

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  21D2282145	<b>(X3) Date Survey Completed</b>  04/26/2024
<b>Name of Provider or Supplier</b>  Legacy Spine And Pain Management Laboratory	<b>Street Address, City, State</b>  14205 Park Center Drive Suite 202, Laurel, MD	
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>D5403</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: I. Based on review of the manufacturer's product insert (PI), the standard operating procedure manual (SOPM), and patient test reports and interview with the technical consultant (TC), the laboratory's SOPM did not include instructions for specimen collection, storage, and transportation for the laboratory's urine drug screening (UDS) assay. Findings: 1. The laboratory tested patient urine specimens that were received from two clinic locations. 2. The PI for the UDS assay reagents stated "Specimens kept at room temperature that do not receive an initial test within 7 days of arrival at the laboratory may be placed into a secure refrigeration unit at 2 to 8C for up to two</p>

months. For longer storage prior to analysis or for sample retention after analysis, urine specimens may be stored at -20C. " 3. The procedure titled "Urine Storage" stated "Freshly collected urine shall be stored at 2 to 8 degrees C with centrifugation being performed within two (2) hours of collection. If rapid centrifugation is not possible, urine specimens shall be stored in the laboratory specimen refrigerator at a temperature of 2-8 degrees C." 4. There was no approved procedure for the laboratory or for the clinics that collected patient specimens describing requirements for specimen collection, storage, and transportation. 5. Records showed that 30 of 104 specimens received for testing were received greater than 7 days from the date of collection. 6. During the exit interview on 04/26/2024 at 3:25 PM, the TC confirmed that the clinics were storing specimens at refrigerated conditions, but that there was no approved procedure describing requirements for specimen collection, storage, and transportation. II. Based on review of the standard operating procedure manual (SOPM) and interview with the technical consultant (TC), the laboratory's SOPM did not include instructions for manually creating the final test report for the urine drug screening (UDS) assay. Findings: 1. Step 6 of the procedure titled "Standard Operating Procedure of in-coming Specimen (Urine samples) process" stated "Once results are ready need to make a UDS report to upload in the Athena EMR [electronic medical record] system for provider" and step 9 of the procedure titled "Operating procedure of Mindray 200" stated "Results are entered in the UDS report and upload to Athena health for provider." 2. At 9:40 AM on 04/26/2024 the TC stated that test reports were manually created within a template and then uploaded to the EMR. 3. During the exit interview on 04/26/2024 at 3:25 PM, the TC confirmed that there were no explicit instructions for how to access and modify the report template and then save and upload the patient test report into the EMR system.

**D5449**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(3)(ii)(g)

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.

This STANDARD is not met as evidenced by:  
Based on review of the procedure manual, patient reports, and quality control (QC) records, and interview with the technical consultant (TC), the laboratory failed to perform QC testing on one of seven days of patient testing for the urine drug screening assay. Findings: 1. The procedure titled "Control Procedures" stated "At least once each day patient specimens shall be assayed or examined ...For each qualitative procedure, include a negative and positive control material." 2. At the time of the survey the laboratory had performed patient testing on a total of seven days from March and April 2024. 3. Review of patient testing records showed that patients were tested on 03/08/2024 between 1:00:10-2:17:11 PM. 4. The "Legacy Spine and Pain Management QC Data Summary" showed that QC was performed on 03/07/2024 beginning at 9:51:52 AM, but was not run on 03/08/2024 prior to patient testing. 5. During the survey on 04/26/2024 at 1:55 PM, the TC confirmed that QC was performed on 03/07/2024, but the instrument ran out of cuvettes so patients could not be run on that day and were run the next day, 03/08/2024, once more cuvettes were loaded onto the machine. The TC also confirmed that QC was not repeated on 03/08/2024 prior to patient testing.

## TEST REPORT

CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on review of the procedure manual, specimen requisitions, and final test reports and interview with the technical consultant (TC), the laboratory's final test report did not contain accurate information for results interpretation for the urine drug screening (UDS) assay. Findings: 1. The laboratory's final test reports included sections for "Specimen Information," "Key Summary," "Specimen Final Outcome-Screening Results," and "Validity Testing." 2. The "Key Summary" section was meant to summarize all patient results to identify which results were consistent with prescribed medication. a. There were three summaries listed: i. "Unprescribed Drug Found" was to list the drugs that tested positive that were not prescribed by the provider. ii. "Prescribed Not Found" was to list the the drugs that tested negative that were prescribed by the provider. iii. "Prescribed Consistent" was to list the drugs that tested positive that were prescribed by the provider. b. All patient test reports stated "N/A" (not applicable) for all three summaries contained in this section. 3. The "Specimen Final Outcome-Screening Results" section identified the analyte tested, the result, and whether the result was "consistent" with the prescribed medications. a. The requisition for patient #1050 did not list any prescribed drugs. The test report showed that the specimen was positive for opiates & opioids and that this result was "consistent." b. The requisition for patient #3097 did not list any prescribed drugs. The test report showed that the specimen was positive for cocaine and ETG (ethyl glucuronide, a metabolite of ethanol) and that these results were "consistent." c. The requisition for patient #3162 listed oxycodone as a prescribed drug. The test report showed that the specimen was negative for oxycodone and that this result was "consistent." 4. The "Validity Testing" section stated the results of creatinine found in the specimen, which was an indicator of potential specimen adulteration, as well as whether the result was "consistent." a. The normal range for creatinine was listed as 20-350. A creatinine value that was within the normal range was reported as "Normal" and a result outside of the normal range was reported as "Abnormal." b. The test report for patient #174 showed that creatinine had a result of 350.3 which was reported as "Abnormal." The report stated that this result was "consistent" even though it was outside the normal range. 5. There was no procedure that described which results should be called "consistent." Cross-refer to tag D5403 II for additional details. 6. The footnote on the reports stated "The toxicology confirmation tests were developed and it's performance characteristics were determined by Legacy Laboratory. It has not been cleared and approved by the FDA. The Laboratory is regulated under CLIA /COLA as qualified to perform Moderate complexity testing." The UDS assay is for toxicology screening not confirmation and is not a laboratory developed test (LDT). 7. During the exit interview on 04/26/2024 at 2:25 PM, the TC confirmed that the final reports did not provide the results in the "Key Summary" section, called all results "consistent" even if they were not consistent with the prescribed medication or the

within the normal ranges (for creatinine), and described the assay as a LDT toxicology confirmation assay when it was a moderate-complexity toxicology screening assay.