

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D0657958	<b>(X3) Date Survey Completed</b>  06/24/2020
<b>Name of Provider or Supplier</b>  East Penn Mfg Co Inc Clinical Lab	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2015</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) reports and interview with Testing Personnel (TP) #1 and #2, the laboratory failed to maintain copies of Wisconsin State Laboratory of Hygiene (WSLH) attestation statements from 2018 to the day of survey. Findings includes: 1. On the day of survey, 06/24/2020, TP#1 could not provide copies of the attestation statements for WSLH PT result for 2018 event 1, 2 and 3 and 2019 event 1, 2 and 3. 2. Testing Personnel #1 confirmed the finding above on 06/24/2020 around 8:40 am.</p>
<b>D5209</b>	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p>

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's procedure manuals and interview with the testing personnel (TP) #1 and #2, the laboratory failed to follow their competency assessment policy to evaluate the competency of 2 of 2 TP for their 6 month, 12 month, and yearly competency and to establish a policy to assess the competency of 3 of 3 regulatory personnel in 2018 to 2020. Findings include: 1. The Competency Assessment Policy states, "For Regular testing personnel, the competency assessment must be performed at least annually. For new hire testing personnel, the competency assessment must be performed at 6 months of employment and again at 12 months of employment. After the first year of employment, the competency assessment can be performed annually". 2. On the day of survey, 06/24/2020, review of laboratory personnel competency assessment records revealed: - TP#2 (hired on 02/2019) was not assessed for 6 month and 12 month competency. - TP#1 was not assessed yearly for competency from 01/09/2019 to 2020. 3. The competency assessment policy reviewed, did not describe how to evaluate the technical supervisor (TS) and general supervisor (GS) for their regulatory responsibilities in the laboratory. 4. 2 of 2 TS and 1 of 1 GS were not assessed for their regulatory responsibilities in the laboratory in 2018, 2019 and 2020. 5. TP#1 confirmed the findings above on 06/24/2020 around 10:00 am.

**D5291**

**GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1239(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's procedure manuals and interview with testing personnel (TP) #1 and #2, the laboratory failed to establish policies and procedures to assess ongoing mechanism to monitor the laboratory's system from 2018 to the day of survey. Findings include: 1. On the day of survey, 06/24/2020, TP#1 could not provide a quality assessment policy to assess the quality of its laboratory systems from 02/07/2018 to 06/24/2020. 2. The TP#1 confirmed the finding above on 06/24/2020 around 8:45 am.