

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0691628	(X3) Date Survey Completed 04/24/2024
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 recertification survey was conducted at Advanced Dermatology & Cosmetic Surgery from 4/16/2024 to 4/24/2024. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D6021	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>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. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to ensure the established quality assessment (QA) program was maintained for one (2023) of two years (2022-2024) reviewed. Findings included: Review of the "Mohs Laboratory Quality Assessment" policy revealed: The Laboratory Director was responsible for compliance with all policies and procedures of the laboratory. The Laboratory Director reviews all quality control (QC) charts and logs on a routine basis. Review of the monthly meeting notes, which included review of QA/QC for 2023, revealed no evidence of review by the Lab Director. On 4/16/2024 at 11:40 AM, the Office Manager confirmed there was no documentation the Laboratory Director reviewed QC for 2023 in accordance with the Mohs Quality Assessment policy.</p>
D6030	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</p>

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. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on record review and interview, the Laboratory Director failed to ensure Testing Personnel (TP) had competency evaluations prior to reporting patient results for 1 (TP #A) of 2 Testing Personnel (TP #A & #B). Findings included: 1. Record review of the policy titled "Job Duties of Laboratories Performing Testing of High to Moderate Complexity" showed the duties of the Laboratory Director included ensuring all personnel have demonstrated they can perform testing reliably prior to testing patients' specimens. 2. Record review of the "Competency Assessment for Testing Personnel" procedure showed competency assessments were to occur at hire, at six months, and then annually. 3. Review of the Form CMS-209, Laboratory Personnel Report, signed by the Laboratory Director on 04/16/2024 revealed the laboratory had 2 TP (#A & #B). 4. Review of competency evaluations revealed only one competency was completed for TP #A. Review of the document for TP #A showed it was an annual competency dated 3/28/24, signed by TP #A on 4/16/24, and no evidence the Laboratory Director had performed this competency. 5. On 4/16/24 at 11:40 AM, the Office Manager confirmed there was no competency evaluations for TP #A signed by the Laboratory Director. The Office Manager was not sure when TP #A started patient testing but thought it was in the middle of 2023.