

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2109579	(X3) Date Survey Completed 12/05/2025
Name of Provider or Supplier Carlisle Dermatology Group Llc	Street Address, City, State 41 Eastgate Drive, Carlisle, 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
D3009	<p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the Clinical Manager (CM), the laboratory failed to monitor and document room temperature to ensure reagent storage conditions were met for 2 of 2 years when virology, mycology, and chemistry testing was performed from 04/03/2024 to 12/05/2025. Findings include: 1. On the day of the survey, 12/05/2025 at 11:15 am, the laboratory failed to provide documentation for the room temperature readings performed to ensure storage conditions were met for the following reagent kits used for virology, mycology, and chemistry testing for 2 of 2 years from 04/03/2024 to 12/05/2025: - QuickVue SARS Antigen Test reagents (manufacturer storage temperature 15 to 30 Celsius). - Henry Schein One Step+ hCG Urine Strip Test reagents (manufacturer storage temperature 2 to 30 Celsius). - EDM3 Solutions Potassium Hydroxide 20% (manufacturer storage temperature states "room temperature"). 2. The CM confirmed the findings above on 12/5/2025 at 1:22 pm.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Clinical Manager (CM), the laboratory</p>

failed to ensure that 2 of 2 reagents used for Potassium Hydroxide (KOH) microscopic slide examinations were not used beyond the expiration dates from 3/3/2025 to 8/10/2025. Findings include: 1. On the day of the survey, 12/05/2025 at 8:45 am, review of the laboratory's chemical log revealed the following 2 of 2 expired reagents used for Potassium Hydroxide (KOH) microscopic slide examinations from 3/3/2025 to 8/10/2025: - 1 opened bottle of Henry Schein Chlorazol Black E (Lot #2103, expired 4/13/2024). - 1 opened bottle of Henry Schein Potassium Hydroxide (KOH), 20% (Lot #2131, expired 5/11/2024). 2. The laboratory performed 33 KOH microscopic examinations from 3/3/2025 to 8/10/2025 (Patient KOH logs dated 2/3/205 to 8/13/2025). 3. The CM confirmed the findings above on 12/5/2025 at 1:22 pm.

D5431

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(2)

(a)(2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturers established limits before patient testing is conducted. (b) Equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer. The laboratory must do the following:

This STANDARD is not met as evidenced by:
Based on review of the laboratory's Microscope Policy, lack of documentation, and interview with the Clinical Manager (CM), the laboratory failed to follow established policies when preventative maintenance was performed for 2 of 3 microscopes used for Potassium Hydroxide (KOH) and Scabies microscopic slide examinations from 4/03/2024 to the day of survey. Findings Include: 1. The laboratory's Microscopes Policy stated, "5. Document daily, monthly care. 6. Annual preventative maintenance". 2. On the day of survey, 12/05/2025 at 12:02 pm, the laboratory failed to provide maintenance records for the annual preventative maintenance performed for the following 2 of 3 microscopes used for KOH and Scabies microscopic examinations from 4/03/2024 to 12/05/2025: - Omax Digital Compound Binocular LED Microscope (model MD827S30L, S/N G2019042782) - Omax Digital Compound Binocular LED Microscope (model MD827S30L, S/N G2019055298) 3. The laboratory performed 229 KOH and Scabies microscopic slide examinations in 2024 (CSM 116, estimated annual volume, dated 12/05/2025). 4. The CM confirmed the findings above on 12/5/2025 at 1:22 pm.

D5441

CONTROL PROCEDURES
CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance.

This STANDARD is not met as evidenced by:
Based on review of laboratory records, lack of documentation, and interview with the Clinical Manager (CM), the laboratory failed to establish and maintain a quality control (QC) procedure for Potassium Hydroxide (KOH) and Scabies examinations performed for 2 of 2 years from 04/03/2024 to the day of survey. Findings include: 1. The laboratory's KOH Quality Control Procedure stated, "For the first case of the day, scrapings are taken in the room on both the affected and non-affected areas and placed on a glass slide." 2. On day of survey, 12/05/2025 at 11:06 am, review of the laboratory's KOH Quality Control (QC) logs revealed the laboratory failed to document the skin scraping results (affected/non affected areas) used as QC per laboratory policy for the first case of the day when KOH examinations were performed for 2 of 2 years from 04/03/2025 to 12/05/2025. 3. The laboratory failed to provide a QC policy for Scabies examinations performed. 4. The laboratory performed 229 KOH and Scabies microscopic slide examinations in 2024 (CSM 116, estimated annual volume, dated 12/05/2025). 5. The CM confirmed the findings above on 12/5/2025 at 1:22 pm.

D6013

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(3)(ii)

(e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and

This STANDARD is not met as evidenced by:
Based on lack of documentation, review of Peer Review records and interview with the Clinical Manager (CM), the Laboratory Director (LD) failed to ensure procedures were established and maintained for the twice annual verification of accuracy of Potassium Hydroxide (KOH) and Scabies examinations performed for 2 of 2 years from 04/03/2024 to 12/05/2025. Findings Include: 1. The laboratory's KOH Peer Review/Proficiency Testing Procedure stated, "Semi-annually, the tech or Risk Manager will send two cases via electronic imaging containing the original images, label it with only the patient chart number, and send it out for a peer review by a Board Certified Dermatopathologist. Upon receipt of the pathology report from the Dermatopathologist, diagnosis of the specimen image will be matched to the in-house diagnosis by the physician." 2. On the day of the survey, 12/5/2025 at 10:49 am, review of the laboratory's Peer Review records revealed the laboratory failed to ensure two cases were sent to the laboratory's designated Board Certified Dermatopathologists for KOH peer review as per laboratory policy for 2 of 2 years from 04/03/2024 to 12/05/2025. 3. Further review of the laboratory's peer review records revealed the following peer review reports were not reviewed or assessed by the physician upon receipt by the laboratory in 2024: - Scabies peer review reports: 3/7/2024, 3/8/2024, 3/13/2024, 7/12/2024, 7/26/2024, 9/10/2024, 9/13/2024. - KOH peer review reports: 1/23/2024, 1/26/2024, 2/21/2024, 2/27/2024, 6/18/2024, 8/1/2024, 8/16/2024, 8/21/2024. 4. The laboratory failed to provide a procedure for the verification of accuracy for Scabies examinations. 5. The laboratory performed 229 KOH and Scabies microscopic slide examinations in 2024 (CSM 116, estimated annual volume, dated 12/05/2025). 6. The CM confirmed the findings above on 12/5/2025 at 1:22 pm.