

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 06D2097807	(X3) Date Survey Completed 10/26/2023
Name of Provider or Supplier Precision Clinical Laboratory	Street Address, City, State 11275 E Mississippi Ave, Ste 2wi, Aurora, CO	
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	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on an unannounced on-site revisit survey on 10/26/2023, a record review, and an interview with the laboratory manager, the laboratory failed to perform and document calibration verification for the electrolytes on the Siemens Dimension chemistry analyzer and the Tosoh Hemoglobin A1c analyzer since 2021. Findings include: 1. A record review revealed the laboratory failed to perform calibration verification for the electrolytes (sodium, potassium, chloride) on the Siemens</p>

Dimension EXL analyzer and hemoglobin A1c on the Tosoh since 2021. 2. The laboratory performed approximately 87,000 chemistry tests per year. 3. An interview on 10/26/2023, at approximately 4:00 PM, with the laboratory manager, confirmed the laboratory failed to perform calibration verification for the electrolytes and the hemoglobin A1c analytes.

D5545

HEMATOLOGY
CFR(s): 493.1269(b)(d)

(b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:
Based on an unannounced on-site revisit survey on 10/26/2023 and an interview with testing personnel, the laboratory failed to test two levels of coagulation quality control samples every 8 hours of operation for Prothrombin time (PT) and Partial Thromboplastin time (PTT) during patient testing since the last survey on 7/26/2023. Findings include: 1. A record review of coagulation quality control printouts revealed that the laboratory failed to test two levels of quality control every 8 hours for PT and PTT since the last survey on 7/26/2023. 2. An interview on 10/26/2023, at approximately 2:30 PM, with the testing personnel, confirmed that they were unaware that quality control material must be performed every 8 hours of patient testing.

D6117

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(4)

The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results.

This STANDARD is not met as evidenced by:
Based on an unannounced on-site revisit survey on 10/26/2023, laboratory records review and an interview with the laboratory manager, the Technical Supervisor (TS) failed to verify that the quality control procedures were established for Prothrombin time (PT), Partial Thromboplastin time (PTT), Clostridium difficile (CDiff), and Excyte M Erythrocyte Sedimentation Rate (ESR) since the last survey on 12/17/2020. Findings include: 1. A review of laboratory records revealed the laboratory failed to test two levels of coagulation quality control (QC) for Prothrombin time (PT) and Partial Thromboplastin time (PTT) every 8 hours of patient testing. (See D5545) 2. A review of laboratory records revealed that the TS failed to ensure the unassayed coagulation QC data statistics for the reference range study was performed prior to testing patient samples and available for review at the time of the survey. (See D3031) 3. A review of laboratory records revealed that the TS failed to ensure that QC procedures for the ESR, CDiff and coagulation testing were followed by testing personnel. 4. A review of laboratory records revealed that the TS failed to document

or retain the lot numbers and expiration dates of reagents and QC materials for CDiff, PT, PTT, and ESR. 5. An interview with the laboratory manager on 10/26/2023 at 4:45 PM confirmed that the TS failed to establish QC procedures for the tests.