

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0657958	(X3) Date Survey Completed 09/28/2022
Name of Provider or Supplier East Penn Mfg Co Inc Clinical Lab	Street Address, City, State Deka Road, Keller Tech Ctr - C/O K Smith, Lyon Station, PA	
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 lack of documentation and interview with Testing Personnel (TP #1), the laboratory failed to perform calibration verification at least once every six months for the Helena Laboratories Protofluor Z Chemistry Analyzer from 06/24/2022 to 09/28/2022. Findings include: 1. On the date of survey, 09/28/2022 at 10:30 am, the laboratory could not provide calibration verification records for the Helena</p>

Laboratories protoflour Z for Zinc protoporphyrin testing from 06/24/2020 to 09/28/2022. 2. TP #1 confirmed the finding above on 09/28/2022 around 11:00 am.

D6121

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(8)(i)

The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing.

This STANDARD is not met as evidenced by:

Based on review of competency assessment records and interview with the testing personnel (TP)#1, the Technical Supervisor (TS) failed to perform direct observations of specimen handling, processing and testing for 3 of 3 testing personnel (TP) who performed Toxicology test from 06/24/2020 to the day of survey. Findings Include: 1. On the day of survey, 09/28/2022 at 09:42 am., review of competency assessment records revealed that direct observations of specimen handling, processing and testing were not included in the competency assessment records for 3 of 3 TP (CMS 209 personnel # 4, #5, and #6) who performed lead and zinc protoporphyrin testing from 06/24/2020 to 09/28/2022. 2. The TP#1 confirmed the finding above on 09/28/2022 around 11:00 a.m.

D6124

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(8)(iv)

The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks.

This STANDARD is not met as evidenced by:

Based on review of competency assessment records and interview with the testing personnel (TP)#1, the Technical Supervisor (TS) failed to perform direct observation of performance of instrument maintenance and function checks for 3 of 3 testing personnel (TP) who performed Toxicology test from 06/24/2020 to the day of survey. Findings Include: 1. On the day of survey, 09/28/2022 at 09:42 am., review of competency assessment records revealed that direct observations for performance of instrument maintenance and function checks were not included in the competency assessment records for 3 of 3 TP (CMS 209 personnel # 4, #5, and #6) who performed lead and zinc protoporphyrin testing from 06/24/2020 to 09/28/2022. 2. The TP#1 confirmed the finding above on 09/28/2022 around 11:00 a.m.