

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0666786	(X3) Date Survey Completed 06/02/2021
Name of Provider or Supplier Regional Medical Center	Street Address, City, State 709 West Main Street, Manchester, IA	
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
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Ortho Vitros chemistry calibration verification records and confirmed by laboratory personnel identifiers #10 and #20 (refer to Laboratory Personnel Report) at approximately 1:00 pm on 06/02/2021, the laboratory failed to perform calibration verification every six months for two out of two time periods for the analyte, vitamin B12. The findings include: 1. The laboratory installed the Ortho Vitros 7600 chemistry analyzer in March 2020. 2. At the time of the survey, the</p>

laboratory did not have calibration verification records for the analyte, vitamin B12. 3. The laboratory personnel confirmed that the laboratory failed to perform calibration verification for the analyte, vitamin B12, from the time of installation through the survey date.

D5775

COMPARISON OF TEST RESULTS

CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:

(A) Based on review of i-STAT and Ortho Vitros chemistry analyzers comparison records, observations made during the survey and interviews with laboratory personnel identifiers #10 and #20 (refer to Laboratory Personnel Report) at approximately 9:30 am and 4:00 pm on 06/02/2021, the laboratory failed to perform comparisons between the chemistry tests performed on both the Ortho Vitros and i-STAT analyzers twice annually for two out of two semiannual time periods (May 2020 - May 2021). The findings include: 1. A tour of the laboratory at 9:30 am indicated that the laboratory performed chemistry testing on the Ortho Vitros 7600 analyzer and i-STAT analyzer. 2. Laboratory personnel identifiers #10 and #20 confirmed that the laboratory performed the majority of the chemistry testing using the Ortho Vitros. They also confirmed that the laboratory used the i-STAT analyzer for backup for the following analytes: troponin, glucose, urea nitrogen, calcium, potassium, sodium, chloride and CO2. 3. At the time of the survey, the laboratory did not have documentation of comparisons performed between the Ortho Vitros and i-STAT analyzers. (B) Based on review of immunohematology records, observations made during the survey, and interviews with the laboratory personnel identifiers #10 and #20 (refer to Laboratory Personnel Report) at approximately 9:30 am and 4:00 pm on 06/02/2021, the laboratory failed to perform comparisons between the automated Ortho Vision, Ortho MTS gel card system and manual tube method for immunohematology testing twice annually for two out of two semiannual time periods (May 2020 - May 2021). The findings include: 1. A tour of the laboratory at 09:30 am indicated that the laboratory performed immunohematology testing using the automated Ortho Vision analyzer, Ortho MTS gel card manual tube methods. 2. Laboratory personnel identifiers #10 and #20 confirmed that the laboratory performed immunohematology testing using all three methods for ABO and Rh typing, antibody screens and compatibility testing. 3. At the time of the survey, the laboratory did not have documentation of comparisons performed between the three immunohematology methods.