

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0661966	(X3) Date Survey Completed 11/13/2024
Name of Provider or Supplier Memorial Hospital Of Lafayette County	Street Address, City, State 800 Clay St, Darlington, WI	
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
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on survey review of laboratory records and procedures and interview the technical consultant, the laboratory director did not sign and date two of two new analyzer procedures prior to patient use. Findings include: 1. Review of the QuidelOrtho Vitros XT-7600 performance specification verification records showed the Vitros XT-7600 go-live date was June 28, 2023. 2. Review of the Sysmex XN-550 performance specification verification records showed the Sysmex XN-550 go-live date was July 10, 2024. 3. Review of the "Ortho Vitros XT-7600 Chemistry Testing Analyzer" procedure showed the laboratory director reviewed and signed the procedure in November 2023. 4. Review of "Sysmex XN-550 Hematology Analyzer Maintenance and Whole Blood Analysis" procedure showed the laboratory director review and signed the procedure in October 2024. 5. Interview with the technical consultant on November 12, 2024, at 2:50 PM confirmed the laboratory director did not sign and date new procedures prior to patient use.</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p>

This STANDARD is not met as evidenced by:
Based on surveyor review of laboratory procedures, observation of hematology quality control (QC) material and interview with the technical consultant, testing personnel did not label three of three opened QC vials with the open expiration date. Findings include: 1. Review of the "Sysmex XN-550 Hematology Analyzer Maintenance and Whole Blood Analysis" procedure stated under the "Quality Control" header: A. Preparation and Handling 1. XN-L Check are the three levels of controls, ordered from Sysmex that will be used on our XN-550. 2. The controls are stored at 2-8 until the expiration date on the vial. 3. Controls are good for 15 days after opening. 4. Continue to store in the refrigerator when not in use. 5. Label the vial with the date opened, and the 15-day expiration date when put into use. 2. Observation of the hematology QC in the laboratory refrigerator on November 12, 2024, at 1:05 PM revealed three vials of hematology quality control, Lot# 42841401, 42841402, and 42841403. Further observation of the vials showed an opened date of November 2, 2024, and no revised expiration date on the vials. 3. Interview with the technical consultant on November 12, 2024, at 1:05 PM confirmed the hematology QC expiration date changes when the vials are opened and testing personnel did not label the QC vials with the new expiration date after they were opened.

D5439

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(b)

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.

This STANDARD is not met as evidenced by:
Based on surveyor review of laboratory records and interview the technical consultant, the laboratory did not perform calibration verification every six months for one of four required chemistry analytes on the QuidelOrtho Vitros XT-7600 chemistry analyzer. Finding include: 1. Review of calibrations performed on the QuidelOrtho Vitros XT-7600 chemistry analyzer showed 2-point calibrations for the Vitamin D, Total Iron Binding Capacity (TIBC), Hemoglobin A1C, and Beta-hydroxybutyrate analytes. 2. Review of QuidelOrtho Vitros XT-7600 calibration verification records showed calibration verification was performed every six months for the Vitamin D,

TIBC and Hemoglobin A1C analytes. Further review showed no calibration verification for the Beta-hydroxybutyrate analyte. 3. Review of test menu provided prior to the survey showed a volume of thirty-two patient tests for Beta-hydroxybutyrate. 4. Interview with the technical consultant on November 13, 2024, at 10:50 AM confirmed the laboratory did not perform calibration verification every six months for all required analytes on the QuidelOrtho Vitros XT-7600 chemistry analyzer.