

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2026684	(X3) Date Survey Completed 09/01/2022
Name of Provider or Supplier Mobile Physical Medicine & Wellness Pc	Street Address, City, State 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
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on reviews of installation and validation records for the Immtox analyzer (used for qualitative Urine Drug Screening), laboratory procedures, and interviews with the Testing Personnel, the laboratory failed to ensure the manufacturer's performance specifications for accuracy and precision were verified, and the Laboratory Director/ Technical Consultant's review and approval was documented before patient testing began. This affected one of one new moderate-complexity instruments in the laboratory. The findings include: 1. During a review of the Immtox records, the surveyor asked if validation studies were performed on the Immtox during the installation. The Testing Personnel stated she and another testing personnel (previously employed) had run eleven positive and eleven negative Quality Controls (QC) on 2/9 and 2/10/2021 for a total of 44 determinations, as per the procedures. The surveyor requested the procedures for review. 2. During record reviews with the Testing Personnel on 9/1/2022 at 11:20 AM, the surveyor reviewed "Verification of Accuracy-Qualitative Moderate Complexity Assays", and "Verification of Precision-Qualitative Moderate Complexity Assays". The Testing Personnel then provided the Positive and Negative QC printouts for 2/9 and 2/10/2021, however there was no evidence the raw data had been analyzed and evaluated to confirm the accuracy and precision of the tests, as stated in the manufacturer's performance specifications. The</p>

validation and installation records further failed to include the Laboratory Director/ Technical Consultant's signature and date indicating his review and approval of the new procedures before patient testing began on 2/19/2021. 3. A review of the procedure, "Verification Protocol for Moderate Qualitative Urine Drug Screening and Validity Assays" revealed: "...3 Validity Study Overview ... 5. The Laboratory Director will review the verification data and determine the acceptability of the test system prior to the laboratory performing any patient testing.5. Evaluation and Summary of Data A summary of the verification studies and raw data will be sent to the Laboratory Director for review and approval. Each study summary will contain acceptability limits and an evaluation statement indicating whether the limits were met. ...". 4. During the exit interview on 9/1/2022 at 1:00 PM, the Testing Personnel confirmed the laboratory had failed to follow the above procedures when validating the Immtox analyzer. .

D6013

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(3)(ii)

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)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

This STANDARD is not met as evidenced by:
Based on reviews of installation and validation records for the Immtox analyzer (used for qualitative Urine Drug Screening), laboratory procedures, and interviews with the Testing Personnel, the Laboratory Director failed to ensure the manufacturer's performance specifications for accuracy and precision were verified, with review and approval by the Laboratory Director documented, before patient testing began on 2/19 /2021. This affected one of one new moderate-complexity instruments in the laboratory. The findings include: 1. Refer to D5421. SURVEYOR IS #32558
Licensure and Certification Surveyor