

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D0968978	<b>(X3) Date Survey Completed</b>  03/03/2026
<b>Name of Provider or Supplier</b>  Dermatology Associates Of Georgia, Llc	<b>Street Address, City, State</b>  4285 Johns Creek Parkway Suite A, Suwanee, GA	
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>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on WSLH (Wisconsin State Laboratory Of Hygiene) Proficiency Testing records review and staff interview, the laboratory failed to have successful performance in two out of three PT events in 2025. Findings: 1. WSLH (PT) documents review revealed the laboratory scored a 0% in event #1 and 0% in event #3 on Dermatophyte (DTM) screening in the subspecialty of Mycology in 2025. 2.) An interview with the office manager on 03/03/2026 in the breakroom at approximately 12:25 PM confirmed the aforementioned findings on (PT) testing in 2025.</p>
<b>D5221</b>	<b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b>

CFR(s): 493.1236(d)

All proficiency testing evaluation and verification activities must be documented.

This STANDARD is not met as evidenced by:

Based on WSLH (Wisconsin State Laboratory Of Hygiene) PT records review and staff interview, the laboratory failed to document corrective action plan on unsuccessful proficiency testing results on Dermatophyte (DTM) screening in the Subspecialty of Mycology in the laboratory in 2025. Findings: 1. A 2025 review of WSLH (PT) results revealed unsuccessful scores of 0% in events #1 and #3 of 2025 on Dermatophyte (DTM) screening. There were no corrective actions documented by the testing personnel or checked by the laboratory director for the (PT) failures. 4. An interview with the office manager, on 03/03/2026, at approximately 12:27 PM, in the break room confirmed the aforementioned (PT) findings in 2025.

**D6004**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(a)(b)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on WSLH (Wisconsin State Laboratory Of Hygiene) (PT) records review and staff interview, the laboratory director failed to ensure that ALL pre analytic, analytic and post analytic Quality Assurance (QA) guidelines were followed to identify and fix problems in the laboratory in 2025 as required by Clinical Laboratory Improvement Amendments (CLIA). Findings: 1. A review of 2025 WSLH (PT) documents review revealed the lab director failed to identify and perform corrective action on unsuccessful proficiency scores (0%) on events #1 and #3 in the subspecialty of Mycology (DTM) screening in 2025. 2. An interview with the office manager in the break room on 03/03/2026, at approximately 12:30 PM confirmed the lab director failed to ensure proper proficiency testing oversight of the laboratory 2025.