Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0676808	05/15/2025
Name of Provider or Supplier	**Street Address, City, State**	
Providence Medical Foundation	500 Doyle Park Dr Ste 100, Santa Rosa, 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	BACTERIOLOGY CFR(s): 493.823(a) 493.823(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on the surveyor's review of the College of American Pathologists (CAP) proficiency testing (PT) records, CASPER Report 155, and interviews with the lead nurse (LN) and medical assistant (MA); it was determined that the laboratory failed to attain an overall testing event score of at least 80 percent in Bacteriology for the first event of 2023 (Q1-2023). The findings include: 1. The laboratory was enrolled under CAP PT program and obtained an unsatisfactory score of 20% for the throat culture test in Bacteriology in the Q1-2023 event. The report as follows: Specimen Laboratory CAP TC-01 Negative Negative TC-02 *Negative Positive TC-03 *Negative Positive TC-04 *Negative Positive TC-05 *Negative Positive Legend: * = unsatisfactory result 2. The LN and MA affirmed by interviews on May 15, 2025, at approximately 10:40 a.m., that the laboratory obtained the unsatisfactory score due to results mentioned in statement #1. 3. According to the laboratory's testing declaration submitted at the time of the survey, the laboratory tested and reported approximately 125 patient tests annually for Bacteriology during the time the unsatisfactory score was obtained. Therefore, the reliability and quality of results reported cannot be assured.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish 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 review of the laboratory's quality assessment (QA) policies and procedures, lack of personnel competency documentation, five (5) patient records, and interviews with the lead nurse (LN) and medical assistant (MA); as specified in the personnel requirements in subpart M, it was determined that the laboratory failed to perform competency assessments for laboratory personnel (LP) for the years 2022 and 2024. The findings include: 1. Documentation related to the QA policy and procedure for competency assessment indicated that annual competency evaluations are conducted for laboratory personnel. However, two LP were identified as lacking competency documentation for 2022 and 2024. 2. Surveyor's review of five randomly selected patient records dated from November 9, 2022, to August 8, 2024, revealed that two records were handled by personnel without documented competency assessments. One record was processed on November 9, 2022, by LP #1, and another on August 5, 2024, by LP #2. Thus, the reliability and accuracy of patient results reported cannot be assured. 3. The LN and MA affirmed by interviews on May 15, 2025, at approximately 11:30 a.m., that LP#1 missed the competency assessment for 2022, whereas, LP#2 missed for 2024. 4. According to the laboratory's annual testing declaration submitted at the time of the survey, the laboratory reported and performed approximately 125 tests for Bacteriology for which competency assessments of both laboratory personnel were not performed.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) (b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on the surveyor's observations during the laboratory tour, review of preventive maintenance (PM) log, service reports, and interviews with the lead nurse (LN) and medical assistant; it was determined that the laboratory failed to perform function check on instruments used for patient testing and maintain records. The findings include: 1. During the laboratory tour, it was observed that eight (8) timers used for patient testing had no calibration records for the years 2022, 2023, and 2024. 2. Review of service report for the incubator was only retrieved for 2022. No other documentation or record was available to indicate PM was performed for the years 2023 and 2024. 3. The LN and MA affirmed by interviews on May 15, 2025, at approximately 12:15 p.m. that none of the 8 timers had ever been calibrated. The LN also added that records are maintained by the BioMed Engineering department and could only provide the service record for 2022, as referenced in statement #2. Therefore, the accuracy and reliability of patient results reported cannot be assured. 4. The testing declaration form submitted at the time of the survey indicated that the laboratory performed and reported 125 Bacteriology test samples annually when instruments used were not calibrated, and service records were not maintained.
D5477	CONTROL PROCEDURES

	CFR(s): 493.1256(e)(4)(g) (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. This STANDARD is not met as evidenced by: Based on the lack of quality control (QC) documentation, review of five patient records, observation of culture media used in the laboratory and an interview with the medical assitant (MA); it was determined that the laboratory failed to perform and document QC testing on the culture media used for patient testing. The findings include: 1. There were no records demonstrating that any culture media received in the laboratory were assessed for sterility, physical characteristics when compromised, or that any deterioration of the media was reported to the manufacturers prior to testing. 2. The laboratory's practice was to test for each different lot number received at the laboratory for a positive and negative control and overlooked the expiration dates resulting in inconsistencies for matching records during the review process. 3. Surveyor's review of 5 randomly selected patient results showed inconsistencies to QC documentation as follows: Test Date Lot Expiration reviewed number date 11-9-2022 512687 11-27-2022 03-29-2023 *518025 02-20-2023 10-28-2023 *607530P 10-25-2023 01-29-2024 619350 04-04-2024 08-08-2024 *619350 04-04-2024 Legend: * = lot number interpreted to had been used for patient testing. 4. The MA affirmed by interview on May 15, 2025, at approximately 11:30 a.m., that the maintained records could have been misinterpreted as the lot numbers utilized for testing.The MA also added that other QC checks were performed for other shipments and possibly other lot numbers but were not documented properly. 5. The laboratory's annual testing declaration form submitted at the time of the survey stated that the laboratory processed and reported 125 Bacteriology tests which results cannot be assured due to lack of QC documentation.
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) (e) The laboratory director must-- (e)(1) 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 deficiencies given, the laboratory director is herein cited for deficient practice in ensuring that systems for the preanalytic, analytic, and postanalytic phases of the laboratory were monitored and followed. Findings include: 1. The laboratory received an unsatisfactory performance score for Bacteriology. See D2020. 2. Competency assessments were missed to be performed. See D5209. 3. Missing maintenance and function check documentation. See D5435.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)

	(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on the surveyor's findings on May 15, 2025, and interviews with the lead nurse and medical assistant, the laboratory director is herein cited for the deficient practice of failure to ensure quality control programs were followed to assure and monitor the quality of laboratory services provided, and to identify issues as it occurred. See D5477.