

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2128061	(X3) Date Survey Completed 03/29/2024
Name of Provider or Supplier Blue Water Pain Solutions	Street Address, City, State 2 Oakwood Blvd Ste#195, Hollywood, FL	
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
D0000	An initial certification survey conducted from 03/19/2024 to 03/29/2024 found that the BLUE WATER PAIN SOLUTIONS clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review and interview, the laboratory had the following expired urine calibrators in use: ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP) since 01/01/2024 and Buprenorphine since 02/01/2024 in the urine drug screen test. Findings included: -During the laboratory tour on 03/19/2021 at 10:30 AM, the surveyor observed that the laboratory was using the following expired calibrators from Immunoanalysis: EDDP lot E48928 expired since 01/01/2024 and Buprenorphine lot E49217 since 02/01/2024 for the Immtox 270 urine drug screen test. -Review of patient records revealed that the laboratory tested 168 patients using the expired calibrators since 01/01/2024 to present for the calibrators listed above. During an interview on 03/19/2024 at 1:30 PM the Technical Supervisor confirmed that the laboratory continue to use expired calibrators for the period listed above.</p>
D5423	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2)</p> <p>Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test</p>

system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

Based on record review and interview the laboratory failed to complete the performance specification verification for the AB Sciex Tripe Quad 4500 LCMS Urine Drug detection for Naltrexone and Tapentadol since 08/29/2023. Findings included: -Review of test menu listed on Form CMS-116, signed by the Laboratory Director (LD) on 03/15/2024, the laboratory listed the following urine drugs detected in the confirmation test using the AB Sciex Triple Quad 4500 LCMS: 6-Monoacetylmorphine (6-MAM), 7-Aminoclonazepam, Alpha-Hydroxy alprazolam, Amitriptyline, Amphetamine, Benzoylcegonine (Cocaine metabolite), Buprenorphine, Butalbital, Carisoprodol, Clonazepam, Codeine, Cyclobenzaprine, Diazepam, Duloxetine, Methadone metabolite (EDDP), Ethyl Glucuronide, Ethyl Sulfate, Fentanyl, Flunitrazepam, Hydrocodone, Hydromorphone, Lorazepam, Methylenedioxyamphetamine (MDA), 3,4-Methylenedioxy-N-ethylamphetamine (MDEA), 3,4-Methylenedioxymethamphetamine (MDMA), Meperidine, Meprobamate, Methadone, Methamphetamine, Morphine, Naloxone, Naltrexone, Norbuprenorphine, Nordiazepam, Nor fentanyl, Normeperidine, Nor oxycodone, O-Desmethyltramadol, Oxazepam, Oxycodone, Oxymorphone, Phencyclidine (PCP), Phenobarbital, Phentermine, Pregabalin, Tapentadol, Temazepam, Tramadol and Zolpidem. -Review of the performance specification verification study performed by the laboratory revealed that for the urine drug confirmation analytes for Naltrexone and Tapentadol the study was incomplete: the laboratory performed the method comparison with another laboratory and the results obtained for these two drugs were not acceptable because they had a bias higher than 25%, no further studies were done to confirm the accuracy of the results before including these two drugs to the test menu since the laboratory started testing on 08/29/2023. -The laboratory tested 323 patients with the test panel that included Naltrexone and Tapentadol from 08/09/2023 to present. During an interview on 03/19/2024 at 1:30 PM, the Technical Supervisor acknowledged that the laboratory included in the confirmation urine drug test panel the Naltrexone and Tapentadol, when the validation was not completed for those two analytes before patients testing started since 08/29/2023.