Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
OMB No. 0938-0391

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0982582	(X3) Date Survey Completed 05/16/2023
Name of Provider or Supplier Sharon Mitchell Medical Clinic Llc	**Street Address, City, State** 13 Village Plaza, Liberal, KS	
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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records from American Proficiency Institute (API) and interview, the laboratory failed to evaluate its unacceptable proficiency testing results for three of six testing events in 2022. Findings: The following samples were scored unacceptable by API. No documentation of the laboratory's evaluation was provided at the time of survey. 1. 2022 Chemistry-Core 2nd Event-Free Thyroxine, sample CH-07. 2. 2022 Chemistry-Core 3rd Event- CK-MB and Troponin, sample CM-12 3. 2022 Hematology/Coagulation 3rd Event-Hematocrit, Lymphocytes %, MCH, MCV, and Platelet, sample HEM-15. 4. Interview with the Laboratory Director on 5/16/23 at 10:25 a.m. confirmed, the laboratory failed to evaluate its unacceptable proficiency testing results for three of six testing events in 2022.
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 the CMS116 non-waived test list, documentation for six month calibration verification, and interview the laboratory failed to perform calibration verification on the Horiba ABX-Micro 60 hematology analyzer at least every 6 months. Findings: 1. Review of the CMS116 lists the Horiba ABX-Micro 60 as the laboratory hematology analyzer for complete blood counts. 2. Review of the 6 month calibration documents revealed calibrations were performed 7/20/21, 6/8/22 and 9/4/22. Calibration verification should have been performed in January 22 and March 23. No other calibration documentation was provided at the time of survey. 3. Interview with the laboratory director on 5/16/23 at 11:05 a.m. confirmed, the laboratory failed to perform calibration verification on the Horiba ABX-Micro 60 hematology analyzer at least every 6 months.