Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D0317542	05/07/2024
Name of Provider or Supplier	**Street Address, City, State**	
Premier Kosciusko Medical Clinic	332 Highway 12 West, Kosciusko, 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
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 observation of Tosoh Hemoglobin A1C (HbA1C) calibrators in the laboratory refrigerator, review of calibration verification records for the Tosoh Automated Glycohemoglobin Analyzer HLC-723 G8, interview with the laboratory director, and annual patient test counts, the laboratory failed to perform calibration verification for HbA1C at least once every six months for three of four calibrations from 8/22/2022 through 5/7/2024. Findings include: 1. Observation of Tosoh

	Hemoglobin A1C (HbA1C) calibrators in the laboratory refrigerator on 5/7/2024 at 10: 30 a.m. revealed HbA1C testing on the Tosoh Automated Glycohemoglobin Analyzer HLC-723 G8 used only two calibrators. 2. Review of calibration verification records for the Tosoh Automated Glycohemoglobin Analyzer HLC-723 G8 from 8/2/2022 through 5/7/2024 revealed the only HbA1C calibration verification performed since the last survey was performed on 8/22/2022. There was no documentation of the performance of three, six-month calibration verifications due from February 2023 through the day of the survey on 5/7/2024, which included fourteen months of patient testing. 3. In an interview on 5/7/2024 at 3:15 p.m., the laboratory director confirmed HbA1C calibration verification was not performed from 8/22/2022 through 5/7/2024. 4. Review of the laboratory's patient test counts revealed the annual volume for HbA1C testing was 6,554.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) scores for the five events performed since the last survey, lack of documentation of corrective action for unsatisfactory scores, and interview with Technical Consultant #2, listed on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, the laboratory director failed to ensure that an approved corrective action plan was followed when proficiency testing results were found to be unsatisfactory for two of five testing events reviewed. Findings include: 1. Review of chemistry proficiency testing scores for Event 3 of 2022, of five events, revealed the following unsatisfactory score, with no documentation of corrective action: High-density lipoprotein (HDL) cholesterol - 60 %. 2. Review of chemistry proficiency testing scores for Event 1 of 2023, of five events, revealed the following unsatisfactory scores, with no documentation of corrective action: Total bilirubin - 60% Parathyroid hormone - 50 % Vitamin D - 50% 3. In an interview on 5 /7/2024 at 5:00 p.m., Technical Consultant #2, listed on the CMS 209 personnel form, confirmed there was no documentation of corrective action for the unsatisfactory scores for two of five testing events reviewed.