

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0992605	(X3) Date Survey Completed 09/30/2025
Name of Provider or Supplier Southeastern Dermatology Inc	Street Address, City, State 2040 Fleischmann Rd, Tallahassee, FL	
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
D0000	An announced CLIA recertification survey was conducted at Southeastern Dermatology on 09/25/2025 - 09/30/2025. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiencies cited are as follows:
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: Based on record review and interview the Laboratory failed to verify the accuracy of KOH (Potassium Hydroxide) and Scabies testing at least twice a year for 1 (2024) out of 2 years reviewed (2024-2025). Findings Included: 1. Review of the CMS 209 (signed by the Laboratory Director on 09/25/2025) revealed that there were 3 Testing Personnel (TP) who performed KOH and Scabies testing in 2024. 2. Review of peer reviews for 2024 revealed: 2a. TP#A only had 1 KOH and 1 Scabies peer review in 2024. 2b. TP#C only had 1 Scabies peer review in 2024. 3. Interview on 09/25/2025 at 11:00 AM the Lab Supervisor confirmed that there were no other peer reviews for 2024.</p>
D6046	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to--</p>

This STANDARD is not met as evidenced by:
Based on record review and interview, the Technical Consultant failed to perform competency evaluations on 4 out of 4 Testing Personnel who performed moderately complex testing for 2 out of 2 years (2024-2025). Findings Included: 1. Review of the CMS 209 (signed by the Laboratory Director 09/25/2024) revealed 4 Testing Personnel (TP) for moderately complex testing. 2. Review of competency evaluations revealed no competency evaluations for 2 years (2024-2025) for TP#A, TP#B, and TP#C. TP#D did not start until 01/2025 and was missing the 6 month competency evaluation. 3. Interview on 09/25/2025 at 11:00 AM the Lab Supervisor confirmed that there was no competency evaluations for the moderately complex TP.

D6080

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(c)

(c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities.

This STANDARD is not met as evidenced by:
Based on record review and interview, the Laboratory Director failed to develop a policy or provide evidence of the required onsite visits for 3 of 3 month period reviewed (01/2025-09/2025). Findings Included: 1. Review of records revealed no policy regarding the Laboratory Director being onsite every 6 months and no evidence of visits for 01/2025 to 09/2025. 2. Interview on 09/25/2025 at 1:30 PM the Lab Supervisor confirmed that they do not have a policy regarding the mandatory visits or documentation of the visits.