Compliance Coordinator during the survey. The laboratory did not have report forms, submitted results confirmations, and signed attestation statements available for either event. During interview at approximately 11:30 a.m., the Clinical Compliance Coordinator stated that the laboratory's results are entered online. She stated they did not realize they needed to maintain copies of signed attestation statements and graded results.</p>

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES

CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies and procedures, review of personnel records, and interview with the Operations Officer 7/16/24, the laboratory failed to follow their established policy for semiannual and annual competency evaluations for 5 of 5 providers who perform patient KOH (potassium hydroxide) preps. Findings: Review of the laboratory's "PROFICIENCY TESTING Competency and CLIA competency assessment" policy revealed "... Evaluation and documenting competency of personnel responsible for testing is required at least semiannually during the first year the individual sees patient specimens. After the first year, competency assessment must be performed at least annually. ... The following procedures are requirements for assessment of competency for all personnel performing laboratory testing. 1. Direct observations of routine patient test performance... 2. Monitoring the recording and reporting test results 3. Review of intermediate test results, and preventive maintenance records 4. Direct observation of performance of instrument maintenance and function checks 5. Assessment of test performance through testing previously testing samples 6. Assessment of problem solving skills. ... Results of each Competency Test will be entered in a log and kept in the laboratory management manual, as part of its permanent records. ..." Review of personnel records revealed no documentation of semiannual or annual competency evaluations for the five providers who perform KOH preps on patients. During interview at approximately 11:05 a.m., the Operations Officer confirmed the laboratory director had not performed and documented competency evaluations for the providers who perform KOH testing.

D5403

PROCEDURE MANUAL

CFR(s): 493.1251(b)

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.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policies and procedures and review of 2023 and 2024 quality control and maintenance records 7/16/24, the laboratory's procedure manual was not complete and current for the testing performed. Findings: 1. Review of the "KOH examination" procedure revealed "... The glass slide is taken directly to the lab read, and reported without an interruption in the chain of possession. All KOH will be logged in the KOH log book with the patient name and the results will be logged after review. All results are then logged and or dictated in the patient chart. ..." The procedure did not include how the slide is "read", the possible results obtained (fungal elements/scabies), and the process for entering results in the electronic medical records system. 2. Review of the 2024 quality control and maintenance records revealed that a new H&E stain protocol was implemented 7/2/24, but the new protocol was not included in the procedure manual. See D6086.

D6086

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(3)(ii)

The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.

This STANDARD is not met as evidenced by:
Based on review of 2023 and 2024 quality control and maintenance records and interview with the Mohs technician on 7/16/24, the laboratory director failed to ensure that verification procedures were performed to determine the quality of a new H&E (Hematoxylin and Eosin) "With Acid Rinse" protocol. Findings: Review of 2023 and 2024 quality control and maintenance records review revealed that a new H&E "With Acid Rinse" stain protocol was placed into operation on 7/2/24. A handwritten notation on the back of the July log stated "July 2nd 2024 New Recipe, the director to approve, then will make protocol." The notation was initialed by the Mohs technician. During interview at approximately 10:30 a.m., the Mohs technician confirmed the handwritten note recorded on the back of the Hematoxylin & Eosin "With Acid Rinse" Quality Control / Maintenance Log. She stated there were no records to document the comparison study between the old and new protocols, including the changes made to the protocol, the number of slides included in the study, the criteria for acceptability, and the results. She verified that the laboratory director had not documented approval of the change in the stain protocol and authorized its implementation prior to use for patient testing.

D6091

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)(iii)

The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.

This STANDARD is not met as evidenced by:
Based on review of 2023 and 2024 API proficiency testing records and interview with the Clinical Compliance Coordinator 7/16/24, the laboratory director failed to ensure all proficiency testing results were reviewed by appropriate staff to evaluate the laboratory's performance and identify any problems requiring corrective action.

Findings: Review of 2023 and 2024 API proficiency testing records revealed the laboratory was enrolled for the 2023 Microbiology 3rd event and for 3 Microbiology events in 2024. The only records available were the graded results from the 2024 Microbiology 1st event which had been initialed by the Mohs technician, but had not been reviewed by the laboratory director. Graded results from the 2023 Microbiology 3rd event were printed by the Clinical Compliance Coordinator during the survey and had not been reviewed by the laboratory director. During interview at approximately 11:30 a.m., the Clinical Compliance Coordinator stated that they did not realize the results needed to be reviewed by the laboratory director.

D6092

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)(iv)

The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:
Based on review of 2023 and 2024 API proficiency testing records and interview with the Clinical Compliance Coordinator 7/16/24, the laboratory director failed to ensure corrective action was taken and documented for all unacceptable proficiency testing results. Findings: Review of 2023 and 2024 API proficiency testing records revealed that on the 2024 1st Microbiology event, the laboratory provided an unacceptable response for sample KOH-02. There was no documentation of corrective action. During interview at approximately 11:30 a.m., the Clinical Compliance Coordinator stated that they did not realize the results needed to be reviewed by the laboratory director.