Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0696505	09/03/2025
Name of Provider or Supplier	**Street Address, City, State**	
Mayers Memorial District Hospital	43563 State Hwy 299 East, Fall River Mills, 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
D2025	BACTERIOLOGY CFR(s): 493.823(c) (c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on the surveyor's review of the American Proficiency Institute (API) proficiency testing (PT) records for Bacteriology in the first event of 2025 (Q1-2025) and an interview with the laboratory manager (LM); it was determined that the laboratory failed to return the PT results to the proficiency testing program within the time frame specified. The findings include: 1. The laboratory obtained an unsatisfactory score of zero percent for the Q1-2025 event upon failure to submit the PT results within the time frame specified. No corrective action report was available for review at the time of the survey. 2. The LM affirmed by interview on September 3, 2025, at approximately 1:30 p.m. that the laboratory received the unsatisfactory score as mentioned in statement #1. 3. According to the testing declaration submitted at the time of the survey, the laboratory performed and reported approximately 3,113 tests for Bacteriology annually, including the time when the unsatisfactory score was obtained.
D2061	VIROLOGY CFR(s): 493.831(c) (c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records, corrective action documentation, and an interview with the laboratory manager (LM); it was determined that the laboratory failed to report results within the specified time frame constituting unsatisfactory performance and a score of 0%. The findings include: 1. API reported a 0% unsatisfactory score for the subspecialty of Virology during the first event of 2025 (Q1-2025). 2. Review of PT documentation revealed that no corrective action was available for review at the time of survey. Thus, the quality and reliability of patient test results reported cannot be assured. 3. The LM affirmed by interview on September 3, 2025, at approximately 1: 30 p.m. that the laboratory received the unsatisfactory score last Q1-2025 as mentioned above. 4. The laboratory's testing declaration showed that 2,127 patient test samples were performed and reported annually including the time when the laboratory received an unsatisfactory score.
D2066	SYPHILIS SEROLOGY CFR(s): 493.835(a) (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 laboratory's policy and procedure, American Proficiency Institute (API) proficiency testing (PT) records, and an interview with the laboratory manager (LM); it was determined that the laboratory failed to attain at least 80 percent of the acceptable score in the subspecialty of Syphilis Serology for the second event of 2023 (Q2-2023). The findings include: 1. The surveyor reviewed the PT records wherein API reported an unsatisfactory score of 0% for the Syphilis antibody (Ab) screen test for Q2-2023). The results were as follows: a. Syphilis Ab screen PT analyte in Q2-2023 Sample Reported Expected SYP-06 *Non-reactive Reactive SYP-07 *Non-reactive Reactive SYP-08 *Non-reactive Reactive SYP-09 *Reactive Non-reactive SYP-10 *Reactive Non-reactive Legend: * = unsatisfactory score reported 2. The LM affirmed by an interview on September 3, 2025, at approximately 1:00 p.m. that the laboratory obtained the unsatisfactory PT scores for Q2-2023 as mentioned in statement #1. 3. According to the laboratory's testing declaration submitted on the day of the survey, the laboratory performed approximately 64 patient test samples for Syphylis Ab screen annually including the time the laboratory received unsatisfactory proficiency testing scores. Thus, the accuracy and reliability of patient test reported cannot be determined.
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a) (a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's policy and procedure, American Proficiency Institute (API) proficiency testing (PT) records, and an interview with the laboratory manager (LM), it was determined that the laboratory failed to attain at least

	80 percent of the acceptable score in Routine Chemistry for the Sodium (Na), Total Iron Binding Capacity (TIBC), and Total Bilirubin (TBil) analytes. The findings include: 1. The surveyor reviewed the PT records wherein API reported unsatisfactory scores for Na, TIBC, and TBil analytes. The results were as follows: a. Na PT analyte in first event of 2023 (Q1-2023), Overall score: 60% Specimen Reported Expected CH-01 125 124 - 133 CH-02 124 123 - 132 CH-03 *160 161 - 170 CH-04 134 134 - 143 CH-05 *149 150 - 159 b. TIBC PT analyte in first event of 2023 (Q1-2023), Overall score: 60% Specimen Reported Expected CH-01 *431 552 - 610 CH-02 57 38 - 75 CH-03 *121 296 - 339 CH-04 135 114 - 154 CH-05 223 217 - 260 c. TBil PT analyte in the third event of 2023 (Q3-2023), Overall score: 20% Specimen Reported Expected CH-11 *3.2 3.4 - 5.2 CH-12 0.9 0.7 - 1.6 CH-13 *2.6 2.8 - 4.2 CH-14 *2.1 2.2 - 3.4 CH-15 *1.6 1.7 - 2.7 Legend: * = unsatisfactory score reported 2. The LM affirmed by an interview on September 3, 2025, at approximately 1:00 p.m. that the laboratory obtained the unsatisfactory PT scores mentioned in statement #1. 3. According to the laboratory's testing declaration form (Lab-144) submitted on the day of the survey, the laboratory annually performed approximately 99,134 patient test samples for Routine Chemistry including the Na, TIBC, and TBil analytes including the time the laboratory received unsatisfactory proficiency testing scores. Thus, the accuracy and reliability of patient test reported cannot be determined.
D2098	ENDOCRINOLOGY CFR(s): 493.843(a) (a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on the surveyor's review of the American Proficiency Institute (API) proficiency testing (PT) records, PT documentation, and an interview with the laboratory manager (LM), it was determined that the laboratory failed to attain at least 80 percent of the acceptable score in Endocrinology for the Human chorionic gonadotropin (hCG) analyte. The findings include: 1. The surveyor reviewed the PT records wherein API reported an unsatisfactory score for Endocrinology. The results were as follows: a. hCG PT analyte in second event of 2023 (Q2-2023), Overall score: 60% Specimen Reported Expected HCG-01 3504.0 2674.9 - 4327.4 HCG-02 1.0 0.0 - 10.0 HCG-03 1155.0 829.2 - 1566.8 HCG-04 *1.0 144.3 - 183.7 HCG-05 *162.0 0.0 - 10.1 Legend: * = unsatisfactory score reported 2. The LM affirmed by an interview on September 3, 2025, at approximately 1:30 p.m. that the laboratory obtained the unsatisfactory PT scores for hCG in the Q2-2023 event as mentioned in statement #1. 3. According to the laboratory's testing declaration, the laboratory performed and reported approximately 67 patient test samples for hCG annually including the time the laboratory received unsatisfactory proficiency testing scores. Thus, the accuracy and reliability of patient test reported cannot be determined.
D2164	UNEXPECTED ANTIBODY DETECTION CFR(s): 493.861(a) (a) Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance.

	This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's policy and procedure, American Proficiency Institute (API) proficiency testing (PT) records, and an interview with the laboratory manager (LM); it was determined that the laboratory failed to attain at least 100 percent of the acceptable score in the Immunohematology specialty. The findings include: 1. The laboratory utilized the tube method for Antibody (Ab) screen test and obtained an unsatisfactory score for the third event of 2023 (Q3-2023). The results are as follows: a. Ab screen PT analyte in Q3-2023, Overall score: 80% Specimen Reported Expected SER-11 NUE NUE SER-12 UAD UAD SER-13 *NUE UAD SER-14 NUE NUE SER-15 NUE NUE b. Ab screen test in Q1-2025, Overall score: 40% Sample Reported Expected SER-01 NUA NUA SER-02 *UAD NUA SER-03 UAD UAD SER-04 *UAD NUA SER-05 *NUA UAD Legend: * = unsatisfactory score reported NUE = No Unexpected Antibodies UAD = Unexpected Antibody Detected 2. The LM affirmed by an interview on September 3, 2025, at approximately 1:30 p.m. that the laboratory obtained the unsatisfactory PT scores for Immunohematology specialty as mentioned in statement #1. 3. According to the laboratory's testing declaration submitted on the day of the survey, the laboratory performed approximately 79 patient test samples for the Ab screen test including the time when the laboratory received unsatisfactory proficiency testing scores. Thus, the accuracy and reliability of patient test reported cannot be determined.
D3005	FACILITIES CFR(s): 493.1101(a)(3) (a)(3) Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation. This STANDARD is not met as evidenced by: Based on direct observation of the facilities' layout, observation of the of the laboratory's Polymerase Chain Reaction (PCR) testing workflow for BioFire, and an interview with the laboratory manager (LM) on September 3, 2025; it was determined that the laboratory failed to ensure that the PCR procedures which are not contained in closed systems have a unidirectional flow with separate areas for specimen preparation, master mix and reagent preparation. The findings include: 1. The laboratory performed PCR testing for the subspecialty of Virology, including but not limited to gastrointestinal and respiratory test panel. 2. Observations during the tour revealed that the laboratory had one biosafety cabinet in the microbiology section wherein specimen preparation, processing, and the master mix and reagent preparation were performed in the same area. 3. The LM affirmed by interview on September 3, 2025, at approximately 3:45p.m. that all steps performed prior to patient testing used the same area. 4. According to the testing declaration submitted at the time of the survey, the laboratory performed and reported approximately 2,127 patient samples annually wherein no unidirectional flow or separate areas for PCR testing were followed.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (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 the interview with the laboratory manager (LM), review of the laboratory's policies and procedures, and document control on September 3, 2025; it was determined that the laboratory failed to have all established policies and procedures approved, signed, and dated by the current laboratory director. The findings include: 1. The surveyor's review of the document control pages showed that policies and procedures created by the laboratory manager were not approved, signed, nor dated by the current laboratory director. 2. On September 3, 2025, at approximately 10:30 a.m., the LM affirmed by interview that the policies and procedures for the laboratory operations and testing were not approved, signed, and dated by the current laboratory director. Laboratory documentation control indicated that procedures had been approved by the director of clinical services who is not qualified under 493.1443 regulation. 3. The testing declaration form submitted at the time of survey showed that the laboratory performed and reported approximately 168,092 patient samples for Microbiology, Diagnostic Immunology, Chemistry, Hematology, and Immunohematology specialties including the time when policies and procedures were not approved, signed, and dated by the current laboratory director.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(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 surveyor's review of the laboratory's policies and procedures, patient test records, proficiency testing (PT) documentation, and an interview with the laboratory manager; it was determined that the laboratory director is herein cited for failure to provide oversight and management of the laboratory. The findings include: 1. PT unsatisfactory score for Syphilis Serology. See D2066 2. PT unsatisfactory score for Chemistry. See D2087 3. PT unsatisfactory score for Endocrinology. See 2098 4. PT unsatisfactory score for Unexpected Antibody Detection. See D2164 5. No unidirectional flow. See D3005 6. Procedure manual not approved. See D5407
D6090	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(ii) (e)(4)(ii) The results are returned within the timeframes established by the proficiency testing program; This STANDARD is not met as evidenced by: Based on the survey findings, the laboratory director (LD) is herein cited for the deficient practice in providing overall administration to ensure proficiency testing results are returned within the timeframes established by the proficiency testing program. The findings include: 1. PT unsatisfactory score for Bacteriology. See 2025 2. PT unsatisfactory score for Virology. See D2061