

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0643967	(X3) Date Survey Completed 03/14/2024
Name of Provider or Supplier Santa Clara County Public Health Department	Street Address, City, State 2220 Moorpark Ave, 2nd Flr, San Jose, 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
D2020	<p>BACTERIOLOGY CFR(s): 493.823(a)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of the College of American Pathologist (CAP) laboratory proficiency testing (PT) results, Casper Report 155, six (6) randomly selected patient records ranging from 01/03/2022 to 03/01/2024, and interviews with the laboratory director (LD) and technical supervisors (TSs); it was determined that the laboratory failed to attain an overall testing event score of at least 80 percent in Bacteriology which is an unsatisfactory performance. The findings included: 1. The laboratory attained a score of 72% for Bacteriology on the analyte "Bacterial Identification" obtaining Unacceptable Grades for samples D-08 and D-10 for the second PT event of 2022 (Q2-2022) 2. The LD and TSs affirmed on 3/14/2024 at approximately 3:25 p.m. that the laboratory received the above unsatisfactory proficiency testing scores. 3. Based on the laboratory's annual testing declaration submitted 3/14/2024 at the time of the survey, the laboratory performed and reported approximately 1,104 bacteriology organisms identifications on patients' samples.</p>
D2056	<p>VIROLOGY CFR(s): 493.831(a)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of the WSLH Proficiency Testing (PT) records and interviews with</p>

the laboratory director (LD) and the technical supervisors (TSs); it was determined that the laboratory failed to attain a score of least 80 percent of acceptable responses for Measles and Mumps (MM) PCR testing. The findings included: 1. Based on review of PT records for the second event of 2023 (Q2-2023), WSLH reported an unsatisfactory score of 66% for MM tests performed as follow: Sample Result Acceptable Score MM-10 Positive Positive Pass MM-11 Negative Positive Fail MM-12 Negative Negative Pass 2. The LD and TSs affirmed that the laboratory received the above unsatisfactory PT score for Q2-2023. 3. Based on the laboratory's testing declaration at the time of the survey on March 14, 2024, the laboratory reported 97 patient samples for Virology including Measles and Mumps tests.

D2077

GENERAL IMMUNOLOGY
CFR(s): 493.837(c)

Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:
Based on review of the proficiency testing (PT) records for the first event of 2023 (Q1-2023), and interviews with the laboratory director (LD) and technical supervisors (TS); it was determined that the laboratory failed to participate a testing event for General Immunology which is unsatisfactory performance and resulted in a score of 0 for the testing event. The findings included: 1. Laboratory proficiency testing records showed the laboratory attained an overall score of 0% for General Immunology testing during Q1-2023 as follow: Oral HIV test = 0.0 % 2. The LD and TS affirmed on March 14, 2024, at approximately 3:25 p.m. the unsatisfactory score of 0% obtained by the laboratory on General Immunology testing for Q1-2023. 3. Based on the annual test volume reported at the time of survey, the laboratory performed and reported approximately 5,236 tests for General Immunology.

D3003

FACILITIES
CFR(s): 493.1101(a)(2)

The laboratory must be constructed, arranged, and maintained to ensure contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized.

This STANDARD is not met as evidenced by:
Based on surveyor observation during the laboratory tour, review of records, and interview with the laboratory director (LD) on March 14, 2024; it was determined that the laboratory failed to perform the decontamination procedure for the cabinet where the master mix used for polymerase chain reaction (PCR) is prepared. Findings include: 1. During the laboratory tour at approximately 4:00 p.m. the surveyors' observed that the cabinet where the master mix is prepared had no log for

decontamination procedure nor was a procedure present at the time of the survey. 2. During an interview on March 14, 2024, at approximately 4:00 p.m., the LD confirmed that the laboratory failed to provide documentation for decontamination of patient specimens, equipment, and desk materials, when processing samples on the bench. 3. The laboratory's testing declaration form, signed by the laboratory director on March 14, 2024, stated that the laboratory performs approximately 20,350 samples annually.

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:
Based on the lack of laboratory written policies and procedures for all the tests performed in the laboratory and interviews with the laboratory director (LD) and technical supervisors (TSs), it was determined that the laboratory failed to have available written procedures at the time of the survey. The findings included: 1. On the day of the survey on March 14, 2024, at approximately 4:45 p.m., the laboratory failed to provide written policies and procedures for all the tests performed in the laboratory including the proficiency testing policy and procedure for non-regulated analytes. 2. For six (6) out of six (6) randomly selected patient test results for tests performed in the lab, no Standard Operating Procedures (SOP) were available at the time of survey that followed the regulated format. 3. The LD and TSs confirmed on 3 /14/2024 at approximately 4:45 p.m. that the laboratory did not have written policies and procedures available for all testing performed.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:
Based on the surveyors' observation during the laboratory tour and interviews with the laboratory director (LD) and technical supervisors (TSs), the laboratory failed to label reagents and solutions for preparation and expiration dates in various sections of the laboratory. The findings included: 1. Based on the surveyor's observation during the laboratory's tour on March 14, 2024, at approximately 3:50 p.m.; no opening, preparation, or expiration date labels were used or documented for the reagents and solutions (ex: saline, lens cleaner, ethanol, methanol, and distilled water). 2. The LD and TSs affirmed in an interview conducted 3/14/2024, at approximately 3:50 p.m. that the reagents and solutions mentioned in statement 1 were not labeled with the opening, preparation, and expiration dates or documented. 3. Based on the laboratory's annual testing declaration submitted at the time of the survey, the laboratory analyzed approximately 20,350 test samples.

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 the surveyor's observation during the tour of the facility and interview with the laboratory director (LD) and technical supervisors (TSs); 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 policies and procedures indicated that annual maintenance and calibration according to manufacturer's requirements be performed on all equipment used in the laboratory (ex: vortex mixer, micro-centrifuge, and thermometers). 2. The LD and TSs confirmed on March 14, 2024, at approximately 4:00 p.m. that the laboratory failed to follow the manufacturer's instructions on preventive maintenance and calibration of small equipment such as vortex mixer, micro-centrifuge, and thermometers. 3. According to the test volume declared by the laboratory on 3/14/2024, the laboratory performs approximately 20,350 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 the surveyor's observation during the laboratory tour, review of records, and interviews with the laboratory director and technical supervisors on March 14, 2024; it was determined that the laboratory director is cited herein due to failure to ensure

that several aspects of the preanalytic, analytic, and postanalytic phases of the laboratory testing were monitored. See D2020, D2056, D2077, D3003, D5403, D5415, and D5429.

D6127

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on the surveyor's review of the laboratory's records for patient documentation, six (6) randomly chosen patient were evaluated and that one (1) out of six (6) records reviewed showed a missing competency record. An interview with laboratory director (LD) and technical supervisors (TS) on 3/14/2024 at approximately 4:45 p.m., it was determined that the staff competency report for 2021 were missing. Findings include:

1. On a laboratory survey conducted on 3/14/2024, one (1) out of six (6) patient records had one personnel missing a competency for 2021.
2. The LD and TS verified that competency is performed annually for personnel employed longer than a year, and every six months for personnel employed less than one year. However, the competency record for the personnel who performed the test had a missing competency record in 2021.