Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0657958	03/17/2026
Name of Provider or Supplier	**Street Address, City, State**	
East Penn Mfg Co Inc Clinical Lab	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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview with the Clinical Lab Coordinator (CLC), the laboratory failed to follow procedures to assess the competency of 1 of 1 Technical Supervisors (TS) for their supervisory responsibilities when toxicology testing was performed from 07/24/2024 to 03/17/2026. Findings Include: 1. The laboratory's Competency Assessment policy stated, "The Laboratory Director is responsible for performing and documenting competency assessments for the Technical and General Supervisors." 2. On the date of the survey, 03/17/2026 at 9: 42 am, the laboratory failed to provide a competency assessment reviewed by the Laboratory Director to assess the competency of 1 of 1 TS (Personnel #2, CMS 209, dated 03/17/2026) for their supervisory responsibilities when toxicology testing was performed in the laboratory from 07/24/2024 to 03/17/2026. 3. Review of the laboratory's Blood Sample Report revealed the laboratory performed 26,625 Toxicology examinations from 07/24/2024 to 03/17/2026. 4. The CLC, (CMS 209 personnel #4, dated 03/17/2026), confirmed the above findings on 03/17/2026 at 1:00 pm.
D5301	TEST REQUEST CFR(s): 493.1241(a) (a) The laboratory must have a written or electronic request for patient testing from an authorized person.

	This STANDARD is not met as evidenced by: Based on record review, lack of documentation and interview with the Clinical Lab Coordinator (CLC), the laboratory failed to have written or electronic requests from an authorized person for toxicology patient testing performed for 2 of 2 years from 07/24/2024 to 03/17/2026. Findings include: 1. On the date of the survey, 03/17/2026 at 10:30 am, the laboratory could not provide written or electronic test requisitions from an authorized person for Lead and Zinc Protoporphyrin (toxicology) testing performed for 2 of 2 years from 07/24/2024 to 03/17/2026. 2. Review of the laboratory's Blood Sample Report revealed the laboratory performed 26,625 Toxicology examinations from 07/24/2024 to 03/17/2026. 3. The CLC, (CMS 209 personnel #4, dated 03/17/2026), confirmed the above findings on 03/17/2026 at 1:00 pm.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: A. Based on review of the laboratory's Analytical Lab Procedure Manual and interview with the Clinical Lab Coordinator (CLC), the laboratory failed to provide a complete procedural manual for toxicology testing performed on 1 of 1 Thermo Scientific iCAP Q Mass Spectrometer analyzer from 07/24/2024 to 03/17/2026. Findings include: 1. On the date of the survey, 03/17/2026 at 10:15 am, review of the laboratory's Analytical Lab Procedure Manual, Document No.: ALP-111-1-7-1, revealed the laboratory failed to include the following applicable requirements under 493.1251 (b) for the Lead testing performed on 1 of 1 Thermo Scientific iCAP Q Mass Spectrometer analyzer from 07/24/2024 to 03/17/2026: - (b)(5) Calibration procedure - (b)(6) The reportable range for test results for the test system as established or verified in 493.1253 - (b)(10) Reference intervals (normal values) 2. The CLC, (CMS 209 personnel #4, dated 03/17/2026), confirmed the above findings on 03/17/2026 at 1:00 pm. B. Based on review of the laboratory's Analytical Lab Procedure Manual and interview with the Clinical Lab Coordinator (CLC), the laboratory failed to provide a complete procedural manual for toxicology testing

	performed on 1 of 1 Helena Protofluor-Z Hematofluorometer analyzer from 07/24 /2024 to 03/17/2026. Findings include: 1. On the date of the survey, 03/17/2026 at 10: 15 am, review of the laboratory's Analytical Lab Procedure Manual, Document No.: ALP-111-1-1-2, revealed the laboratory failed to include the following applicable requirements under 493.1251 (b) for the Zinc Protoporphyrin testing performed on 1 of 1 Helena Protofluor-Z Hematofluorometer analyzer from 07/24/2024 to 03/17 /2026: - (b)(6) The reportable range for test results for the test system as established or verified in 493.1253 - (b)(10) Reference intervals (normal values) 2. The CLC, (CMS 209 personnel #4, dated 03/17/2026), confirmed the above findings on 03/17/2026 at 1:00 pm.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: A. Based on lack of documentation and interview with the Clinical Lab Coordinator (CLC), the laboratory failed to monitor and document room temperature and humidity for 601 of 601 days to ensure operating conditions were met for analyzers used for Toxicology testing performed from 07/24/2024 to 03/17/2026. Findings include: 1. On the date of the survey, 03/17/2026 at 11:32 am, the laboratory failed to provide documentation for temperature and humidity readings taken to ensure operating conditions were met for 601 of 601 days for the following analyzers used for Toxicology testing performed from 07/24/2024 to 03/17/2026: - Thermo Scientific iCAP Q Mass Spectrometer, manufacturer operating conditions: 15 to 35 C, relative humidity 20 to 80% - Helena Protofluor-Z Hematofluorometer, manufacturer operating conditions: 15 to 30 C. 2. Review of the laboratory's Blood Sample Report revealed the laboratory performed 26,625 Toxicology examinations from 07/24/2024 to 03/17/2026. 3. The CLC, (CMS 209 personnel #4, dated 03/17/2026), confirmed the above findings on 03/17/2026 at 1:00 pm. B. Based on lack of documentation and interview with the Clinical Lab Coordinator (CLC), the laboratory failed to monitor and document temperatures for 195 of 601 days to ensure manufacturer storage conditions were met for reagents used for Toxicology testing performed from 07/24 /2024 to 03/17/2026. Findings include: 1. On the date of the survey, 03/17/2026 at 11: 32 am, the laboratory failed to provide documentation for refrigerated temperature readings taken to ensure manufacturer storage conditions were met for 195 of 601 days for the following reagent used for Toxicology testing performed from 07/24 /2024 to 03/17/2026: - Bio-Rad Lyphochek Whole Blood Controls, manufacturer storage temperature: 2 to 8 C. 2. Review of the laboratory's Blood Sample Report revealed the laboratory performed 26,625 Toxicology examinations from 07/24/2024 to 03/17/2026. 3. The CLC, (CMS 209 personnel #4, dated 03/17/2026), confirmed the above findings on 03/17/2026 at 1:00 pm.
D5805	TEST REPORT

	CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient test reports and interview with the Clinical Lab Coordinator (CLC), the laboratory failed to include the address of the location where testing was performed for 1 of 1 patient test reports reviewed for Toxicology testing performed from 07/24/2024 to 03/17/2026. Findings Include: 1. On the date of the survey, 03/17/2026 at 11:40 am, review of 1 of 1 patient test reports revealed the laboratory failed to include the address of the laboratory location where Lead and Zinc Protoporphyrin testing was performed from 07/24/2024 to 03/17/2026. 2. Review of the laboratory's Blood Sample Report revealed the laboratory performed 26,625 Toxicology examinations from 07/24/2024 to 03/17/2026. 3. The CLC, (CMS 209 personnel #4, dated 03/17/2026), confirmed the above findings on 03/17/2026 at 1:00 pm.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) (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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the Clinical Lab Coordinator (CLC), the laboratory failed to establish and maintain written policies for an ongoing mechanism to monitor, assess and when indicated, correct problems identified in the postanalytic systems specified in 493.1291 for 20 of 20 months from 07/24/2024 to 03 /17/2026. Findings include: 1. On the date of the survey, 03/17/2026 at 11:03 am, the laboratory could not provide a procedure for the ongoing mechanism to monitor, assess, and correct problems found in the postanalytic system specified in 493.1291 for 20 of 20 months from 07/24/2024 to 03/17/2026. 2. The laboratory failed to provide records for the following periodic checks performed to verify the accuracy of the Laboratory's Information System (LIS) from 07/24/2024 to 03/17/2026: - Calculated Data - Patient results transmitted between instruments and LIS - Patient Specific data. 3. The CLC, (CMS 209 personnel #4, dated 03/17/2026), confirmed the above findings on 03/17/2026 at 1:00 pm.
D6080	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(c) (c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may

	elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the Clinical Lab Coordinator (CLC), the Laboratory Director (LD) failed to be onsite at least once every 6 months for 1 of 1 years while Toxicology testing was performed from 07/24/2024 to 03/17/2026. Findings include: 1. On the date of the survey, 03/17/2026 at 11:40 am, interview with the CLC stated that "the LD visited the laboratory on an annual basis", for 1 of 1 years (2025) while Toxicology testing was performed from 07/24/2024 to 03/17/2026. 2. The laboratory failed to provide documentation for the onsite visits performed by the LD at least once every 6 months in 2025. 3. The CLC, (CMS 209 personnel #4, dated 03/17/2026), confirmed the above findings on 03/17/2026 at 1:00 pm.