Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D2083212	01/12/2022
Name of Provider or Supplier	**Street Address, City, State**	
Precision Labs, Llc	8150 Us Highway 42 N, Plain City, OH	

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 record review and an interview with the Technical Supervisor, the laboratory failed to perform and document calibration verification procedures for urine creatinine at least every 6 months. All patients tested at this laboratory from 08 /21/2019 through 09/15/2021 had the potential to be affected. Findings Include: 1. Review of the laboratory's calibration verification policy for urine creatinine found the following statement: "Criteria for Calibration and Calibration Verification The

	following criteria are applied to determine the need for calibration verification...: ...5. At least every 6 months." 2. Review of the laboratory's calibration verification data for urine creatinine found the following: Dates calibration verification was performed 08 /21/2019 09/15/2021 3. An interview with the Technical Supervisor,on 01/12/2022 at 3:06 PM, confirmed that the lab failed to perform calibration verification for urine creatinine at least every 6 months from 08/21/2019 through 09/15/2021. The current Technical Supervisor confirmed that the error was caught when they took over the role in August of 2021. The Technical Supervisor confirmed that the policy of performing calibration verification every 6 months will be followed going forward.