

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0992605	(X3) Date Survey Completed 04/10/2023
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	A recertification survey was conducted on April 10, 2023 at Southeastern Dermatology, Inc., a clinical laboratory. The laboratory was not in compliance with 42 CFR 493, Requirements for Laboratories.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with Testing Person (TP) #B, the laboratory failed to ensure that 1 of 2 Histotechnologists had an annual competency for 2022. This is a repeat deficiency from the survey on June 16, 2021. The findings include: A review of personnel records for TP #B revealed an annual competency for 2021 and 2023 but no competency was found for 2022. An interview with Testing Person #B on April 10, 2023 at 1:00 pm confirmed an annual competency was not performed or documented in 2022 for TP #B.</p>
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 Mycology, Parasitology, and Virology testing at least twice annually for 1 of 2 years</p>

reviewed for 4 of 4 moderate complexity Testing Personnel. (Testing Personnel #D, #E, #F, and #G) The findings include: A review of personnel records found no peer reviews for KOH (Potassium Hydroxide), Scabies, Tzanck tests for 2022. A review of the policy titled, "Quality Assurance Protocol", noted PPM quality assurance is performed semi-annually. An interview with Testing Person #B on April 10, 2023, at 1:00 pm, confirmed Testing Personnel #D, #E, #F, and #G did not verify the accuracy at least twice annually for the tests KOH, Scabies, or Tzanck for 2022.