| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 33D2168229 | 10/21/2025 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Brain And Spine Medical Services Pllc | 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 |
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| **D5209** | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of SOPs (Standard Operating Procedures), personnel competency assessment records, as well as interview with the TS (Technical Supervisor), the laboratory failed to follow written policies and procedures to assess employee and consultant competency. FINDINGS: 1. There was no documentation of competency assessment performance for the Clinical Consultant (CC), TS, and General Supervisor (GS). 2. The current SOPs did not include instructions for performing CC, TS, and GS competency assessments. 3. There was no documentation of initial training and six-month competency assessment for the Testing Person (TP) #1 hired November 10, 2023. 4. This is contrary to instructions indicated in the current, approved SOPs. 5. It was noted that a TP #1 annual competency assessment was performed and documented on September 23, 2024. 6. The TS confirmed the findings October 21, 2025, at approximately 1:00 P.M. |
| **D5293** | GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1239(b)(c)<br><br>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. |

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| | This STANDARD is not met as evidenced by:<br>Based on review of documented training and competency assessment documents, SOPs, laboratory Quality Assurance Plan, as well as interview with the TS, the laboratory failed to comply with established general laboratory systems quality assessment procedures to ensure initial TP training and six-month competency assessments were performed and documented. Refer to D5209. |
| **D5415** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(c)<br><br>(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.<br><br>This STANDARD is not met as evidenced by:<br>Based on direct observations, review of SOPs, as well as interview with the TS, the laboratory failed to label reagents to indicate identity, storage requirements, preparation and expiration dates. FINDINGS: 1. The surveyor's observations in the laboratory confirmed on October 21, 2025, at approximately 10:00 A.M. the following reagents stored in the Frigidaire refrigerator were not labelled with lot number, expiration date, or in use date: FENT R1, FENT R2, EtG R1, and EtG R2. 2. This was contrary to instructions in the Indiko Plus Reagents SOP. 3. The TS confirmed the findings October 21, 2025, at approximately 4:30 P.M. |
| **D5417** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(d)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on direct observations, review of SOPs, as well as interview with the TS, the laboratory failed to remove from inventory expired reagents, calibrators, quality controls, and solutions utilized for patient specimen processing. FINDINGS: 1. The surveyor's observations in the laboratory confirmed on October 21, 2025, at approximately 10:00 A.M., the following reagents, calibrators, quality controls and solutions located in the Frigidaire refrigerator were not removed from inventory: a. Thermo Scientific DRI Amphetamines Assay Reagent; Lot: 75144694; Expiration: 05-31-2025; Received: 08-02-2024. b. Thermo Scientific DRI Amphetamines Assay Reagent; Lot: 74347785; Expiration: 9-30-2022; Put in Use (PIU): 07-01-2025. c. Thermo Scientific DRI Benzodiazepine Assay Reagent; Lot: 74370994; Expiration: 10-31-2022; PIU: 07-01-2025. d. Thermo Scientific DRI Methadone Assay Reagent; Lot: 74207570; Expiration: 01-31-2023; PIU: 07-15-2025. e. Thermo Scientific DRI Opiate Assay Reagent; Lot: 74347053; Expiration: 06-30-2023; PIU: 07-29-2025. f. Thermo Scientific DRI Cannabinoid Assay Reagent; Lot: 74994872; Expiration: 11-30-2024; Received: 08-02-2024; PIU: 08-18-2025. g. ARK Diagnostics EtG Assay Reagent; Lot: W019218; Expiration: 05-31-2025; Received: 09-14-2024. h. ARK |

Diagnostics EtG Fentanyl II Reagent; Lot: W011773; Expiration: 09-30-2021; Received: 01-06-2021; PIU: 07-29-2025. i. Microgenics Corporation CEDIA Buprenorphine Assay ED Buffer; Lot: 74275682; Expiration: 02-28-2023. j. Microgenics Corporation CEDIA Heroin Metabolite (6-AM) Assay Reagent; Lot: 74817248; Expiration: 01-31-2025. k. Microgenics Corporation DRI Oxycodone Assay Antibody/Substrate Reagent; Lot: 75066365; Expiration: 10-31-2025. l. Microgenics Corporation DRI Oxycodone Assay Enzyme Conjugate Reagent; Lot: 75066369; Expiration: 10-31-2025 m. Microgenics Corporation DRI Multi-Drug Urine Cal 2; Lot: 75172047; Expiration: 03-31-2025. n. Microgenics Corporation Negative Urine Calibrator; Lot: 75434011; Expiration: 03-31-2025. o. Thermo Scientific DRI Negative Urine Calibrator; Lot: 74970724; Expiration: 07-31-2025; Received: 03-19-2024. p. Microgenics Corporation CEDIA Buprenorphine 50 ng/mL Calibrator; Lot: 75133651; Expiration: 08-31-2025. q. Microgenics Corporation CEDIA Buprenorphine 75 ng/mL Calibrator; Lot: 75133652; Expiration: 08-31-2025. r. Microgenics Corporation DRI Creatinine-Detect 2.0 mg/dL Calibrator; Lot: 75180794; Expiration: 06-30-2025. s. Microgenics Corporation DRI Creatinine-Detect 20.0 mg/dL Calibrator; Lot: 75180784; Expiration: 06-30-2025. t. ARK EtG Calibrator C; Lot: W020821; Expiration: 12-31-2024. u. ARK Fentanyl Calibrator A; Lot: W019997; Expiration: 09-30-2025. v. ARK Fentanyl Calibrator B; Lot: W020724; Expiration: 09-30-2025. w. Microgenics Corporation CEDIA Heroin Metabolite (6-AM) (Cutoff); Lot: 74855909; Expiration 11-30-2024; PIU: 08-18-2023. x. Microgenics Corporation CEDIA Buprenorphine 0 ng/mL Calibrator; Lot: 75133648; Expiration 08-31-2025. y. Microgenics Corporation CEDIA Buprenorphine 5 ng/mL Calibrator; Lot: 75133649; Expiration 08-31-2025. z. Microgenics Corporation CEDIA Buprenorphine 20 ng/mL Calibrator; Lot: 75133650; Expiration 08-31-2025. aa. Microgenics Corporation DRI Drugs of Abuse Low Calibrator; Lot: 75058114; Expiration: 03-31-2025. bb. Microgenics Corporation DRI Multi-Drug urine Calibrator 2; Lot: 74284401; Expiration: 04-30-2022. cc. Microgenics Corporation DRI THC 50 ng/mL Urine Calibrator; Lot: 75011963; Expiration: 11-30-2024. dd. ARK EtG Calibrator; Lot: W019562; Expiration: 12-31-2024. ee. ARK EtG Control 625 ng/mL; Lot: W020816; Expiration: 11-30-2024. ff. ARK EtG Control 625 ng/mL; Lot: W021442; Expiration: 05-31-2025. gg. ARK EtG Control 375 ng/mL; Lot: W021441; Expiration: 05-31-2025. hh. Microgenics Corporation CEDIA Buprenorphine High Control; Lot: 75133660; Expiration: 08-31-2025. ii. Microgenics Corporation CEDIA Buprenorphine Low Control; Lot: 75133650; Expiration: 08-31-2025. jj. Microgenics Corporation MGC Select DAU High Control; Lot: 74139947; Expiration: 10-31-2022. kk. Microgenics Corporation MGC Select DAU Low Control; Lot: 74139946; Expiration: 10-31-2022. ll. Microgenics Corporation MGC Select DAU Low Control; Lot: 75027089; Expiration: 08-31-2025. mm. Microgenics Corporation MGC Primary DAU High Control; Lot: 74400924; Expiration: 07-31-2023. nn. Microgenics Corporation MGC Primary DAU Low Control; Lot: 74400923; Expiration: 07-31-2023. oo. Microgenics Corporation MGC Primary DAU Low Control; Lot: 75053275; Expiration: 09-30-2025. pp. ARK Fentanyl Low Control; Lot: W019915; Expiration: 09-30-2025; PIU: 05-15-2023. qq. Microgenics Corporation DRI pH-Detect Test Reagent; Lot: 74862350; Expiration: 06-30-2024. rr. Microgenics Corporation DRI pH-Detect pH 3.6 Control; Lot: 75104797; Expiration 02-28-2025; PIU: 08-19-2024. ss. Microgenics Corporation DRI pH-Detect pH 7.0 Control; Lot: 75104799; Expiration 02-28-2025; PIU: 08-19-2024. tt. Microgenics Corporation DRI pH-Detect pH 10 Control; Lot: 75104800; Expiration 02-28-2025; PIU: 08-19-2024. uu. Microgenics Corporation DRI pH-Detect pH 11.5 Control; Lot: 75104796; Expiration 02-28-2025; PIU: 08-19-2024. vv. Microgenics Corporation DRI pH-Detect pH 3.0 Calibrator; Lot: 74537907; Expiration: 03-31-2023. ww. Microgenics Corporation DRI pH-Detect pH 11.0

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| | Calibrator; Lot: 74537870; Expiration: 03-31-2023. xx. Microgenics Corporation DRI pH-Detect pH 3.0 Calibrator; Lot: 75106184 Expiration: 03-31-2025. yy. Microgenics Corporation DRI pH-Detect pH 11.0 Calibrator; Lot: 75106232 Expiration: 03-31-2025. zz. Microgenics Corporation DRI pH-Detect pH 23 Control; Lot: 75178740; Expiration 05-31-2025. aaa. Microgenics Corporation DRI Creatinine Detect 1.13 mg /dL Control; Lot: 75178737; Expiration 05-31-2025. bbb. Microgenics Corporation DRI Creatinine Detect 7.5 mg/dL Control; Lot: 75178738; Expiration 05-31-2025. ccc. Microgenics Corporation MGC Select DAU Low Control; Lot: 74139946; Expiration: 10-31-2022. ddd. Microgenics Corporation MGC Primary DAU Low Control; Lot: 74400923; Expiration: 07-31-2023. eee. Thermo Scientific MGC Primary DAU Low Control; Lot: 75053275; Expiration: 09-30-2025; Received: 04-18-???? fff. Thermo Scientific MGC Primary DAU High Control; Lot: 75053276; Expiration: 09-30-2025; Received: 04-18-???? ggg. Thermo Scientific MGC Select DAU Control Set; Lot: 74970720; Expiration: 08-31-2025; Received: 03-19-2024. hhh. Microgenics Corporation CEDIA Heroin Metabolite (6-AM) High Calibrator; LOT: 74855910; Expiration: 10-31-2024. iii. Thermo Scientific Washing Solution 4.5%; Lot: W874; Expiration: 08-31-2024. jjj. Thermo Scientific Tubing Maintenance Solution; Lot: W658; Expiration: 06-30-2025. kkk. Surine Product: 720; Lot: 72132; Expiration: 01/2024. 2. This is contrary to instructions indicated in the current, approved SOPs. 3. The TS confirmed the findings on October 21, 2025, at approximately 5:30 P.M. |
| **D5781** | CORRECTIVE ACTIONS<br>CFR(s): 493.1282(b)(1)<br><br>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of temperature and humidity records, SOPs, lack of corrective action records, as well as interview with the TS, the laboratory failed to perform and document corrective action for test systems that did not meet the laboratory's established performance specifications. FINDINGS: 1. The documented humidity on the room temperature and humidity log deviated from the specified range of 35% - 85% for several days during the survey period. The humidity was out of range for the following months and number of days, respectively: May 2024, 12 days; June 2024, 12 days; July 2024, 11 days; August 2024, 9 days; September 2024, 5 days. 2. There was no documentation of corrective action performance for the respective out-of-range humidity. 3. This is contrary to instructions included in the current, approved SOPs. 4. The TS confirmed the findings on October 21, 2025, at approximately 4:50 P. M. |
| **D5793** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(b)(c) |

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| | (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.<br><br>This STANDARD is not met as evidenced by:<br>Based on inventory of expired reagents, lack of documented corrective action, improper reagent labeling, as well as interview with the TS, the laboratory failed to follow analytic systems quality assessment to identify, resolve, and prevent recurrence of problems in the analytic phase of testing. Refer to D5415, D5417, and D5781. |
| **D6093** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5)<br><br>(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;<br><br>This STANDARD is not met as evidenced by:<br>Based on inventory of expired reagents, lack of documented corrective action, improper reagent labeling, as well as interview with the TS, the Laboratory Director (LD) failed to ensure established quality assessment plans were followed and maintained to identify failures in laboratory services and prevent reoccurrence of problems in the general laboratory and analytical systems. Refer to D5415, D5417, and D5781. |
| **D6103** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(13)<br><br>(e)(13) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;<br><br>This STANDARD is not met as evidenced by:<br>Based on review of SOPs, personnel competency assessment records, as well as interview with the TS, the LD failed to perform and document training and competency assessments. Refer to 5209. |
| **D6107** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(15)<br><br>(e)(15) Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory |

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| | or director review is required prior to reporting patient test results.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of SOPs, lack of job descriptions and competency assessments, as well as interview with the TS, the LD failed to specify, in writing, CC responsibilities and duties. FINDINGS: 1. There was no documentation of CC job description and responsibilities. 2. The TS confirmed the findings on October 21, 2025, at approximately 4:50 P.M. |