

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0643758	(X3) Date Survey Completed 11/15/2023
Name of Provider or Supplier Contra Costa County Public Health Lab	Street Address, City, State 2500 Alhambra Ave Rm 209, Martinez, 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
D3003	<p>FACILITIES CFR(s): 493.1101(a)(2)</p> <p>The laboratory must be constructed, arranged, and maintained to ensure contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation during the laboratory tour of the molecular testing lab and interview with the technical supervisor (TS) and testing personnel (TP) on November 15, 2023; it was determined that the laboratory failed to minimize contamination of patient specimens, equipment, and materials used during specimen processing for the real time polymerase chain reaction (RT-PCR) testing. Findings include: 1. During the laboratory tour at approximately 2:00 p.m. the surveyor observed the area assigned for PCR sample processing, addition of template, and sample analysis for RT-PCR test took place in the same area/room. In addition, the addition of the template to the 96 well plate was performed in an opened bench. 2. No documentation of decontamination of sample processing, preparation of master mix, or template addition areas was found. 3. During an interview on November 15, 2023, at approximately 2:30 p.m. the TS and TP confirmed that the molecular testing laboratory failed to minimize contamination of patient specimens, equipment, and desk materials, when processing samples in an opened bench in the same area/room. 4. The laboratory's testing declaration form, signed by the laboratory director on November 13, 2023, stated that the laboratory performs approximately 5,000 molecular testing samples annually.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish</p>

and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:

Based on the lack of documentation, review of testing personnel competency assessment records, and interview with the general supervisor (GS) and technical supervisor (TS) on November 15, 2023, as specified in the personnel requirements in subpart M, it was determined that the laboratory failed to establish and follow written policies and procedures to assess the TS competency for the years 2022 and 2023. Findings include: 1. Based on review of the laboratory's policies and procedure and competency evaluations' records the laboratory failed to follow written policies and procedures for competency assessment of the TS. 2. The laboratory fail to provide documentation of competency assessment for the TS performing sample processing, testing, and reporting at the laboratory for the years 2022 and 2023. 4. This deficient practice was affirmed by interview with the GS on November 15, 2023, at approximately 1:30 p.m.

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

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.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's procedure manual, lack of documentation, the surveyor's observation during the laboratory tour, and interview with the laboratory's technical supervisor (TS) 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 small equipment 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 TS and TP confirmed on November 15, 2023, at approximately 2:15 p.m. that the laboratory failed to follow the manufacturer's instructions on preventive maintenance and calibration of small equipment such as vortexes, spinner, and timers. 3. According to the test volume declared by the laboratory on 11/13/2023 the laboratory performs approximately 126,575 diagnostic 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 for policies and procedures, patients' test results records, preventive maintenance documentation, lack of decontamination

documentation, direct observation by the surveyors during the lab tour, and interviews with the laboratory's general supervisor, technical supervisor, and testing personnel on November 15, 2023; it was determined that the laboratory director failed to ensure that several aspects of the preanalytic, analytic, and postanalytic phases of the laboratory testing were monitored. See D3003, D5209, and D5429.