Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 05D0589686	**(X3) Date Survey Completed** 05/07/2024
Name of Provider or Supplier Fresno County Public Health Laboratory	**Street Address, City, State** 4525 E Hamilton Ave, 2nd Fl, Fresno, 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**
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures manual and interview with the technical supervisor (TS); it was determined that the laboratory failed to provide a protocol in place signed and dated by the laboratory director when reporting SARS-CoV-2 positive results to CALRedie. The findings included: 1. On the day of the survey May 7, 2024, at approximately 11:00 a.m. the policies and procedure manual in place did not include a reporting policy signed and dated by the laboratory director for the reporting of positive SARS-CoV-2 tests to CALRedie. 2. The TS affirmed on May 7, 2024; that the laboratory failed to have a policy in place indicating a step by step protocol for the current reporting practice of laboratory positive SARS-CoV-2 testing to CALRedie. 4. The laboratory's testing declaration form stated that the laboratory processes approximately 2,525 Virology samples including SARS-CoV-2 test annually.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

	This STANDARD is not met as evidenced by: Based on the incomplete laboratory's verification of performance characteristics for high complexity testing for Clostridium difficile and carbapenem-resistant Enterobacterales (CRE) by Rapid PCR Diagnostic Testing using the |Cepheid GeneXpert instrument, interview with the laboratory's technical supervisor (TS), and review of five (5) randomly selected patient test records from 12/26/2022 to 03/16/2024; the laboratory failed to demonstrate that it established performance specifications comparable to those established by the manufacturer. The findings included: 1. The laboratory had only partial documentation to show for performance specifications, lacking precision testing performance characteristic and documentation. The laboratory must be able to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics and those to be approved by the laboratory director before starting testing patients' samples: (A) Accuracy (B) Precision (C) Reportable range (D) Reference Range 2. The laboratory was unable to provide for review additional documents using patient samples to establish precision performance specification for Clostridium difficile and CRE testing by Rapid PCR using the |Cepheid GeneXpert instrument. 3. The TS affirmed at the time of the survey on 05/07/2024 at approximately 11:30 a.m. that no additional documents could be retrieved to show that precision performance specification was performed prior to reporting patient test results when the laboratory went live testing and reporting Clostridium difficile and CRE diagnostic tests. 4. Based on the estimated annual tests volumes reported on 05/06/2024 signed by the laboratory director; the laboratory performed and reported approximately 11 Bacteriology test which include Clostridium difficile and CRE diagnostic tests. The precision of the reported tests results could not be assured.
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 review of the laboratory's records, policies and procedures, patients' test results records, verification of performance specifications documentation, and interviews with the laboratory's technical supervisor on May 7, 2024; it was determined that the laboratory director failed to ensure that several aspects of the analytic phase of the laboratory testing were monitored. See D5407 and D5421.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.

	This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's policies & procedures, performance specifications verification records, and interview with the laboratory's technical supervisor on May 7, 2024, at approximately 11:30 a.m.; the laboratory director failed to perform verification of precision performance characteristic for the detection of Clostridium difficile and carbapenem-resistant Enterobacterales (CRE) by Rapid PCR Diagnostic Testing using the |Cepheid GeneXpert instrument. Findings include See D5421.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: The laboratory director is cited herein for failing to ensure all proficiency testing (PT) reports received identify any problems that require corrective action, such as review of quality control, calibration, and preventive maintenance records on the day the testing was performed. Findings include: 1. The laboratory received a score of 83% in bacteriology proficiency testing by the College of American Pathologists (CAP) for the second event in 2022 (Q2-2022). 2. No corrective action documentation to identify any problems on the unsatisfactory analyte CAP report was found at the time of the survey on May 7, 2024, for (Q2-2022) bacteriology PT report. 3. The technical supervisor confirmed the lack of corrective action documentation for CAP (Q2-2022) CAP bacteriology PT report.