

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2168229	(X3) Date Survey Completed 09/27/2023
Name of Provider or Supplier Brain And Spine Medical Services Pllc	Street Address, City, State 400 International Dr, Williamsville, NY	
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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's liquid chromatography mass spectrometry (LCMS) analysis records, lack of Agilent quality control (QC) and calibration records, as well as confirmed by interview with the testing person (TP), the laboratory failed to save the Agilent 1260/6460 LCMS system final results analysis from August 25, 2022, through September 26, 2023. FINDINGS: 1. The TP confirmed on September 27, 2023, at approximately 3:30 P.M. that final results analysis documentation was not saved after completion of analysis and integration. Surveyor was informed that final result analysis data regeneration from the archived files was not likely to be successful. 2. Due to lack of documented pending logs, it was not possible to determine the approximate number of patients affected.</p>
D5022	<p>TOXICOLOGY CFR(s): 493.1213</p> <p>If the laboratory provides services in the subspecialty of Toxicology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on review of the laboratory's standard operating procedures (SOP); Agilent LC /MS/MS and Thermo Scientific Indiko Plus control and calibration records; direct</p>

	<p>observation of reagent, control and calibration, and stock solution inventory; as well as interview with the TP, the laboratory failed to ensure that control results were within acceptable ranges; that expired reagents, control materials, and stock solutions were removed from inventory; errors were identified, corrective action was performed, and documented. FINDINGS: 1. Due to lack of documented pending logs, it was not possible to determine the approximate number of patients affected. Refer to D5209, D5413, D5417, D5481, and D5781.</p>
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 TP 2022 annual competency evaluation documentation, approved competency evaluation policy, and interview with TP, the laboratory director (LD) failed to ensure that the TP was complying with approved laboratory procedures. FINDINGS: 1. The LD performed, documented, and approved the 2022 TP competency evaluation but failed to: a. Ensure proper handling of reagent, control, and calibration materials; b. Recognize unacceptable quality control and calibration results; c. Document Agilent analyzer maintenance; d. Identify errors as well as perform and document corrective actions. These are contrary to instructions indicated in the approved competency evaluation policy. 2. No documentation of TP retraining was available for review. 3. Due to lack of documented pending logs, it was not possible to determine the approximate number of patients affected.</p>
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the 2022 College American Pathologist (CAP) Proficiency Testing (PT) reports, the laboratory failed to review and perform corrective action for the Urine Drug Screen (UDS) and Drugs Monitoring for Pain Management (DMPM) A2022 event. FINDINGS: 1. The LD failed to perform and document corrective action for the following unsatisfactory PT score events: a. UDS-A-2022 pH-03 2022A reported result: 3.7. CAP acceptable range: 11.5 - 25.0. b. DMPM-A 2022- DMPM-03 (Norbuprenorphine) reported result: 371.8. CAP acceptable range: 116.3 - 257.1. c. UDS-B 2022 pH-4 reported result: 7.9. CAP acceptable result: 6.1 - 7.5; pH-5 reported result: 4.4. CAP acceptable result: 3.3 - 4.2; pH-5 reported result: 12.4. CAP acceptable result: 10.9 - 12.2. It was noted that acceptable corrective action was performed, documented for UDS-B 2022 and DMPM B 2022 events.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or</p>

procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

Based on review of the twice year verification procedure, lack of 2023 DMPM and UDI verification records, as well as interview with the TP, the laboratory failed to perform twice year DMPM and UDI testing verification for the calendar year 2023. FINDINGS: 1. The TP confirmed on September 27, 2023, at approximately 2:30 P.M. that the laboratory did not participate in the 2023 American Proficiency Institute (API) first event. 2. The laboratory failed to perform the twice year verification for toxicology DMPM, UDS and adulterants, as well as ethanol for the first half of 2023. 3. These are contrary to the instructions indicated in the approved twice year verification procedure.

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 the Agilent and Indiko Plus analyzer and reagent storage temperature requirements; temperature and humidity records; lack of freezer temperature documentation; as well as interview with the TP, the laboratory failed to perform and document corrective action for nonfunctional thermometers and out of range freezer and refrigerator temperatures. FINDINGS: 1. Two digital thermometers utilized for monitoring the freezer and refrigerator where calibration and control materials are stored were not functional at the time of the survey. The TP was not aware that the freezer and refrigerator thermometers were not functional. a. There was no documentation of freezer temperatures from August 2022 through the survey date. b. Refrigerator temperatures were monitored by a thermometer located inside the refrigerator. The refrigerator temperatures were out of acceptable (20.0 - 22.6) range for seven days in July 2022 and five days in August 2022. 2. Acceptable Agilent analyzer room temperature range: 18.0 - 32.0 C; humidity range: 10 - 50 %; refrigerator reagent storage temperature: 2 - 8 C; and freezer reagent storage temperature: -40 to -70 C. 3. Acceptable Indiko Plus analyzer room temperature range: 18 - 30 C; humidity range: 35 - 85 %; refrigerator reagent storage temperature: 2 - 8 C; and freezer reagent storage temperature: -20 to -40 C. 4. Due to lack of documented pending logs, it was not possible to determine the approximate number of patients affected.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on direct observation of refrigerator and freezer reagent, control, calibration, and stock solution inventory, as well as interview with the TP, the laboratory failed to remove expired reagent, control, calibration, and stock solution inventory from the toxicology laboratory as required by the laboratory's approved SOP. FINDINGS: 1. On September 27, 2023, at approximately 12:30 P.M., the surveyor observed the following examples of expired reagent, control, calibration, and stock solution inventory located in the toxicology laboratory refrigerator and freezer: a. Control and calibration materials prepared on August 31, 2023, included stock reagents which expired July 20, 2022. Affected control and calibration materials stored in the freezer included: Oxycodone D3, Ketamine D4, Benzoyllecgonine D3, Morphine D3, Codeine D6, Tramadol D3, Zolpidem D7, Methadone D3, Levorphanol D3, EDDP D3, Norhuprenmlame D3, Diazepam D5, Naltrexone D3, Diphephyolranine D3, THC-OO D9, Secobarbital D5, Butalbital D5, Meperidine D4, Oxymorphones D3, Hydromorphone D3, Phencyclidine D5, Amphetamine D5, Dregealin D6, Fentanyl D5, Nonfentanyl D5, Phenobarbital D5, 6-Acetyl morphine D4, Cocaine D3, and Carisoprodol D7. b. Refrigerator inventory included: ETG/ETS Ser 8101 ISTD and Sero 8100 ISTD stock standard, expired July 20, 2022; Stock Calibrator X & Y for Indiko Plus, expired August 23, 2023; Toxicology Calibrator and QC Urine Kit #85092120, expired March 12, 2021; DAI Level 5 #21055A, expired May 31, 2021; DAI Level 4 and Level 2 #2212A, expired December 31, 2022; MAS DOA Total Control #22123A expired December 31, 2022; DAI Negative Calibrator #73980992, expired June 30, 2022; ETG 09131815, expired March 13, 2019; Urine Calibrator #85092120 and Urine Control #8509212, expired March 2021; Urine Calibrator #85102721 and Urine Control #85102721, expired May 2021; DRI Oxycodone Calibrator #73923251, expired April 30, 2022; DRI THC Calibrator #72971427, expired May 2019; DRI Urine Calibrator #73980992, expired June 30, 2022; DRI Cannabinoid Control #74327800, expired September 30, 2022; ARK ETG Calibrator #10011968, expired July 31, 2021; ARK ETC Calibrator #10014860, expired July 31, 2023; ARK ETC Control #W014759, expired June 30, 2023; ARK ETC Control #W014789, expired June 30, 2023; DRU Calibrator Low #74209260, expired September 30, 2022; Cedia Buprenorphine Calibrator #74278812, expired January 31, 2023. Cedia Negative Calibrator #74282015, expired March 2023; Cedia Heroin Calibrator #94186215, expired November 30, 2022; ARK Fentanyl Reagent W014956, expired August 31, 2023; Fentanyl Reagent W011350, expired July 31, 2023; pH Calibrator (3.0) #74088253, expired December 31, 2021; pH Calibrator (11.0) #74064193, expired December 31, 2021; Specific Gravity Calibrator #73733611, expired December 2022; Specific Gravity Low Calibrator #737333610, expired December 2022; Specific Gravity High Calibrator #74355025, expired June 30, 2022; DAT Control Level 5 #21055A, expired May 31, 2021; DAT Control Level 4 #22202A, expired December 31, 2021; DAT Control Level 2 #22122A, expired December 31, 2021; MAS DOA Total Control DAT #22123A, expired December 31, 2022; Cedia Low Control Buprenorphine #74222507, expired January 31, 2022; Cedia High Control Buprenorphine #74378485, expired July 31, 2022; ARK ETG Control W014781, expired June 30, 2023; MGE Low control #7429830, expired April 30, 2023; ARK Fentanyl High Control #W014321, expired May 31, 2023; Creatinine (1.3) Detector #74432358, expired September 30, 2022; Creatinine (7.5) Detector #74432358, expired October 31, 2022; pH Detector #74064134, expired December 31, 2021; pH Detector #73827426, expired April 30, 2021; pH Control (11.5) #73528371, expired June 30, 2020; Tubing Solution #U714, expired March 31, 2023; Wash Solution #U813, expired July 31, 2022; DRI Multi Drug Calibrator #74042241,

expired August 31, 2021; MGC Primary Low Control #74291175, expired April 30, 2023; MGC Primary High Control #7429830, expired April 30, 2023; Oxycodone Calibrator (100) #73886909, expired March 31, 2022; Benzodiazepine Positive Control #74638941, expired August 31, 2023; DRI pH Detector (5.0)#74378248, expired October 31, 2022; ARK Fentanyl Calibrator #W014696, expired May 31, 2023; Hydrolysis Buffer #RhB20-06001, expired June 2021; SMPDIL Buffer Concentrate Diluent pack sample, no expiration date on label; Three Bottles of Wash Solution #980929, expired May 31, 2022; Acid Wash #73730541, expired October 2021. 2. These are contrary to instructions indicated in the approved SOP regarding the preparation and handling of reagents, control, and calibration materials. 3. Due to lack of documented pending logs, it was not possible to determine the approximate number of patients affected.

D5481

CONTROL PROCEDURES

CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the Indiko Plus and Agilent QC records as well as interview with the TP, the laboratory failed to ensure that toxicology QC test results were within acceptable ranges prior to patient specimen testing. FINDINGS: 1. The following Indiko Plus screening analyzer and Agilent confirmatory LC/MS/MS analyzer controls were not within acceptable range: July 31, 2023: Buprenorphine Low, Control Result: 8.7, Acceptable Range: 1.2 - 4.8; July 31, 2023: Buprenorphine (Bup) High, Control Result: 14.7, Acceptable Range: 5.1 - 9.9; July 21, 2023: Cannabinoid High, Control Result: 51, Acceptable Range: 52 - 100; July 21, 2023: Benzoylcegonine (Benzo) High, Control Result: 190, Acceptable Range: 205 - 401; July 21, 2023: Bup Low, Control Result: 5.4, Acceptable Range: 1.2 - 4.8; July 21, 2023: Bup High, Control Result: 11.3, Acceptable Range 5.1 - 9.9; July 19, 2023: Bup Low, Control Result: 5.4, Acceptable Range: 1.2 - 4.8; July 19, 2023: Bup High, Control Result: 11.7, Acceptable Range: 5.1 - 9.9; July 19, 2023: Cannabinoid High, Control Result: 4.9, Acceptable Range: 5.2 - 10.0; July 19, 2023: Oxycodone Low, Control Result: 296, Acceptable Range: 97 - 289; July 11, 2023: Bup Low, Control Result: 5.4, Acceptable Range: 1.2 - 4.8; July 11, 2023: Bup High, Control Result: 11.9, Acceptable Range: 5.1 - 9.9; July 11, 2023: Oxycodone Low, Control Result: 30, Acceptable Range: 97 - 289; July 11, 2023: Cannabinoid High, Control Result: 50, Acceptable Range: 52 - 100; June 29, 2023: Fentanyl Low, Control Result: 7.4, Acceptable Range: 0.1 - 0.9; June 29, 2023: Fentanyl High, Control Result: 7.4, Acceptable Range: 1.1 - 1.9; June 29, 2023: Bup Low, Control Result: 5.4, Acceptable Range: 1.2 - 4.8; June 29, 2023: Bup High, Control Result: 12.2, Acceptable Range: 5.1 - 9.9; June 27, 2023: Cocaine High, Control Result: 684, Acceptable Range: 248 - 544; June 27, 2023: Cocaine Low, Control Result: 471, Acceptable Range: 171 - 363; June 27, 2023: Oxycodone Low, Control Result: 298, Acceptable Range: 97 - 289; June 27, 2023: Cannabinoid High, Control Result: 51, Acceptable Range: 52 - 100; June 27, 2023: Creatinine (1.3), Control Result: 2.5, Acceptable Range: 0.8 - 2.2; June 27, 2023: Creatinine (7.5), Control Result: 8.0, Acceptable Range: 5.4 - 13.4; June 27, 2023: Creatinine (23.0), Control Result: 19.7, Acceptable Range: 21.2 - 30.2; June 19, 2023: Fentanyl High, Control Result: 2.0, Acceptable Range: 1.1 - 1.9; June 19, 2023: Benzo Low, Control Result: 250,

Acceptable Range: 51-195; June 19, 2023: Benzo High, Control Result: 458, Acceptable Range: 205-401; June 19, 2023: Oxycodone Low, Control Result: 373, Acceptable Range: 97 - 289; June 9, 2023: Benzo Low, Control Result: 254, Acceptable Range: 51 - 195; June 9, 2023: Benzo High, Control Result: 454, Acceptable Range: 205 - 401; May 16, 2023: Cocaine High, Control Result: 193, Acceptable Range: 248 - 544; May 16, 2023: Cocaine Low, Control Result: 22, Acceptable Range: 171 - 363; May 16, 2023: Oxycodone Low, Control Result: 305, Acceptable Range: 97 - 289; May 10, 2023: Bup Low, Control Result: 6, Acceptable Range: 1.2 - 4.8; September 14, 2022: 6-Acetylmorphine Low, Control Result: 3.6, Acceptable Range: 4.2 - 10.2; September 14, 2022: 6-Acetylmorphine High, Control Result: 6.3, Acceptable Range: 10.5 - 20.1. 2. Due to lack of documented pending logs, it was not possible to determine the approximate number of patients affected.

D5783

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:

Based on review of the Indiko Plus screening analyzer and Agilent confirmatory LC /MS/MS analyzer control records, test analyte assay sheets, acceptable QC ranges, as well as interview with the TP, the laboratory failed to identify, perform, and document corrective action for Indiko Plus and Agilent LC/MS/MS analyzer unacceptable control ranges. FINDINGS: 1.The laboratory failed to identify out-of-range Indiko Plus and Agilent LC/MS/MS analyzer controls as well as perform, document corrective action from September 14, 2022, through July 21, 2023. 2.The TP confirmed on September 27, 2023, at approximately 3:30 P.M. that no such corrective action was performed and documented. 3. Due to lack of documented pending logs, it was not possible to determine the approximate number of patients affected.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on review of approved SOPs, laboratory records, and interview with the TP, the laboratory failed to draft and approve written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems in the analytic phases of toxicology testing. Refer to D5413, D5417, D5481, and D5783.

D6079

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(a)(b)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies, procedures, and records, as well as confirmed by interview with the TP, the LD and technical supervisor (TS) failed to ensure adequate operation and administration of the laboratory including compliance with the applicable regulations and performance of LD duties and responsibilities. Refer to D5209, D5211, D5217, D5413, D5417, D5481, D5783, and D5791.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control 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 review of laboratory's SOP, toxicology QC records, and confirmed by interview with the TP, the LD failed to ensure compliance with the approved toxicology quality control program to assure toxicology testing quality and identify failures. Refer to D5783.

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 review of laboratory policies and procedures, laboratory records, and interview with the TP, the LD failed to ensure compliance with the quality assessment program to assure laboratory service quality and identify failures in quality as they occur. Refer to D5209, D5211, D5217, D5413, D5417, D5481, D5783, and D5791.

D6175

TESTING PERSONNEL RESPONSIBILITIES

CFR(s): 493.1495(b)(1)

Each individual performing high complexity testing must follow the laboratory's

procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's quality control and calibration records, Indiko Plus and Agilent LC/MS/MS procedure manuals, as well as interview with the TP, the laboratory (TP) failed to comply with the approved SOPs. Refer to D5413, D5417, D5481, D5481, and D5791.

D6177

TESTING PERSONNEL RESPONSIBILITIES

CFR(s): 493.1495(b)(3)

Each individual performing high complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's quality control and calibration records, Indiko Plus and Agilent LC/MS/MS procedure manuals, as well as interview with the TP, the laboratory (TP) failed to comply with the toxicology analyzer quality control requirements. Refer to D5417, D5481, and D5483.

D6179

TESTING PERSONNEL RESPONSIBILITIES

CFR(s): 493.1495(b)(5)

Each individual performing high complexity testing must be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the general supervisor, clinical consultant, or director.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's quality control and calibration records, Indiko Plus and Agilent LC/MS/MS procedure manuals, as well as interview with the TP, the laboratory (TP) failed to identify problems and perform, document toxicology analyzer corrective action. Refer to D5209, D5413, D5417, D5481, D5481, and D5791.