

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D1044073	<b>(X3) Date Survey Completed</b>  09/12/2019
<b>Name of Provider or Supplier</b>  United Laboratory Services Corp	<b>Street Address, City, State</b>  7095 Sw 47th St Bldg B, Miami, 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>	A recertification survey conducted, 9/11-12/2019 found that United Laboratory Services Corp clinical laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories.
<b>D2009</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have proficiency testing attestations with laboratory director (LD) and/or testing personnel (TP) signatures for 4 out of 6 (2017 3rd ; 2018 (1st, 2nd and 3rd) events; 2019 (1st and 2nd) events reviewed for the specialties of Microbiology, Diagnostic Immunology, Chemistry and Hematology . The findings include: -Review of the American Association of Bioanalysts (AAB) proficiency testing records for 2017 (3rd event), 2018 (1st, 2nd and 3rd) events and 2019 (1st, and 2nd) events, revealed no signed attestation for the following tests: Detection of Human Immunodeficiency Virus (HIV), Hepatitis, Cytomegalovirus, Herpes Type I and II Immunoglobulin (IgG), toxoplasma, Erythrocyte Sedimentation Rate (ESR), Leukocytes, Erythrocytes, Hemoglobin, Hematocrit, Platelets, Neutrophil, Lymphocytes, Monocyte, Eosinophil, Basophil, Prothrombin Time, International Normalized Ratio (INR), International Sensitivity Index (ISI), Normal Mean (GMNPT), Activated Partial Thromboplastin, IgG, Immunoglobulin A (IgA), Immunoglobulin M (IgM), Immunoglobulin E (IgE), Complement C3 and C4, Reticulocyte Count, antinuclear Antibody (ANA), Sickle Cell, Syphilis RPR, C reactive Protein, Rheumatoid factor, Infectious mononucleosis, Anti-streptolysin O, Hemoglobin A1c, in 2017 for 3rd event. -Review of College of American Pathologist (CAP) proficiency testing records 2017 (3rd event), 2018 (1st,</p>

	<p>2nd and 3rd) events and 2019 (1st and 2nd) events, revealed that there was no signed attestation for the following tests: - Syphilis, Infectious Mononucleosis and Anti-streptolysin tests by LD and TP for 3 out of 3 proficiency testing (PT) events in 2018 During an Interview on 9/11/2019 at 2:30 pm, the Technical Supervisor confirmed that the attestations were not signed by the LD or TP for the events of reference.</p>
<p><b>D2076</b></p>	<p><b>GENERAL IMMUNOLOGY</b> CFR(s): 493.837(b)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have a score above 80 percent for 2 out of 6 proficiency testing (PT) events in the specialty of General Immunology for 2 out of 2 years reviewed. Findings Include: -Review of the American Association of Bioanalysts (AAB) proficiency testing records of 2018 and 2019 revealed a 0 % score for Complement 3(C3) and Complement 4(C4) in the second event of 2018, resulting in an overall score of 77 % for the General Immunology specialty. -Review of the College of American Pathologists (CAP) proficiency testing record in 2018 and 2019 revealed a 0 % score for Hepatitis Core Antigen Antibodies (Anti-Hbc) in the second event of 2019, resulting in a overall score of 66 % for the General Immunology Specialty During an interview on 9/11 /2019 at 12:30 pm, the Technical Supervisor confirmed that the laboratory failed the events of reference for Diagnostic Immunology.</p>
<p><b>D2087</b></p>	<p><b>ROUTINE CHEMISTRY</b> CFR(s): 493.841(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to ensure a proficiency testing score above 80 percent for each analyte for 1 out of 6 events reviewed in the Chemistry specialty for the last 2 years. Findings include: A review of the American Association of Bioanalysts (AAB) proficiency testing records for 2017 3rd event, 2018 (1st, 2nd and 3rd) events and 2019 (1st and 2nd) events, revealed the following: - Alanine Amino Transferase (ALT) test received a score of 40 percent in 2018 for the 3rd PT event. During an interview on 9/12/2019 at 2:30 PM, testing personnel # 3 confirmed that analyte of reference received a score of less than 80 percent for the event of reference.</p>
<p><b>D2098</b></p>	<p><b>ENDOCRINOLOGY</b> CFR(s): 493.843(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on record review and staff interview, the laboratory failed to ensure a proficiency testing score above 80 percent for each analyte for 2 out of 6 events reviewed in the Endocrinology specialty for the last 2 years. Findings include: -A review of the American Association of Bioanalysts (AAB) proficiency testing records for 2017 3rd event, 2018 (1st, 2nd and 3rd) events and 2019 (1st and 2nd) events, revealed the following: Thyroxine received a 60 % score for the 3rd event of 2017. - Review of the College of American Pathologists (CAP) proficiency testing record in 2017 3rd event, 2018 (1st, 2nd and 3rd) events and 2019 (1st and 2nd) events revealed 20 % score for Free Thyroxine analyte for the 3rd event of 2018. During an interview on 9/12/2019 at 2:30 PM, testing personnel # 3 confirmed that analytes of reference received a score of less than 80 percent for the events of reference. .

**D5211**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**  
CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:  
Based on record review and staff interview, the Laboratory Director (LD) failed to document the review and evaluation of the proficiency testing (PT) results for 2 out of 6 events reviewed. Findings include: Review of College of American Pathologists (CAP) PT records, for 2017 1st event, 2018 1st, 2nd and 3rd events and 2019 (1st and 2nd ) events, showed that the LD failed to sign and date the results for the Special Immunology test package that includes the following tests: Haptoglobin, Immunoglobulin G (IgG), Transferrin, Helicobacter pylori, Anti Dexoribonucleic acid antibody double and single strand (Anti-DNA ds) for 1st and 2nd events during 2018. During an interview on 9/12/2019 at 2:30 PM, testing personnel # 3 confirmed that the LD failed to sign and date the results review for the events of above reference.

**D6091**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(4)(iii)

The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.

This STANDARD is not met as evidenced by:  
Based on proficiency testing (PT) records review and interview with laboratory staff, the laboratory director (LD), failed to document the review of PT results and the signing of the attestations for 2 out of 2 years reviewed. Findings include: -Failure to have attestation signed (refers to D 2009) -Failure to sign and date PT results review (refers to D5211) During an interview on 9/12/2019 at 2:30 PM, testing personnel # 3 confirmed missing documentation listed above.