

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2005372	<b>(X3) Date Survey Completed</b>  02/11/2025
<b>Name of Provider or Supplier</b>  Orthopedic Center Of Palm Beach County	<b>Street Address, City, State</b>  180 John F Kennedy Dr Suite 100, Atlantis, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced CLIA initial survey was conducted at Orthopedic Center of Palm Beach County on February 4, 2025 to February 11, 2025. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following Condition was cited: D5400 - Analytic Systems 493.1250
<b>D5400</b>	<p><b>ANALYTIC SYSTEMS</b> CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on record review, and interview, the laboratory failed to complete performance specifications for Pain Panel Screening, Pain Panel Confirmation and sample stability before testing patients. (See D5423)</p>
<b>D5413</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(b)</p> <p>(b) 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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test</p>

reports.

This STANDARD is not met as evidenced by:

Based on observation, interview, review of the manufacturer's temperature requirements, procedure manual, temperature logs and performance specification (validation) for AB Sciex 4500 Liquid Chromatography-Mass Spectrometry (LC-MS), the laboratory failed to record the temperature of the refrigerator, freezer, and the room, and failed to monitor the humidity of the laboratories from 03/13/2024 to 03/31/2024, Findings: 1. Observations on 02/04/2025 at 11:50 AM, showed the Genetically Modified Beta-glucuronidase showed the storage temperature was 2-8 degrees Celsius (C). 2. Observations on 02/04/2025 at 11:50 AM, showed the Rapid Hydrolysis Buffer showed the storage temperature was 2-30 degrees C. 3. Review of the Certificate of Analysis for the Cerilliant showed the storage temperature was 10 to -20 degrees C. 4. Review of the Site Planning Guide for the AB Sciex 4500 Liquid Chromatography-Mass Spectrometry (LC-MS) noted, "An ambient temperature of 15 to 30C 2 per hour (46 to 86F 3.6 ) and a "Relative humidity from 20 to 80%, non-condensing." 5. Review of the procedure titled, Lab 105.1 Daily Temperature Checks noted, "All analyzers/testing environments that are sensitive to temperature and humidity are monitored daily and documented on the appropriate logs." 6. Review of the laboratory's temperature logs showed the laboratory started recording the temperatures on 04/03/2024. 7. Review of the performance specification for LC-MS analyzer showed the laboratory performed the performance specification on 03/13/2024 to 03/18/2024. 8. On 02/04/2024 at 11:09 AM, the Technical Supervisor stated there were not any temperatures logs before April 2024.

**D5423**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**  
CFR(s): 493.1253(b)(2)

(b)(2) 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 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: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(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 performance specifications for Pain Panel Screening, Pain Panel Confirmation and sample stability before testing patients. Findings Included: 1. Review of the test menu for the screening panel showed the following analytes were tested: Alprazolam, Amphetamine, Benzoylcegonine, Buprenorphine, Butalbital, MDMA (3,4-Methylenedioxymethamphetamine), Methadone, Morphine, Nortriptyline Oxazepam, Oxycodone, Phencyclidine, and THC (Tetrahydrocannabinol). 2. Review of the test menu for the confirmation panel showed the following analytes were tested : 6-Monoacetylmorphine, 7-Aminoclonazepam, Alpha-Hydroxyalprazolam, Alprazolam, Amitriptyline, Amphetamine, Benzoylcegonine, Buprenorphine, Bupropion, Butalbital, Carboxyzolpidem, Carisoprodol, Clonazepam, Codeine, Cyclobenzaprine,

Desipramine, Diazepam, Doxepin, Duloxetine, EDDP (2-Ethylidene-1,5-Dimethyl-3,3-Diphenylpyrrolidine), ETS (Ethyl sulfate), Fentanyl, Fluoxetine, Gabapentin, Hydrocodone, Hydromorphone, Imipramine, Ketamine, Lorazepam, MDMA, Meperidine, Meprobamate, Methadone, Methamphetamine, Midazolam, MitragynineMorphine, Naloxone, Naltrexone, N-desmethyl-Tapentadol, Norbuprenorphine, Norcodeine, Nordiazepam, Norfentanyl, Norhydrocodone, Normeperidine, Noroxycodone, Nortriptyline, O-Desmethyltramadol, Oxazepam, Oxycodone, Oxymorphone, Phencyclidine, Phenobarbital, Pregabalin, Ritalinic Acid, Secobarbital, Sertraline, Tapentadol, Temazepam, Tramadol, THC-COOH, Venlafaxine, and Zolpidem. 3. Review of Sample Stability Validation Report LC/MS /MS Pain Panel Confirmation signed by Technical Supervisor on 2/3/2025 revealed no written defined room, refrigerator and freezer temperatures for how to store and transport urine specimens for Pain Panel Screening and Pain Panel Confirmation. There was no negative specimen tested in the stability study. The study was not signed by the Laboratory Director. 4. Review of Analytical Method Validation Report LC/MS/MS Pain Panel Confirmation signed on 3/31/2024 by the Laboratory Director revealed there was no documentation of the interfering substance used. There was no written defined positive and negative cutoffs for 64 out of 64 toxicology targets. There were no defined concentrations used for precision and accuracy. There was no written documentation for what lot was used for the working control. 5. Review of Analytical Method Validation Report LC/MS/MS Pain Panel Screening signed on 03/31 /2024 by the Laboratory Director revealed there was no documentation of interfering substance. The was no written defined positive and negative cutoffs for 14 out of 14 toxicology targets. There were no defined concentrations used for precision and accuracy. There was no written documentation for what lot was used for the working control. 6. Review of Patient records revealed 1022 patients were tested from 04/01 /2024-02/04/2025 in toxicology. 7. On 2/4/2025 at 11:09 AM, the Technical Supervisor confirmed incomplete performance specifications for Pain Panel Screening, Pain Panel Confirmation and sample stability before testing patients.