

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2034743	(X3) Date Survey Completed 04/01/2019
Name of Provider or Supplier Mobility Metabolism & Wellness Pc	Street Address, City, State 4357 Midmost Drive, 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
D5449	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on a review of quality control (QC) reports, patient worksheets, and an interview with the Laboratory Director (also the Testing Personnel), the surveyor determined the laboratory failed to ensure qualitative Negative and Positive QC produced expected results each day of patient testing. The findings include: 1. During the initial tour of the laboratory on 4/1/2019 at approximately 11:30 AM, the Laboratory Director explained he performed random drug analysis (to ensure compliance in pain management therapy) on urine and serum samples. The laboratory performed high-complexity testing (a 39-drug analysis panel) two to four times a week using the Agilent Technologies 6460 Quad LC/MS (Liquid Chromatography / Mass Spectrometry) analyzer. 2. A review of laboratory records revealed monthly files with hand-written patient worksheets, and print outs of the daily QC. The laboratory ran Negative, Low Positive QC (at the cutoff for each drug), and High Positive QC. While reviewing the 2017-2019 files, the surveyor noted the following: A) Report date-2/15/2019: The Low Positive and High Positive QC for Codeine were "Negative" B) Report date-3/08/2019: The Negative QC for Alprazolam, Amitriptyline, Ketamine, Methamphetamine, Methylphenidate, and Phentermine was "Positive". 3. During an interview with the Laboratory Director on 4/1/2019 at approximately 3:00 PM, the surveyor explained the CLIA requirement of performing Negative and Positive QC with each LC/MS run, and asked if patient testing was affected since the QC performed did not produce the expected results. The Laboratory</p>

Director reviewed the 2/15/2019 QC and stated there had been a "computer analysis problem", and the QC "needs reintegration". The Laboratory Director then reviewed the 3/8/2019 QC, and described the results as a "mediocre run" because of a "calibrator stability problem". He further stated patients results were reported from both runs, however the data took longer to review and analyze. 4. During the survey summation on 4/1/2019 at approximately 4:30 PM, the surveyor reviewed the findings and explained the CLIA requirement of ensuring the positive and negative produce acceptable results each day of patient testing. If the Laboratory Director accepted patient runs when QC produced unexpected results, the Director should document what was done to ensure the patient results were not affected that day.

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 a review of quality control (QC) reports, patient worksheets, and an interview with the Laboratory Director (also the Testing Personnel), the surveyor determined the laboratory failed to implement a mechanism to ensure: (1) the "Date Tested" was recorded on QC reports to document QC was performed each day of patient test runs. The findings include: 1. During the initial tour of the laboratory on 4/1/2019 at approximately 11:30 AM, the Laboratory Director explained he performed random drug analysis (to ensure compliance in pain management therapy) on urine and serum samples. The laboratory performed high-complexity testing (a 39-drug analysis panel) two to four times a week using the Agilent Technologies 6460 Quad LC/MS (Liquid Chromatography / Mass Spectrometry) analyzer. 2. A review of laboratory records revealed monthly files with hand-written patient worksheets, and print outs of the daily QC. The laboratory ran Negative, Low Positive QC (at the cutoff for each drug), and High Positive QC. While reviewing the 2017-2019 files, the surveyor noted on more than half of the QC reports for the two year period, only the "Report date and time" was documented. Thus the surveyor was unable to match the QC with the patient runs to ensure QC was performed each day of patient testing. For example, dates at the tops of the March 2019 patient worksheets were 3/1, 3/8, 3/13, and 3/15, whereas report dates on the QC were 3/8, 3/19, 3/20, and 3/22/19. 3. During an interview with the Laboratory Director on 4/1/2019 at approximately 3:00 PM, the surveyor explained the CLIA requirement of performing QC with each LC/MS run. The surveyor then asked the Laboratory Director why the Report dates on the QC reports did not match dates on the patient worksheets. The Director explained he always ran QC with every patient test run, and demonstrated the Agilent Technologies computer recorded the date and time for each of the QC and patient samples run thru the analyzer. He then printed the QC for each of the patient runs in March 2019, however the run date was still not recorded on the QC report. 4. As the interview continued on 4/1/2019, the Director further explained the run date was not on the QC reports because this information needed to be entered when manually loading the worklist onto the Agilent computer. This information was on some of the QC reports because the Lab Assistant had entered the worklist with the test date noted, however the Director often failed to enter the test date when he entered the worklist himself. The director further stated the date on the hand-written worksheets was the

"Preparation date" for the patient specimens, and this could be different from the run date, and the report date (the date all the data was reviewed, analyzed and interpreted); he stated he often analyzed data from several run dates, thus the QC reports for different run dates may all have the same report date. 5. During the survey summation on 4/1/2019 at approximately 4:30 PM, the surveyor reviewed the findings and explained the laboratory's current mechanism of documentation did not demonstrate performance of QC with each LC/MS run. The laboratory needed a mechanism that documented the date patient samples were prepared, the run date for each batch of QC and patient samples, and the date the data was analyzed and interpreted. SURVEYOR ID#32558 Licensure and Certification Surveyor