

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0912267	(X3) Date Survey Completed 04/21/2022
Name of Provider or Supplier Northern California Childrens	Street Address, City, State 2825 J Street, Ste 435, Sacramento, 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
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview with testing personnel (TP); it was determined that the laboratory lacked an eye wash station and a evacuation route for the laboratory. The laboratory failed to observe safety procedures to ensure protection from biohazardous materials. The findings included: 1. On the day of the survey April 21, 2022, at approximately 11:15 a.m. the surveyor observed that the laboratory lacked an eye wash station in the area where samples are processed, neither was an evacuation route posted in the laboratory. 2. The TP affirmed the lack of an eye wash station and an evacuation route posted in the laboratory. 3. Based on the laboratory's annual testing volume declaration signed by the laboratory director on 4/11/2022, the laboratory processes and reports approximately 8,628 hematology patients' samples annually.</p>
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures manual and interview with the testing personnel (TP); it was determined that the laboratory failed to update</p>

protocols in place when changes in the practice occurred in the laboratory and the effective date and signature of approval by the laboratory director of such changes. The findings included: 1. On the day of the survey April 21, 2022, at approximately 11:30 a.m. the procedure manual in place had not been approved, signed, and dated by the laboratory director. 2. The TP affirmed on April 21, 2022, that the laboratory failed to update protocols for the current testing performed in the laboratory and that the effective date and the laboratory director's signature were missing. 4. The laboratory's testing declaration form stated that the laboratory processes approximately 8,628 patients test annually.

D5437

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:
Based on the surveyor's observation during the laboratory tour, lack of calibration records, and interview with the testing personnel (TP); it was determined that the laboratory failed to follow the thermometers' instructions on the periodic calibration of all thermometers (refrigerator and room temperature.) used in the laboratory. The findings included: 1. The laboratory used digital thermometers to monitor temperature on various equipment used in the laboratory. 2. The laboratory did not have available calibration documentation or calibration labels on the thermometers used in the laboratory. 3. The TP affirmed on April 21, 2021, at approximately 10:45 a.m. that no calibration had been performed on the thermometers used in the refrigerator for storage of reagents as well as on the thermometer used to record room temperature . 4. According to the testing volume declaration at the time of the survey, the laboratory performed 8,628 tests annually.

D5813

TEST REPORT
CFR(s): 493.1291(g)

The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policy and procedure manual, lack of a policy and a list of critical values for hematology and its reporting procedure, review of five (5) randomly chosen patient sampling test results and interview with the testing personnel (TP); it was determined that the laboratory failed to have and follow a policy for reporting of critical values. The findings included: 1. The laboratory's policy and

procedure manual did not have a critical results notification policy, neither was a list of established critical values for hematology. 2. For two (2) out of five (5) patients results reviewed there was no documentation notes on how critical values were handled and reported by the TP. 3. The TP affirmed on April 21, 2022, at approximately 11:30 a.m. that the laboratory did not have a written policy and procedure on critical values documentation for reporting.

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; lack of calibration documentation, lack of critical values list and reporting policy, and interview with the testing personnel on April 21, 2022; it was determined that the laboratory director failed to ensure that several aspects of the preanalytic, analytic, and postanalytic phases of laboratory testing were monitored. See D5813, D5407, and D5437.

D6084

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(2)

The laboratory director must ensure that the physical plant and environmental conditions provide a safe environment in which employees are protected from physical, chemical, and biological hazards.

This STANDARD is not met as evidenced by:
Based on the survey findings and deficiencies cited, the laboratory director is herein cited for deficient practice in providing overall administration of the laboratory to ensure a safe environment in which personnel are protected from biohazardous materials. Findings include: See D3011.