| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 01D2026684 | 08/28/2024 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Mobile Physical Medicine & Wellness Pc | 3929 Airport Blvd Building 2 Ste 100, Mobile, AL | |

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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| **D2009** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(1)<br><br>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the College of American Pathologists (CAP) Proficiency Testing (PT) records and interview with Testing Personnel #1, the laboratory failed to ensure the Laboratory Director (or designee) signed the attestation statement on four out of four PT events from 2022 to 2024. The findings include: 1. A review of the CAP PT records revealed no signature by the Laboratory Director (or designee) on the attestation statements for the following events: a. 2022 UDS6-B PT Event b. 2023 UDS6-A PT Event c. 2023 UDS6-B PT Event d. 2024 UDS6-A PT Event 2. TP#1 confirmed these findings in an interview on 8-28-2024 at 11:30 AM. |
| **D3037** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(4)<br><br>Proficiency testing records. Retain all proficiency testing records for at least 2 years.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the College of American Pathologists (CAP) Proficiency Testing (PT) records and an interview with Testing Personnel #1 (TP#1), laboratory failed to retain records of evaluation, scores, and reviews of PT events from 2022 through 2024. The findings include: 1. A review of the CAP PT records, revealed the lab |

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| | failed to retain copies of evaluation, scores, and reviews for the following events: a. 2022 UDS6-B PT Event b. 2023 UDS6-B PT Event c. 2024 UDS6-A PT Event 2. TP#1 confirmed these findings in an interview on 8-28-2024 at 11:30 AM. |
| **D5211** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(a)<br><br>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the College of American Pathologists (CAP) Proficiency Testing (PT) records and an interview with Testing Personnel #1 (TP#1), the laboratory failed to ensure review of CAP evaluation and scores by the Laboratory Director (or designee) for three out of four PT events from 2022 to 2024. The findings include: 1. A review of the CAP PT revealed no evidence of evaluation, scores, and review by the Laboratory Director (or designee) for the following events: a. 2022 UDS6-B PT b. 2023 UDS6-B PT c. 2024 UDS6-A PT 2. During an interview on 8/28/24 at 12:37 PM, TP#1 stated the CAP website went down and the laboratory was not able to print 2022 UDS6-B, 2023UDS6-B and 2024 UDS6-A. The surveyor confirmed CAP website went down 8/18/24, 10 days prior to survey date. PT reports could have been accessed prior to 8/18/24. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation during the entrance tour, the ImmTox user manual, and an interview with Testing Personnel #1 (TP#1), the laboratory failed to ensure the correct type of water was utilized on the ImmTox analyzer as per manufacturer's instructions. This was noted from the date of the previous survey (9-1-2022) to date of the current survey (8-28-2024). Findings include: 1. During the entrance tour, the surveyor noted distilled water was utilized for the ImmTox analyzer. 2. A review of the ImmTox operator's manual revealed on page 3, "1.a. Fill water tank with de-ionized water." 3. TP#1 confirmed the above findings during an interview on 8-28-2024 at 10:15 AM. |
| **D5439** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(b)<br><br>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) |

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| | -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.<br><br>This STANDARD is not met as evidenced by:<br>Based on review Urine Drug Screen 6 (UDS6) analyte package inserts, a lack of Calibration Verification (CV) records, and an interview with Testing Personnel #1 (TP#1), it was determined the laboratory failed to perform CV on UDS6 analytes on the ImmTox analyzer at least every six months. The laboratory failed to perform and document four out of four CV's due September 2022 through August 2024. Findings include: 1. A review of the UDS6 analytes package inserts revealed calibration information of less than three standards for each analyte. CLIA regulation requires analytes calibrated with less than three calibrators will require CV performed and documented at least every six months. There was no evidence of CV documentation provided during the survey. 2. TP#1 confirmed these findings during the exit conference on 8-28-2024, at 2:04 PM. |
| **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 a review of the room humidity logs, the Immtox wash station (WSH) temperature logs, the ImmTox operator's manual, and an interview with Testing Personnel #1 (TP#1), the laboratory failed to document corrective actions when room humidity, and ImmTox WSH temperatures were out of range. Room humidity was recorded lower than manufacturer's required environmental specification of 40-80 percent (%) for 8 days out of 26 days of patient testing; and the ImmTox WSH temperatures were recorded higher than manufacturer's required environmental specification of 37-39 degrees Celsius for 8 days out of 25 days of patient testing. |

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| | Findings include: 1. A review of the room humidity logs revealed room humidity was lower than the manufacturer's required ranges with no evidence of corrective action for the following days: a. October 2022; 2 out of the 7 days were recorded 31% - 33%, b. November 2022; 4 out of the 9 days were recorded 20% - 36%, c. December 2022; 2 out of the 10 days were recorded 29% - 32%. 2. A review of the Immtox operator's manual on page 1-10 revealed, "Ambient humidity 40-80%..." 3. A review of the Immtox WSH temperature logs revealed temperatures were greater than 39 degrees Celsius which is higher than the manufacturer's required ranges, with no evidence of corrective action for the following days: a. December 2022; 3 out of the 10 days of patient testing, b. April 2023; 3 out of the 7 days of patient testing, c. July 2024; 2 out of the 8 days of patient testing. 4. A review of the Immtox maintenance manual revealed on page 10 #3-B, "The acceptable WSH Temp is 38 degrees Celsius +/- 1 degree." 5. TP#1 confirmed these findings during the exit conference on 8-28-2024, at 2:04 PM. |
| **D5791** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(a)(c)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of Quality Assurance (QA) documentation and an interview with Testing Personnel #1 (TP#1), the laboratory failed to perform QA reviews according to the monthly QA chart in the procedure manual. This was noted from the previous survey (9-1-2022) through the current survey (8/28/2024). Findings include: 1. A review of the procedure manual revealed a schedule of monthly QA chart, however, there was no evidence of documentation of a monthly review from the previous survey (9-1-2022) through the current survey (8-28-2024). Failure to have a mechanism to monitor, assess, and correct laboratory issues contributed to the following deficiencies: A. Proficiency Testing 1. No signature on attestation statements (refer to D-2009). 2. No review of PT evaluation documentation (refer to D-5211). 3. No retention of PT for at least two years (refer to D-3037). B. General Laboratory System (Analytical) 1. Incorrect water utilized on the ImmTox analyzer (refer to D-5413). 2. No CV performed on the ImmTox analyzer (refer to D-5439). 3. No corrective action for days when room temperatures and ImmTox WSH humidity were outside the manufacturer's required specifications. 2. TP#1 confirmed these findings during the exit conference on 8-28-2024, at 2:04 PM. |
| **D6000** | MODERATE COMPLEXITY LABORATORY DIRECTOR<br>CFR(s): 493.1403<br><br>The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.<br><br>This CONDITION is not met as evidenced by:<br>Based on record review and an interview with the Laboratory Director (LD), the LD failed to fulfill responsibilities in providing overall laboratory management and |

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| | direction. Findings include: 1. Refer to D 6010 2. Refer to D 6014 3. Refer to D 6018 4. Refer to D 6021 |
| **D6010** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(2)<br><br>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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation of the entrance tour, record review, and an interview with Testing Personnel #1 (TP#1), the Laboratory Director (LD) failed to follow the required environmental testing conditions specified by the manufacturer. Findings include: 1. The LD failed to ensure the laboratory utilized the correct type of water during testing on the ImmTox analyzer (Refer to D-5413). 2. The LD failed to ensure environmental requirements for the ImmTox analyzer were within manufacturer's required specifications (Refer to D-5781) |
| **D6014** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(3)(iii)<br><br>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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review of calibrations, a lack of Calibration Verification (CV) records for the ImmTox Urine Drug Screen 6 (UDS6), and interview with Testing Personnel #1 (TP#1), the Laboratory Director failed to ensure CV's were performed every six months. Findings include: 1. Refer to D-5439 |
| **D6018** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(4)(iii)<br><br>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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;<br><br>This STANDARD is not met as evidenced by: |

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| | Based on review of College of American Pathologists (CAP) Proficiency Testing (PT), and an interview with Testing Personnel #1 (TP#1), the Laboratory Director failed to document, review, and evaluate all PT reports, and implement corrective action when necessary. Findings include: Refer to D 2009 Refer to D 5211 Refer to D 3037 |
| **D6021** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<br><br>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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review of the monthly Quality Assurance (QA) chart, College of American Pathologists (CAP) Proficiency Testing (PT), Policies and Procedures, and a lack of monthly QA documentation, the Laboratory Director failed to establish, document, and maintain a QA program to assure the quality of laboratory services. Findings include: Refer to D-5791 |