

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 05D1075041	<b>(X3) Date Survey Completed</b> 11/28/2022
<b>Name of Provider or Supplier</b> Center For Advanced Dermatology, Inc	<b>Street Address, City, State</b> 301 W Huntington Dr Ste 215, Arcadia, CA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5429</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on the laboratory's policies and procedures, lack of documentation, and interview with the laboratory director (LD), it was determined that the laboratory failed to perform and document maintenance and calibration of the microscopes as defined by the manufacturer and with at least the frequency specified by the manufacturer for the laboratory equipment. The findings included: 1. The laboratory's policies and procedures indicated that annual maintenance and calibration according to manufacturer's requirements be performed on the microscopes used in the laboratory (WESCO CX3). 2. The LD confirmed on November 28, 2022 at approximately 10:45 a.m. that the laboratory failed to follow policies and procedures for maintenance and calibration of the microscope for the years 2021 and 2022. 3. According to the annual test volume declared by the laboratory LD the laboratory performs approximately 430 microscopic tests annually.</p>
<b>D5791</b>	<p><b>ANALYTIC SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p>

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's policies and procedures (P&P) and records, and interview with the laboratory director (LD) and the laboratory staff, it was determined that the laboratory failed to follow written P&P to maintain an ongoing quality assessment, and to ensure accuracy, reliability, and timely of the patient test results reports. The findings included: 1. The laboratory failed to follow its quality assessment written P&P stating, " the laboratory will review random patient slides and records to ensure maintenance for accuracy, appropriateness, and confidentiality of testing ". 2. On the day of the survey (11/28/2022) the laboratory staff failed to have any documentation of an ongoing mechanism to monitor, assess, and ensure accuracy, reliability and timely of the patient test result reports for the years 2021 and 2022. 3. The LD and laboratory staff confirmed by interview on November 28, 2022, at approximately 12: 15 pm that the laboratory failed to follow its policies and procedures to maintain an ongoing quality assessment program. 4. Based on laboratory records the laboratory performed and reported approximately 430 diagnostic histopathology tests annually.

**D6082**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(1)

The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's records, failure to follow Quality Assessment policies and procedures, lack of calibration records for the microscope, and interview with the laboratory director and staff on November 28, 2022, it was determined that the laboratory director failed to ensure that several aspects of the analytic phases of laboratory testing were monitored. See D5429 and D579.