

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D2081934	(X3) Date Survey Completed 06/20/2019
Name of Provider or Supplier St Dominic's Internal Medicine	Street Address, City, State 106 Highland Way, Suite 200, Madison, MS	
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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on review of temperature records from 11/29/17 through 6/20/19 and confirmation with the technical consultant at 10:55 a.m. on the day of survey 6/20/19, the laboratory failed to monitor and document the temperature and humidity of the room where the Sysmex XP 300 and Alfa Wassermann ACE Axcel were stored and operated. Findings include: Maintaining appropriate conditions according to the instructions of the manufacturer is essential for optimal test performance. A. The Sysmex XP 300 manufacturer's instructions state: 1. Operate the instrument at ambient temperature range between 15-30 degrees Celsius (C). Optimal room temperature is 23 degrees C. 2. Allow quality control (QC) material to come to room temperature at 18-25 degrees C for 15 minutes. 3. Store Cell Pack, Stromatolyser-WH, reagents and bleach at room temperature of 15-30 degrees C. 4. Operate the instrument with relative humidity ranges between 30% and 85% B. The Alfa Wassermann manufacturer's instructions state: 1. Operate analyzer at ambient room temperature between 15 degrees Celsius (C) and 26.7 degrees Celsius (C). 2. Operate analyzer in room with 20%-80% relative humidity (RH).</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</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.

This STANDARD is not met as evidenced by:

Based on interview with testing personnel and observation of the Alfa Wassermann ACE Axcel chemistry controls, lot #1213UNCM (Level 1) and lot #937UECM (Level 2), in use by the laboratory on 6-20-19 at 10:30 a.m. and review of the manufacturer's instructions for the controls, the laboratory failed to follow the manufacturer's instructions for reconstitution and storage of the Alfa Wassermann chemistry controls in use with patient testing. Findings include: Manufacturer's instructions for the Alfa Wassermann chemistry controls state that the controls are stable for three days after reconstitution, when stored refrigerated. Observation of two vials of Alfa Wassermann chemistry controls, lot # 1213UNCM (Level 1) and lot # 937UECM (Level 2), in use on the day of the survey revealed there was no open date on the vials to ensure the controls were not used past the stability date.

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on surveyor review of preventive maintenance records, review of the Alfa Wassermann ACE Axcel Operator's manual, and interview with the technical consultant, the laboratory failed to perform and document the daily, weekly, monthly and bi-annual maintenance on the Alfa Wassermann ACE Axcel chemistry analyzer according to the manufacturer's instructions from 10-4-2018 through 6-20-2019. Findings include: The laboratory failed to document as performed the following required maintenance for the Alfa Wassermann ACE Axcel chemistry analyzer: Daily Maintenance 1. Remove condensation from reagent compartment 2. Touchplate cleaning 3. Exterior probe cleaning 4. Check probe alignment 5. Clean and condition ISE Weekly Maintenance 1. Clean ISE sample port 2. Clean exterior surface 3. Inspect air filters and clean, if necessary 4. Weekly touchplate cleaning Monthly Maintenance 1. Rinse probe and fluid lines with bleach 2. Clean cap assemblies 3. Calibrate table offset and sample delay switch 4. Clean ISE reference housing Bi-Annual Maintenance 1. Replace ISE pump tubing The technical consultant confirmed during an interview on 6-20-19 at 11:55 a.m. the testing personnel did not perform any maintenance on the ACE Axcel chemistry analyzer from the date of installation 10-4-2018 through the date of survey 6-20-2019.

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 with the technical consultant, the laboratory failed to perform and document the calibration verification procedure according to the manufacturer's instructions for the 16 analytes tested on the Alfa Wassermann ACE Axcel chemistry analyzer from 10-4-18 through 6-20-19. Findings include: 1. The laboratory had no records showing calibration verification performance for ALT, Albumin, Alkaline Phosphatase, AST, Total Bilirubin, Calcium, Chloride, Cholesterol, CO₂, Creatinine, Glucose, Potassium, Sodium, Total Protein, Triglycerides and BUN. 2. The technical consultant confirmed on 6-20-19 at 11:40 a.m., the laboratory had performed no calibration verification for 16 chemistry analytes on the ACE Axcel analyzer since installation on 10-4-18. 3. The manufacturer's instructions require calibration verification when control materials are unacceptable, following specific maintenance procedures, and at a minimum every 6 months. 4. The laboratory reported approximately 101 patient results each month from 10-4-18 through 6-20-19.

D6049

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)(iii)

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:

Based on interview with the technical consultant on 6-20-19 at 11:00 a.m. and surveyor review of laboratory records from 11-29-17 through 6-20-19, the technical consultant documented monthly Quality Assessment review of records but failed to detect the lack of calibration verification and preventive maintenance (including documentation of room temperature) for the Alfa Wassermann chemistry analyzer as specified by the manufacturer. Findings include: 1. No documentation of room temperature as specified by the manufacturer since 11-29-17. (Refer to D5413). 2. No performance of preventive maintenance as specified by the manufacturer since installation of the Alfa Wassermann ACE Axcel chemistry analyzer on 10-4-18.

(Refer to D5429). 3. No performance of calibration verification as specified by the manufacturer for all analytes on the Alfa Wassermann chemistry analyzer. (Refer to D5439). 4. Failure to follow the manufacturer's reconstituted, open-vial stability procedure for the Alfa Wassermann chemistry controls. (Refer to D5415).