Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2162857	08/24/2022
Name of Provider or Supplier	**Street Address, City, State**	
Outreach Recovery Laboratory	14205 Park Center Dr Suite 201, Laurel, MD	

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**
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review of the procedure and instrument comparison study results and interview with the technical supervisor (TS), the laboratory failed to define the acceptability criteria when detected values were above the upper limit of quantification (ULOQ) for the urine drug confirmation testing performed using liquid chromatography tandem mass spectrometry (LC/MS/MS) analyzers. Findings: 1. The procedure titled "Comparison Study between Two instruments (LC-1/LC2)" was reviewed. 2. The procedure stated that either proficiency testing (PT) samples or samples spiked with drug standards would be run on both LC/MS/MS analyzers designated "LC-1" and "LC-2" and the results compared. 3. The procedure stated that each analyte should be within plus or minus 10% of PT samples and plus or minus 15% of spiked samples to be considered acceptable. 4. The laboratory routinely performed instrument comparison studies using the PT results from the urine drug screening (UDC) programs. 5. The comparison using the PT event UDC-B 2022 showed that specimen UDC-07 tested positive for morphine with a value of 8574 for LC-1 and value of 6720.3 for LC-2, greater than 10%. 6. The comparison using the PT event UDC-A 2022 showed that specimen UDC-04 tested positive for the drug phenobarbital with a value of 6462.8 for LC-1 and 5510.3 for LC-2, greater than 10%. 7. The TS stated that when the values were above the ULOQ, it was acceptable for the results to be greater than 10%. This was not stated in the procedure or on the results summary from each comparison study. 8. During the survey on 08/19/2022 at 4:15

	PM, the TS confirmed that the instrument comparison study procedure and results summary did not define acceptability criteria for results that were above the ULOQ.
D5805	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 final test reports and interview with the technical supervisor (TS), the laboratory's final test reports failed to provide correct interpretation of urine drug screening and confirmation test results. Findings: 1. The laboratory's final report included a section stating the patients' prescribed medications titled "Medications", a section listing all drugs detected as positive titled "Positive Summary", a section titled "Inconsistent: Prescribed - Not Detected" for drugs that were prescribed and not detected, a section titled "Inconsistent: Not Prescribed - Detected" for drugs that were not prescribed and detected, and sections for the results of individual drugs tested on the screening and confirmation assays. 2. All final test reports reviewed listed drugs that were prescribed and were detected in the patient urine specimens under the "Inconsistent: Not Prescribed - Detected" section. 3. For example, the final test report for accession number 104090 listed prescribed medications as "buprenorphine-naloxone." 4. The "Positive Summary" listed "Benzodiazepines", "Buprenorphine", and "THC" (tetrahydrocannabinol) as positive from the screening assay and "7-Aminoclonazepam", "Buprenorphine", "Norbuprenorphine", and "THC" as positive from the confirmation assay. 5. The drug "Naloxone" was listed under the section titled "Inconsistent: Prescribed - Not Detected" as the patient was prescribed a form of naloxone and tested negative for the drug in the confirmation assay. 6. The drugs "Benzodiazepines", "7-Aminoclonazepam" (a metabolite of the benzodiazepine clonazepam), and "THC" were listed in the section titled "Inconsistent: Not Prescribed - Detected" as the patient tested positive but was not prescribed any of these drugs. 7. The drugs "Buprenorphine" and "Norbuprenorphine" (a metabolite of buprenorphine) were, however, also listed in the section titled "Inconsistent: Not Prescribed - Detected" when these drugs were consistent with the patient's prescribed medication. 8. The TS stated that there was an error in the reporting software that enabled detected drugs that were consistent with prescribed medications to be reported as "Inconsistent: Not Prescribed - Detected" and the error had not been fixed. 9. During the survey on 08/19/2022 at 4:15 PM, the TS confirmed that the laboratory's final reports for urine drug screening and confirmation testing incorrectly interpreted drugs that were detected and consistent with prescribed medications as "Inconsistent: Not Prescribed - Detected."