

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  23D2040138	<b>(X3) Date Survey Completed</b>  02/19/2020
<b>Name of Provider or Supplier</b>  Unique Laboratory Solutions	<b>Street Address, City, State</b>  8560 N Silvery Lane Suite 300, Dearborn Heights, MI	
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>D2015</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Supervisor (TS), the laboratory failed to maintain a copy of the College of American Pathologists (CAP) signed attestation statement sheets and documentation of review of the final graded PT reports by the testing personnel (TP) for 3 (Urine Toxicology (UT) -B and C 2019 and Drug Monitoring Pain Management (DMPM) - B 2019) of 7 events reviewed. Findings include: 1. Record review of the final graded CAP proficiency testing reports revealed the laboratory failed to maintain the following for 3 of 7 events: a. No documentation of review of the final graded report by the TP for UT-B, C and DMPM-B in 2019 b. No signed attestation statement sheet for UT-B, C and DMPM-B in 2019 2. During the interview on 2/19/2020 at 2:25 pm, the TS confirmed the laboratory did not maintain all the documentation listed above for 2019. .</p>
<b>D5407</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p>

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Technical Supervisor (TS), the Laboratory Director (LD) failed to approve, sign, and date each procedure with a change in laboratory name and Clinical Laboratory Improvement Act (CLIA) number for 12 (March 2019 to February 2020) of 12 months of operation. Findings include: 1. A review of the "Quality Assurance (QA) Book" revealed the LD failed to approve, sign, and date procedures with the change in the laboratory name and CLIA number for 12 of 12 months of operation. Procedures include: a. "Infection Control Policy" b. "Biohazardous Safety Policy" c. "Reporting Devices - Related Adverse Events to FDA" d. "Incident Management Plan" e. "QA goals, objective and responsibility scope" f. "Internal QA" g. "Quality Assurance Plan" 2. During the interview on 2/19 /2020 at 2:25 pm, the TS confirmed the above procedures were not signed and dated by the LD when the laboratory changes took place.