

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 05D2057857	<b>(X3) Date Survey Completed</b> 09/27/2023
<b>Name of Provider or Supplier</b> Sansum Clinic - Hitchcock	<b>Street Address, City, State</b> 215 Pesetas Ln, Santa Barbara, 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 review of the laboratory's procedure manual, lack of documentation, the surveyor's observation, and interview with the laboratory's technical consultant (TC); it was determined that the laboratory failed to perform and document maintenance and calibration as defined by the manufacturer and with at least the frequency specified by the manufacturer for the laboratory's small equipment. The findings included: 1. The laboratory's standard operating procedure (SOP) indicated that preventive maintenance and calibration be performed on all equipment and instruments used in the laboratory. 2. The TC confirmed on September 27, 2023, at approximately 12:15 p. m. that the laboratory failed to follow the manufacturer's instructions on preventive maintenance and calibration of small equipment such as thermometers (refrigerator, room temperature) and timers used daily in the laboratory. 3. According to the test volume declared by the laboratory on 9/27/2023 the laboratory performs approximately 2,300 diagnostic tests annually.</p>
<b>D6007</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(1)</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)(1) Ensure that testing systems developed and used for each of the</p>

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 observation, review of the laboratory records, and interview with the technical consultant; it was determined that the laboratory director failed to be responsible for the overall operation, including, but not limited to ensure that testing systems, such preventive maintenance and calibration of thermometers located in the refrigerator where reagents are kept and room temperature as well as timers used for the tests performed in the laboratory, provide quality laboratory services for all aspects of test performance. See D5429.