

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  14D0677225	<b>(X3) Date Survey Completed</b>  12/05/2024
<b>Name of Provider or Supplier</b>  Dermatology Associates Of La Grange	<b>Street Address, City, State</b>  5201 S Willow Springs Rd- Suite 440, La Grange, IL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5217</b>	<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 review of laboratory records, lack of documentation and interview with the practice manager (PM), the laboratory failed to ensure the bi-annual accuracy evaluations of mycology analyte Potassium Hydroxide (KOH) preparations for three of three testing years 2022, 2023, and 2024, affecting 97 KOH patient tests. Findings include: 1. Review of the "Dermatology Associates of LaGrange Chapter 2: Quality Assurance 2.04 Quality Management and Competency Testing Evaluators" policy revealed the following information. "Principle: ...An integral part of these responsibilities is a clear and comprehensive assessment of the competence required to deliver quality services as mandated by CLIA 88 ... General supervisor responsibilities: ...The director or technical supervisor may delegate to the general supervisor the responsibilities for ...D. 2. Proficiency testing ... c. Accurate running and reporting of survey specimens. d. Accurate resulting of samples split for peer performance." 2. Review of laboratory records and lack of documentation revealed the laboratory failed to ensure the bi-annual accuracy evaluations of KOH for three of three testing years 2022, 2023, and 2024. 3. On 12/05/2024, at 12:07 p.m., the PM stated no bi-annual accuracy evaluations of KOH were performed in 2022, 2023, and 2024. 4. Review of laboratory records found 97 KOH patient tests were performed in 2022 through the date of survey, 12/05/2024.</p>
<b>D5219</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or</p>

procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program.

This STANDARD is not met as evidenced by:

Based on review of laboratory records, lack of documentation and interview with the practice manager (PM), the laboratory failed to ensure accuracy evaluations of the parasitology analyte scabies preparations for three of three testing years 2022, 2023, and 2024, affecting 5 scabies patient tests. Findings include: 1. Review of the "Dermatology Associates of LaGrange Chapter 2: Quality Assurance 2.04 Quality Management and Competency Testing Evaluators" policy revealed the following information. "Principle: ...An integral part of these responsibilities is a clear and comprehensive assessment of the competence required to deliver quality services as mandated by CLIA 88 ... General supervisor responsibilities: ...The director or technical supervisor may delegate to the general supervisor the responsibilities for ... D. 2. Proficiency testing ... c. Accurate running and reporting of survey specimens. d. Accurate resulting of samples split for peer performance." 2. Review of laboratory records and lack of documentation revealed the laboratory failed to ensure accuracy evaluations of the parasitology analyte scabies for three of three testing years 2022, 2023, and 2024. 3. On 12/05/2024, at 12:07 p.m., the PM stated no accuracy evaluations of scabies preparations were performed in 2022, 2023, and 2024. 4. Review of laboratory records found five scabies patient tests were performed in 2022 through the date of survey, 12/05/2024.

**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 laboratory records, lack of documentation and interview with the practice manager (PM), the laboratory failed to ensure procedures for two of two microscopic examinations (Potassium Hydroxide (KOH) and scabies preparations) included quality control procedures. Findings include: 1. Review of the "Dermatology Associates of LaGrange 1.08: Potassium Hydroxide (KOH) Examination for Fungi and 1.09: Microscopic Examination for Scabies" procedure manuals failed to outline

control procedures for KOH and scabies preparations. 2. On 12/05/2024, at 2:10 p.m., the PM noted KOH and scabies QC documentation failed to be included in the laboratory's procedure manuals.

**D5485**

**CONTROL PROCEDURES**

CFR(s): 493.1256(h)

If control materials are not available, the laboratory must have an alternative mechanism to detect immediate errors and monitor test system performance over time. The performance of alternative control procedures must be documented.

This STANDARD is not met as evidenced by:

Based on review of laboratory records, lack of documentation and interview with the practice manager (PM), the laboratory failed to establish and document quality control (QC) procedures utilized for patient testing for two of two analytes (mycology analyte Potassium Hydroxide (KOH) preparations and parasitology analyte scabies preparations) in December 2022 through December 2024, affecting 54 KOH and 5 scabies patient tests. Findings include: 1. Review of the "Dermatology Associates of LaGrange 1.08: Potassium Hydroxide (KOH) Examination for Fungi and 1.09: Microscopic Examination for Scabies" procedure manuals and lack of documentation revealed the laboratory failed to include quality control requirements for patient testing for two of two analytes KOH and scabies preparations (refer to D5403). 2. Review of patient test reports, KOH test logs and no documentation revealed the laboratory failed to ensure quality control procedures were performed for three of three KOH patient test reports. a) Date: 12/23/2022 Chart #: 263200 KOH log: No QC documented b) Date: 05/08/2023 Chart #: 93675 KOH log: No QC documented c) Date: 11/15/2024 Chart #: 312951 KOH log: No QC documented 3. Review of the "Dermatology Associates of LaGrange KOH Log" and lack of documentation revealed the laboratory failed to document KOH quality control evaluations for three of three testing years 2022, 2023, and 2024. 4. On 12/05/2024, at 2:10 p.m., the PM noted KOH and scabies QC documentation failed to be provided for surveyor review. 5. Review of laboratory records found 97 KOH patient tests were performed in 2022 through the date of survey, 12/05/2024.

**D6076**

**LABORATORY DIRECTOR**

CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:

Based on review of laboratory records, lack of documentation and interview with the practice manager (PM), the laboratory director (LD) failed to ensure 1 of 11 testing personnel (TP 10) received the appropriate training prior to reporting mycology analyte Potassium Hydroxide (KOH) preparations and parasitology analyte scabies preparations patient test results in 2024 (refer to D6102); the LD failed to ensure 2 of 11 testing personnel (TP 9 and TP 11) received annual competency assessments in 2022, 2023, and 2024 prior to reporting KOH and scabies patient test results in December 2022 through December 2024, affecting 97 KOH and 5 scabies patient tests (refer to D6103).

**D6102**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(12)

The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on review of laboratory records, lack of documentation and interview with the practice manager (PM), the laboratory director failed to ensure 1 of 11 testing personnel (TP 10) received the appropriate training prior to reporting mycology analyte Potassium Hydroxide (KOH) preparations and parasitology analyte scabies preparations patient test results in 2024. Findings include: 1. Review of the "Dermatology Associates of LaGrange Quality Assurance 2.05 Training and Competency Assessment Guideline" revealed the following information. "PRINCIPLE Competency assessment is the initial and periodic evaluation of an employee's knowledge and ability to perform specific procedures ... PROCEDURE 1. Frequency of Evaluation A. Initial training and competency is performed as each task is completed in the first six months of employment ... B. Selected competency is repeated by the first year's end. Evaluations are kept in each employee's HR folder." 2. Review of laboratory records revealed no documentation of initial training and six-month competency evaluation of KOH and scabies patient testing for 1 of 11 TP (TP 10 - start date 03/01/2024). 3. On 12/05/2024, at 2:10 p.m., the PM stated the training and competency records for TP 10 were not provided for surveyor review.

**D6103**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(13)

The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:

Based on review of laboratory records, lack of documentation and interview with the practice manager (PM), the laboratory director failed to ensure 2 of 11 testing personnel (TP 9 and TP 11) received annual competency assessments in 2022, 2023, and 2024 prior to reporting mycology analyte Potassium Hydroxide (KOH) preparations and parasitology analyte scabies preparations patient test results in December 2022 through December 2024, affecting 97 KOH and 5 scabies patient tests. Findings include: 1. Review of the "Dermatology Associates of LaGrange Quality Assurance 2.05 Training and Competency Assessment Guideline" revealed the following information. "PRINCIPLE Competency assessment is the initial and periodic evaluation of an employee's knowledge and ability to perform specific procedures ... PROCEDURE C. Competencies tasks are selected by the Technical Supervisor in conjunction with the Medical Director ...and are performed annually after the initial 6-month. The original is placed in the employee's HR folder." 2.

	<p>Review of laboratory records revealed no documentation of annual competency assessments for 2 of 11 testing personnel (TP 9 - start date 11/01/2018 and TP 11 - start date 07/15/1991) in 2022, 2023, and 2024 prior to reporting mycology analyte KOH and parasitology analyte scabies patient test results in December 2022 through December 2024. 3. On 12/05/2024, at 2:10 p.m., the PM stated the 2022, 2023, and 2024 annual competency records for TP 9 and TP 11 were not provided for surveyor review. 4. Review of laboratory records found 97 KOH and 5 scabies patient tests were performed in 2022 through the date of survey, 12/05/2024.</p>
<p><b>D8100</b></p>	<p><b>INSPECTION REQUIREMENTS</b> CFR(s): 493.1771</p> <p>Each laboratory issued a CLIA certificate must meet the requirements in 493.1773 and the specific requirements for its certificate type, as specified in 493.1775 through 493.1780. All CLIA-exempt laboratories must comply with the inspection requirements in 493.1773 and 493.1780, when applicable.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory records, lack of documentation and interview with the practice manager (PM), the laboratory failed to provide requested documentation of scabies preparations performed in 2022, 2023, and 2024 (refer to D8103).</p>
<p><b>D8103</b></p>	<p><b>BASIC INSPECTION REQUIREMENTS</b> CFR(s): 493.1773(b)(c)(d)</p> <p>(b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation and interview with the practice manager (PM), the laboratory failed to provide requested documentation of scabies preparations performed in 2022, 2023, and 2024. Findings include: 1. On 12/05/2024, at 12:07 p.m., during an interview with the PM a request was made for documentation of scabies preparations performed in 2022, 2023, and 2024. 2. Review of the laboratory records submitted by the PM on 12/05/2024 and lack of documentation revealed the laboratory failed to submit the documentation listed in Finding 1.</p>