

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0992605	(X3) Date Survey Completed 06/16/2021
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	Southeastern Dermatology Inc. clinical laboratory is in compliance with the 42 CFR Part 493, Requirements for Laboratories. A CLIA recertification survey was conducted 06/16/2021. 44394 An announced CLIA recertification survey was conducted at Southeastern Dermatology Inc on 6/16/2021. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
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 personnel (TP) A, the laboratory failed to ensure that two (TP F and TP G) of seven (TP A, TP B, TP C, TP D, TP E TP F, and TP G) testing personnel did not complete annual competencies for the year of 2020. Findings included: Record review revealed both TP F and TP G were missing competency for scabies competencies for 2020. Record review of the Monthly Laboratory Quality Assurance Checklist revealed Personnel Policies were all checked off as completed for the months of August 2020 and October 2020. Interview on 6/16/2021 at 1420 with TP A confirmed competencies were not complete or not performed on four of the seven testing personnel.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have</p>

deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview with testing personnel (TP) A, the laboratory failed to ensure that expired reagents were not utilized for testing. The laboratory was utilizing expired KOH (Potassium Hydroxide) for patient testing since July 25, 2020. A total of 464 patients were tested with expired KOH. The findings included: During the tour of the lab on 6/16/2021 at 1600 it was observed that the KOH reagent bottle (lot #1820403) was expired on July 25, 2020. Record review of the Monthly Laboratory Quality Assurance Checklist revealed that "All reagents that exceeded their expiration date were discarded" had been checked with a Y for the months of August 2020, October 2020, January 2021, February 2021, March 2021, April 2021, and May 2021. Review of patient logs revealed 61 patients were tested in August of 2020, 43 patients were tested in September of 2020, 74 patients were tested in October of 2020, 49 patients were tested in November of 2020, 26 patients were tested in December of 2020, 28 patients were tested in January of 2021, 51 patients were tested in February of 2021, 43 patients were tested in March of 2021, 48 patients were tested in April of 2021, 23 patients were tested in May of 2021, and 18 patients were tested through June 16, 2021. During interview on 6/16/2021 at 1600 with TP A, it was confirmed that the KOH reagent bottle was dated to expire July 25, 2020.