

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2147959	(X3) Date Survey Completed 10/31/2023
Name of Provider or Supplier Jb Pain Free Md Pllc DbA The York Pain Ctr	Street Address, City, State 718 S Main St, Red Lion, 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	<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> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's competency assessment procedure and interview with the general supervisor (GS), the laboratory failed to follow their established procedure to assess the competency of 2 of 2 technical supervisor (TS) and 1 of 1 GS for their supervisory responsibilities performed from 11/17/2021 to the date of the survey. Findings include: 1. The laboratory's GEN 9 GEN: Competency procedure states, " Competency must be assessed for Technical Supervisor, General Supervisor, Technical Consultant, and Clinical Consultant as well as for all delegated duties at least annually. The section director or Laboratory Director is responsible for performing and recording competency assessment for high complexity testing." 2. On the day of survey, 10/31/2023 at 11:30 am, the laboratory failed to provide site specific competency assessment records for 2 of 2 TS (CMS 209 personnel # 2, and # 8) and 1 of 1 GS (CMS 209 personnel # 3) for their supervisory responsibilities performed from 11/17/2021 to 10/31/2023. 3. The GS confirmed the findings above on 10/31/23 at 03:00 pm.</p>
D5213	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)</p> <p>The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.</p>

This STANDARD is not met as evidenced by:
 Based on review of the laboratory's procedures, College of American Pathologists (CAP) proficiency testing (PT) records and interview with the general supervisor (GS), the laboratory failed to verify the accuracy of the PT results obtained for 4 of 4 CAP chemistry testing events reviewed for 2023. Findings include: 1. The laboratory's GEN 11 GEN: Proficiency Testing procedure states, " Ungraded PT challenges such as: Results submitted after the cut-off date, Failure to submit results, Incorrect completion of the result, PT challenges that were not graded because of lack of consensus, and All other ungraded PT results will be reviewed and evaluated against the participant summary and/or materials provided by the PT vendor." 2. On the day of survey, 10/19/2023 at 09:54 am, review of the laboratory's CAP PT records revealed that the laboratory did not verify the accuracy for the following 4 of 4 CAP chemistry testing events for 2023 that were not graded by the PT agency: - Drug Monitoring for Pain Management (DMPM-A-2023, DMPM-B-2023) -Urine Drug Adulterant/Integrity (DAI-A-2023, DAI-A-2023) 3. The CAP's actions laboratories should take when a PT result is not graded document states, "the laboratory is required to review participant summary for comparative results and document performance accordingly. Evaluation criteria is not established for educational challenges. Laboratories should determine their own evaluation criteria approved by their laboratory director for self-evaluation." 4. The GS confirmed the findings above on 10/31/2023 at 03:00 pm

D5221

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
 CFR(s): 493.1236(d)

All proficiency testing evaluation and verification activities must be documented.

This STANDARD is not met as evidenced by:
 Based on a review of the College of American Pathologists (CAP), and Pennsylvania Department of Health Drugs of Abuse (PA DOH DOA) proficiency testing (PT) records and interview with the general supervisor (GS), the laboratory failed to document the evaluation and verification activities for PT testing performed in chemistry (toxicology) from 11/17/2021 to the date of the survey. Findings Include: 1. On the day of the survey, 10/31/2023 at 09:54 am, review of PT records revealed that the laboratory did not document the review and corrective action taken for the following PT events that received an unacceptable result from 10/08/2020 to 01/05/2023: - CAP DMPM-A 2023 Drug Monitoring for Pain Management - CAP DMPM-B 2023 Drug Monitoring for Pain Management 2. The laboratory could not provide documentation that the following PT attestation sheets were reviewed and assessed by the LD or designee: - CAP DMPM-B 2023 Drug Monitoring for Pain Management - CAP DAI-A 2023 - CAP DAI-B 2023 - CAP DAI-A 2022 3. The laboratory could not provide the following records upon request: - PA DOH DOA 2022 I, II, III result forms - CAP DMPM-B 2022 - CAP DMPM-A 2022 4. The GS confirmed the findings above on 10/31/2023 at 03:00 PM.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
 CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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:

Based on review of the laboratory's temperature records, and interview with the general supervisor (GS), the laboratory failed to monitor and document the room, refrigerator and freezer temperatures, and humidity to ensure operating conditions were met for the proper storage of toxicology reagents and to ensure reliable test system operation of the LCMS from 11/17/2021 to 10/31/2023. Findings Include: 1. On the day of the survey, 10/31/2023 at 1:33 pm, review of the laboratory's temperature and humidity log revealed the laboratory failed to monitor and document the temperatures for the room (acceptable range: 15-30 degrees Celsius), refrigerator (acceptable range: 2-8 degrees Celsius), freezer (acceptable range: -40--10 degrees Celsius), and humidity (acceptable range: 40-80%) to ensure operating conditions were met for the following days in March 2022 and May 2022: -10 of 31 days in May 2022 - 11 of 30 days in March 2022 2. The hours of laboratory testing per the CMS 116 are Monday 09:00-23:59, Tuesday-Thursday 00:00-23:59, and Friday 00:00-08:59. 3. The GS during an interview, 10/31/2023 at 03:00 pm, revealed that temperatures were not monitored on weekends, holidays, and when personnel are not on site in the laboratory from 11/17/2021 to 10/31/2023.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, lack of documentation, and interview with the general supervisor (GS), the laboratory failed to assess the maintenance/ function checks for 5 of 5 thermometers used to monitor refrigerator and freezer temperatures used for storage of toxicology reagents and patient specimens from 09/15/2022 to the day of survey. Findings Include: 1. On the day of survey, 10/31/2023 at 01:53 pm, the laboratory could not provide maintenance/function check records for the following 5 of 5 thermometers used to monitor refrigerator and freezer temperatures used for storage of toxicology reagents and patient specimens from 11/17/2021 to 10/31/2023: - Thermo Scientific Thermometer # 6 Deep Freezer: S/N #: 210223606: exp: 03/18 /2023 - Thermo Scientific Thermometer # 2 Refrigerator: S/N #: 200728801: exp: 11 /17/2022 - Thermo Scientific Thermometer #3: S/N #: 210223591 exp: 03/18/2023 - Thermo Scientific Thermometer #4: S/N #: 210223612 exp: 03/18/2023 - Thermo Scientific Thermometer #1: S/N #: 2005478717 exp: 09/15/2022 2. The GS confirmed the findings above on 10/31/2023 at 03:00 pm.

D5775

COMPARISON OF TEST RESULTS
CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must

have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's procedures, instrument to instrument comparison records, and interview with the general supervisor (GS), the laboratory failed to have a system that twice a year evaluates the relationship between 2 of 2 LCMS analyzers used for toxicology testing from 11/17/2021 to the date of the survey. Findings include: 1. The laboratory's Gen 16 Gen: Instrument Method Comparison procedure states, " Verify comparability of instruments performing the same tests by conducting instrument correlation studies at least semi-annually." 2. On the date of the survey, 10/31/23 at 02:00 pm , the laboratory failed to provide documentation of the biannual comparisons of test results performed for 2 of 2 LCMS analyzers used for toxicology testing from 11/17/2021 to 10/31/23. 3. The GS confirmed the findings above on 10/31/2023 at 03:00 pm.

D5785

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(3)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's temperature and humidity log and interview with the general supervisor (GS), the laboratory failed to document all corrective actions taken when temperatures exceeded acceptable ranges in February 2022. Findings include: 1. The laboratory's Tox 4 TYPC TYPC: Environmental Conditions procedures states, " Daily verify that the temperature and relative humidity of the lab are within the acceptable range based on instrument manufacturer's instructions. Daily verify that the temperature-controlled storage units for reagent/sample storage are operating within the acceptable range. Monthly, review the Temperature and Humidity Log. If the environmental conditions have exceeded the acceptable range, assess any data and/or quality controls from test methods to determine if the data is valid." 2. On the day of the survey, 10/13/2023 at 01:31 pm, review of the laboratory's temperature and humidity log revealed the temperatures for the following days in February 2022 exceeded the laboratory's acceptable ranges: - Room temperature (acceptable range: 15-30 degrees Celsius (C)) - 1 of 17 days in February 2022: - 02/14/2023: 31 C - Refrigerator temperature (acceptable range: 2-8 C) - 2 of 17 days in February 2022: - 02/14/2023: 9 C - 02/18/2023: 10 C - Humidity (acceptable range: 40-80%) - 14 of 17 days in February 2022: - 02/08/2022 21% - 02/09/2022: 31% - 02/14/2022 16% - 02/15/2022: 20% - 02/16/2022: 32% - 02/17/2022: 29% - 02/18/2022: 34% - 02/19/2022: 21% - 02/22/2023: 32% - 02/23/2022: 32% - 02/24/2022: 26% - 02/25/2022: 26% - 02/26/2023: 29% - 02/28/2022: 30% 3. The laboratory could not provide documentation of the corrective actions taken for out-of-range temperatures in February 2022. 4. The GS confirmed the findings above on 10/31/2023 at 03:00 pm.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:
Based on lack of documentation, review of laboratory procedures, and interview with the general supervisor (GS), the laboratory director (LD) failed to ensure a QA program was maintained to ensure the quality of services provided by the laboratory from 11/17/2021 to the date of the survey. Findings include: 1. The laboratory's Gen 13 Gen: QA Policy and forms states, " All Quality Assessment Documentation must be retained for a minimum of two years. Review the monitor (s) assigned for each month. Document the review on the appropriate form and attach all supporting data and information. Biannually, complete the Analytical, Proficiency, Personnel, and Procedure Manual checklists. The Analytical Checklist includes Maintenance, Calibration/Calibration Verification, Quality Control, Temperatures, and Reagents. Review as applicable. Quarterly, complete the Patient Test Management Checklist of the Post-Analytical Phase as part of the routine laboratory operation." 2. On the day of the survey, 10/31/2023 at 02:30 pm., the laboratory could not provide documentation for the periodic QA evaluation performed to assess the laboratory's pre-analytical, analytical, and post-analytical processes from 11/17/2021 to 10/31/2023. 3. The GS confirmed the findings above on 10/31/23 at 03:00 pm.

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 (CA) records and interview with the general supervisor (GS), the technical supervisor (TS) failed to perform direct observation of routine patient testing, specimen handling and processing for 1 of 15 testing personnel (TP) who performed toxicology testing from March 2022 to the day of survey. Findings Include: 1. On the day of survey, 10/31/2023 at 11:20 am, review of CA records revealed that the TS performed direct observations through Zoom for routine patient testing, specimen handling and processing for 1 of 15 TP (CMS 209 TP # 1) who performed toxicology testing from March 2022 to October 2023. 2. The GS confirmed on 10/31/2023 at 03:00 pm that the TS had not been on site to perform direct observations for CA * Please note: Virtual observations are unacceptable.

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 (CA) records and interview with the

general supervisor (GS), the technical supervisor (TS) failed to perform direct observation of performance of instrument maintenance and function checks for 1 of 15 testing personnel (TP) who performed toxicology testing from March 2022 to the day of the survey. Findings Include: 1. On the day of survey, 10/31/2023 at 11:20 am, review of CA records revealed that the TS performed direct observations through Zoom for instrument maintenance and function checks for 1 of 15 TP (CMS 209 TP # 1) who performed toxicology testing from March 2022 to October 2023. 2. The GS confirmed on 10/31/2023 at 03:00 pm that the TS had not been on site to perform direct observations for CA. * Please note: Virtual observations are unacceptable.