

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0696505	(X3) Date Survey Completed 04/06/2021
Name of Provider or Supplier Mayers Memorial District Hospital	Street Address, City, State 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
D2094	<p>ROUTINE CHEMISTRY CFR(s): 493.841(e)</p> <p>(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy and procedure, proficiency testing (PT) performance review and corrective actions records for the years of 2019, 2020 and 2021, and interview with the laboratory technical consultant (TC) on April 6, 2021 at 12:27 pm, the laboratory failed to undertake any remedial actions for unacceptable analyte score for 4 analytes out of 30 analytes, reviewed. The findings include: 1. The laboratory participated in the API PT program at the 1st event of 2021, and obtained an unacceptable analyte score for direct bilirubin, creatine kinase, measured TIBC and hemoglobin. However, it did not take any remedial action for the unacceptable analyte scores. Hence the quality of the patient test results could not be assured. 2. The laboratory TC on April 6, 2021 at 12:27 pm, affirmed that the laboratory did not take any remedial actions for the unacceptable analyte scores, received. 3. The laboratory's testing declaration form, signed by the laboratory Director on 4/16/2021, stated that the laboratory performs 36,000 tests in routine chemistry, annually.</p>
D5537	<p>ROUTINE CHEMISTRY CFR(s): 493.1267(b)(d)</p>

For blood gas analyses, the laboratory must perform the following: (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. (d) Document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's policy & procedure, random patient sample & quality control (QC) records, and interview with the laboratory technical consultant on April 6, 2021 at 3:27 pm, the laboratory failed to provide documentation of QC records for last 2 years. The findings include: 1. The laboratory uses iSTAT handheld instrument to test blood gases. The instrument requires to have an electronic simulator control to check the system, every day. Moreover, it requires to have an external liquid control every 8 hours that include a combination of low and high values on each day of testing. However, the laboratory never tested any liquid control on the instrument. Therefore, the accuracy of the laboratory's rendered patient test result using this instrument could not be assured. 2. The laboratory technical consultant on April 6, 2021 at 3:27 pm, affirmed that the laboratory did not use any liquid control material to test on the iSTAT instrument. 3. The laboratory's testing declaration form, signed by the laboratory Director on 4/16/2021, stated that the laboratory performs 213 tests in blood gases, annually.

D6079

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(a)(b)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's policy & procedure, random patient sample, quality control (QC) and proficiency testing records, and interview with the laboratory technical consultant on April 6, 2021 at 3:27 pm, the laboratory director failed to assure laboratory's compliance with the applicable regulations. The findings include: See D2094, D5537, D6092 and D6093.

D6092

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(4)(iv)

The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's policy and procedure, proficiency testing

(PT) records for the years of 2019, 2020 and 2021, and interview with the laboratory technical consultant on April 6, 2021 at 12:27 pm, it was determined that the laboratory director failed to ensure that an approved corrective action plan is followed when an unacceptable PT results were received. The findings include: See D2094.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control 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 Surveyor review of laboratory's policy & procedure, random patient sample & quality control (QC) records, and interview with the laboratory technical consultant on April 6, 2021 at 3:27 pm, it was determined that the laboratory director failed to ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur in blood gas analysis. The findings include: See D5537.