

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  16D0385424	<b>(X3) Date Survey Completed</b>  06/22/2021
<b>Name of Provider or Supplier</b>  Hegg Health Center	<b>Street Address, City, State</b>  1202 21st Avenue, Rock Valley, IA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5439</b>	<p><b>CALIBRATION AND CALIBRATION VERIFICATION</b> 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 Vitros 5600 chemistry analyzer calibration verification records and confirmed by laboratory personnel identifier #2 (refer to Laboratory Personnel Report) at approximately 10:45 am on 06/22/2021, the laboratory failed to perform calibration verification for the analytes, vitamin D and total iron binding capacity (TIBC), every six months for two out of two time periods from 02/19/2020 through 06/22/2021. The findings include: 1. Records revealed that laboratory performed</p>

calibration for vitamin D and TIBC using two calibrators. The laboratory performed calibration verification for vitamin D and TIBC on the Vitros 5600 chemistry analyzer on 02/19/2020. 2. At the time of the survey, the laboratory did not have calibration verification records for the time period between 02/19/2020 and 6/22/2021.

**D5555**

**IMMUNOHEMATOLOGY**

CFR(s): 493.1271(c)(f)

(c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's blood bank refrigerator alarm procedure and plan of correction from survey conducted on 04/10/2019, blood bank system alarm check records, and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 12:20 pm on 06/22/2021, the laboratory failed to inspect and perform twice yearly alarm system checks for the blood bank refrigerator for three out of four periods from 04/23/2019 - 06/22/2021. The findings include: 1. The laboratory's "Testing Refrigerator Alarms Blood Bank (Temp of Activation)" procedure stated: "High and low temperatures of activations should be checked twice yearly..." 2. According to the plan of correction from the survey conducted on 04/19/2019: "Temp of activation (testing refrigerator temps) will be done twice yearly for laboratory staff. First 2019 testing was done by general supervisor on April 23, 2019." 3. The laboratory performed the blood bank refrigerator alarm checks on 04/23/2019 and 12/11/2020. 4. The laboratory did not blood bank refrigerator alarm check records for the time periods between 04/23/2019 and 12/11/2020 or 12/11/2020 an 06/22/2021. 5. Personnel identifier #2 confirmed that the laboratory did not perform the blood bank refrigerator alarm checks in accordance with its procedure and plan of correction. This is a repeat deficiency.