

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2162857	(X3) Date Survey Completed 03/20/2024
Name of Provider or Supplier Outreach Recovery Laboratory	Street Address, City, State 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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of the competency procedure and interview with the technical supervisor (TS), the laboratory failed to ensure that a competency assessment was performed for the TS who is also the general supervisor (GS) in their regulatory roles as TS and GS. Findings: 1. Procedure OR-028 titled "Competency Assessment" stated "Documented competency assessment shall be required for individuals fulfilling the following staff responsibilities as outlined in Subpart M of the CLIA regulations: Clinical consultant (CC), Technical consultant (TC), Technical supervisor (TS), General supervisor (GS), Testing personnel (TP)" and "CCs, TCs, TSs and GSs who perform testing on patient specimens are required to have the six (6) required procedures in their competency assessment in addition to a competency assessment based on their federal regulatory responsibilities." 2. During the exit interview on 03/20/2024 at 4:15 PM, the TS confirmed that a competency assessment was not performed by the laboratory director for the TS/GS in their regulatory responsibilities as the TS and GS.</p>
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)</p>

The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the quality control (QC) records and interview with the technical supervisor (TS), the laboratory failed to ensure that two levels of QC were run each day patient specimens were tested for the urine drug screening assay. Findings: 1. The QC Levey-Jennings charts were reviewed from 01/2023-02/2024 for a total of 14 months. 2. A single level of QC for buprenorphine was run for 6 of 14 months reviewed and for 19 of 20 days tested in 07/2023; 20 of 21 days tested in 01/2023 and 11/2023; 21 of 22 days tested in 03/2023, 05/2023, and 01/2024; and 22 of 23 days tested in 06/2023 and 08/2023. 3. A single level of QC for phencyclidine was run for 9 of 19 days tested in 04/2023. 4. A single level of QC for cannabinoids was run for 21 of 21 days in 01/2023. 5. During the exit interview on 03/20/2024 at 4:20 PM, the TS confirmed that two levels of QC were not run each day patient specimens were tested for the urine drug screening assay.