

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0691628	(X3) Date Survey Completed 07/20/2022
Name of Provider or Supplier Advanced Dermatology & Cosmetic Surgery	Street Address, City, State 202 Lake Miriam Dr S-1, Lakeland, 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 initial survey was conducted at Advanced Dermatology and Cosmetic Surgery on 07/20/22. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview with the Office Manager, the laboratory failed to have an expiration date on the mineral oil reagent used to perform one of one Scabies test between 11/05/21 and 07/20/22. Findings included: During a tour of the laboratory on 07/20/22 at 10:10 a.m., one bottle of mineral oil reagent used for Scabies testing (subspecialty of Parasitology) with no expiration date was observed. Review of the "KOH" Log and the "Bi-annual KOH and/or Scabies Competency and Proficiency Testing for Laboratory Testing Personnel" revealed that one Scabies test had been performed from 11/05/21 through 07/20/22. On 7/20/22 at 12:05 p.m., the Office Manager confirmed the mineral oil bottle did not have an expiration date.</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</p>

supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview with the Office Manager, the laboratory failed to ensure the Potassium Hydroxide (KOH) reagent used for the subspecialty mycology (Fungi) testing was not expired prior to performing 10 patient tests from 11/05/21 to 07/20/22. Findings Included: A tour of the laboratory on 07/20/22 at 10:10 a.m. revealed a bottle of KOH reagent with an expiration date of 04/09/20. Review of the "KOH" Log and the "Bi-annual KOH and/or Scabies Competency and Proficiency Testing for Laboratory Testing Personnel" revealed that 10 Fungi tests had been performed from 11/05/21 through 07/20/22. On 07/20/22 at 12:05 p.m., the Office Manager stated she was unaware the KOH reagent was expired.