

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0187270	(X3) Date Survey Completed 01/22/2026
Name of Provider or Supplier Dermatology Associates	Street Address, City, State 246 Hanover Street, Gettysburg, 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
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the Laboratory Supervisor (LS), the laboratory failed to perform and document scheduled preventive maintenance as defined by the manufacturer for 1 of 1 Linistain Automatic Slide Stainer used to perform dermatopathology microscopic examinations from 08/12/2024 to 01/22/2026. Findings include: 1. The Linistain Automatic Slide Stainer Owner's Manual, Preventative Maintenance procedure stated, "Periodic Maintenance: This part of the maintenance section contains information that extends the life of the stainer and assures that it is ready for use when needed. Case Cleaning, Internal Cleaning, Cleaning/Disinfecting Staining Jars and Evaporation Covers." 2. On the day of the survey, 01/22/2026 at 10:05 am, the laboratory failed to provide documentation for preventive maintenance (as defined by the manufacturer) performed on 1 of 1 Linistain Automatic Slide Stainer used to stain dermatopathology microscopic examinations from 08/12/2024 to 01/22/2026. 3. The laboratory performed 400 dermatopathology microscopic examinations in 2025 (CMS 116, estimated annual volume, dated 1/22/2026). 4. The LS confirmed the above findings on 01/22/2026 at 12:40 pm.</p>
D6054	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>(b)(9) Thereafter, evaluations must be performed at least annually</p>

This STANDARD is not met as evidenced by:
Based on record review and interview with the Laboratory Supervisor (LS), the Technical Consultant (TC) failed to evaluate the annual competency of 11 of 11 Testing Personnel (TP) that performed mycology and parasitology microscopic examinations in 2024 and 2025. Findings Include: 1. On the day of the survey, 01/22/2026 at 10:05 am, during an interview the LS stated, "the competency assessment forms combined assessments performed at both sites that the LD oversees." 2. Review of the laboratory's personnel competency assessment records revealed the TC failed to evaluate the site-specific annual competency of 11 of 11 TP (CMS 209, TP #3, TP #4, TP #5, TP #6, TP #7, TP #8, TP #9, TP #10, TP #11, TP #12, TP #13, dated 01/22/2026) that performed mycology and parasitology microscopic examinations in 2024 and 2025. 3. The laboratory performed 52 mycology and parasitology microscopic examinations in 2025 (CMS 116, estimated annual volume, dated 1/22/2026). 4. The LS confirmed the above findings on 01/22/2026 at 12:40 pm.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

This STANDARD is not met as evidenced by:
Based on record review and interview with the Laboratory Supervisor (LS), the Laboratory Director (LD) failed to ensure a Quality Assurance (QA) program was established, maintained, and documented to ensure the quality of services provided by the laboratory for 16 of 16 months from 08/12/2024 to 01/22/2026. Findings include: 1. On the day of the survey, 01/22/2026 at 10:05 am, during an interview the LS stated, "Quality Assurance reports were combined for both sites the LD oversees." 2. The laboratory failed to provide site-specific documentation for the QA evaluation performed to assess the laboratory's pre-analytical, analytical, and post-analytical processes for 16 of 16 months from 08/12/2024 to 01/22/2026. 3. The LS confirmed the above findings on 01/22/2026 at 12:40 pm.

D6106

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(14)

(e)(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and

This STANDARD is not met as evidenced by:
Based on review of the laboratory procedure manual and interview with the Laboratory Supervisor (LS), the Laboratory Director (LD) failed to ensure 1 of 1 approved procedure manual was available to laboratory staff for any aspect of mycology, parasitology, and histopathology microscopic examinations performed from 08/12/2024 to 01/22/2026. Findings Include: 1. On the day of the survey, 01/22/2026 at 10:05 am, review of the laboratory procedure manual revealed the cover page stated, "Dermatology Associates of York". 2. During an interview at 10:05 am, the LS stated, "The Procedure Manual is shared between both sites the LD oversees." 3. The laboratory failed to maintain availability to an approved procedure manual for any aspect of mycology, parasitology, and histopathology microscopic examinations

performed from 08/12/2024 to 01/22/2026. 4. The laboratory performed 452 mycology, parasitology and histopathology microscopic examinations in 2025 (CMS 116, estimated annual volume, dated 1/22/2026). 5. The LS confirmed the above findings on 01/22/2026 at 12:40 pm.