

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2076698	(X3) Date Survey Completed 11/13/2025
Name of Provider or Supplier Phoenixville Valley Forge Dermatology Assoc	Street Address, City, State 1260 Valley Forge Road Suite 103, Phoenixville, 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
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:</p> <p>A Based on the review of the laboratory's peer review records, and interview with the Nurse Manager (NM), the laboratory failed to ensure that the verification of accuracy for microscopic examinations for histopathology (Mohs) was performed at least twice annually, as required for tests not included in subpart I for 1 of 1 year in 2024. Findings Include: 1. On the day of the survey, 11/13/2025 at 09:35 am, review of the laboratory's peer review records revealed the laboratory failed to ensure the verification of accuracy for histopathology slide examinations was performed at least twice annually for 1 of 1 year in 2024. 2. The laboratory performed 1,045 microscopic slide examinations (histopathology) in 2024 (CMS-116, estimated annual volume, dated 11/12/2025). 3. The NM confirmed the findings above on 11/13/2025 at 09:40 am</p> <p>B Based on policy review, lack of documentation, and interview with the Nurse Manager (NM), the laboratory failed to ensure that the verification of accuracy for 2 of 3 microbiology microscopic examinations was performed at least twice annually, as required for tests not included in subpart I from 11/07/2023 to date of survey. Findings include: 1. The laboratory's PEER Review/ Proficiency Policy states: Peer review will be performed for Scabies prep and KOH prep every 6 months." 2. On the day of the survey, 11/13/2025 at 9:00 am, the laboratory could not provide documentation that the verification of accuracy for 2 of 3 microbiology microscopic examinations (KOH and Scabies prep) were performed twice annually from 11/07/2023 to date of survey. 3. The laboratory performed 26 microbiology slide examinations in 2024 (CMS 116, estimated annual volume, dated 11/12/2025). 4. The NM confirmed the findings above on 11/13/2025 at 09:15 am.</p>

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(b)

(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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 lack of documentation and interview with the Nurse Manager (NM), the laboratory failed to monitor and document room humidity to ensure operating conditions were met for 1 of 1 Labomed CXL microscope, 1 of 1 Lecia DM 1000 microscope, 1 of 1 Bristoline Brisolscope and 1 of 1 Avantix QS-11 cryostat used to perform histopathology (Mohs) microbiology microscopic slide examinations from 11/07/2023 to 11/13/2025. Findings include: 1. The manufacturers operating environment specifications stated the following: 5-40 degrees Celsius (ambient temperature); maximum 80 % relative humidity. 2. On the day of the survey, 11/13/2025, the laboratory failed to provide documentation for the monitoring of room humidity to ensure operating conditions were met for the following instruments used to perform histopathology (Mohs) and microbiology microscopic examinations (scabies, KOH, dermatophyte screenings) from 11/07/2023 to 11/13/2025: - 1 of 1 Labomed CXL microscope - 1 of 1 Lecia DM 1000 microscope - 1 of 1 Bristoline Brisolscope - 1 of 1 Avantix QS-11 cryostat 3. The laboratory performed 1,045 histopathology (Mohs) slide examinations and 26 microbiology (scabies, KOH dermatophyte screenings) slide examinations in 2024 (CMS 116, estimated annual volume, dated 11/12/2025). 4. The NM confirmed the above findings on 11/13/2025 at 09:30 am.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

(b)(9) Thereafter, evaluations must be performed at least annually

This STANDARD is not met as evidenced by:

Based on review of the laboratory's competency policy, personnel competency records, CLIA laboratory personnel report (CMS 209), and interview with Nursing Manager (NM), the Technical Consultant (TC) (CMS 209 personnel #1) failed to evaluate the annual competency of 2 of 2 testing personnel (TP) who performed microbiology microscopic slide examinations from 11/07/2023 to 11/13/2025. Findings include: 1. The laboratory's Competency/Training Policy stated: "Competency/training will be completed by all test performing personnel prior to performing test for the first time. It will then be completed 6 months later and every year after that." 2. On the day of survey 11/13/2025 at 8:50 am, review of the laboratory's personnel competency records and CMS 209 form revealed the TC failed to evaluate the annual competency of 2 of 2 TP #2 and TP#3 (CMS 209 personnel #2 and #3, dated 11/12/2025) who perform microbiology slide examinations (Scabies and KOH prep) from 11/07/2023 to 11/13/2025. 3. The laboratory performed 26

microbiology slide examinations in 2024 (CMS 116, estimated annual volume, dated 11/12/2025). 4. The NM confirmed the above findings on 11/13/2025 at 9:00 am.