

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2073229	(X3) Date Survey Completed 11/16/2023
Name of Provider or Supplier Contra Costa Pathology Associates	Street Address, City, State 399 Taylor Blvd Ste 200, Pleasant Hill, CA	
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
D5429	<p>MAINTENANCE AND FUNCTION CHECKS 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 for preventive maintenance, the surveyor's observation during the laboratory tour, and interview with the laboratory director (LD) and testing personnel (TP); 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 Histopathology processing cabinet, conventional thermometers and automated delivering pipettes used in the laboratory. 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 LD and TP confirmed on November 15, 2023, at approximately 12:30 p.m. that the laboratory failed to follow the manufacturer's instructions on preventive maintenance and calibration of the MOPEC Sample processing cabinet for Histopathology samples, conventional thermometers (Example: Cat #89095-676) and automated pipettes. 3. According to the test volume declared by the laboratory on 11/16/2023 the laboratory performs approximately 68,590 diagnostic tests annually.</p>