Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1044073	05/15/2025
Name of Provider or Supplier	**Street Address, City, State**	
United Laboratory Services Corp	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An announced CLIA recertification survey was conducted at UNITED LABORATORY SERVICES CORP from 04/22/2025 to 05/15/2025. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D2075	GENERAL IMMUNOLOGY CFR(s): 493.837(a) (a) 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. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to score at least 80 % in the following analytes: Complement C3 protein (C3), Complement protein (C4), Immunoglobulin A (IgA), Immunoglobulin G (IgG) and Immunoglobulin M (IgM) in the first event of 2024 and for Rheumatoid antibody test in 3rd event of 2024. Findings included: 1- Review of proficiency testing records for American American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) revealed that the laboratory had unsatisfactory scores for the following analytes of the immunology specialty: - 60 % score of C3, C4, IgA, IgG and IgM tests in the 1st event of 2024. - 0 % score in the Rheumatoid antibody test in the 3rd event of 2024 2- During an interview on 05/15/2025 at 9:05 AM, the owner confirmed the laboratory failed proficiency testing score of the analytes of reference.
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a) (a) 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. This STANDARD is not met as evidenced by: Based on records review and staff interview, the laboratory failed to score at least 80% in Proficiency Testing (PT) for the following analytes Cholesterol Total, Cholesterol-HDL, Iron Total, Bilirubin Total, Prostate-Specific Antigen (PSA) Total, Folate and Uric Acid for Routine Chemistry reviewed for 2024 and 2025. Findings include: 1- Review of American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) records for 2024 (1st, 2nd and 3rd) and 2025 (1st event) revealed the following failing scores: - 1st event 2024: 60% Total Bilirubin; - 2nd event 2024: 60% Cholesterol Total, 40% Iron Total; - 3rd event 2024: 40% Cholesterol-HDL; - 1st event 2025: 20% Creatinine, 20% PSA total. 2- During an interview on 05/15/2025 at 09:20 AM, the owner confirmed the failing PT score for the analytes of reference in Routine Chemistry.
D2098	ENDOCRINOLOGY CFR(s): 493.843(a) (a) 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. This STANDARD is not met as evidenced by: Based on records review and staff interview, the laboratory failed to score at least 80% in Proficiency Testing (PT) for the following analytes: Cortisol, Free Thyroxine (Free TY), Luteinizing Hormone, Follicle Stimulating Hormone (FSH), Thyroxine (TY) for Endocrinology specialty reviewed for 2024 and 2025. Findings included: 1- Review of American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) records for 2024 (1st, 2nd and 3rd) and 2025 (1st event) revealed the following failing scores: - 1st event 2024: 20% Cortisol; - 3rd event 2024: 0% T3 Uptake, 20% TY; - 1st event 2025: 20% Folate serum, 60% Free TY, 0% LH, 0% Prolactin (PRL). 2- During an interview on 05/15/2025 at 09:22 AM, the owner confirmed the failed PT score for the analytes of reference in Endocrinology specialty.
D2121	HEMATOLOGY CFR(s): 493.851(a) (a) 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. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and staff interview, the laboratory failed to score at least 80% on the Platelets in the second event of 2024. Findings included: 1-Review of American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) records for 2024 and 2025 revealed that the laboratory received a score of 40% for the Platelets in the second event of 2024. 2-During an interview on 05/15/2025 at 09:26 AM, the laboratory owner confirmed the failling PT score for the Platelet analyte in the event of reference.

D2122	HEMATOLOGY CFR(s): 493.851(b) (b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and staff interview, the laboratory received an unsatisfactory score in the first event of 2024 and in the first event of 2025 for the specialty of Hematology. Findings included: 1-Review of American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) records for 2024 and 2025 revealed the following results: 1st event 2024: 0% Hematocrit, 40% Hemoglobin (HGB), 0% Partial Thromboplastin Time (PTT) and 0% Prothrombin Time (PT) resulting in an overall score of 55% in the first event of 2024. 1st event 2025: 0% Red Blood Cells (RBC), 0% Hematocrit, 0% Hematocrit and 60% PT resulting in an overall score of 71% in the first event of 2025 2-During an interview on 05/15/2025 at 09:25 AM, the laboratory owner confirmed the laboratory failed the PT testing for the Hematology events of reference.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on review of Beckman Coulter Access 2 Analyzer Manual, instrument printouts review and staff interview the laboratory failed to follow manufacturer instructions using expired reagents, controls and calibrations for Carcinogen Embryonic Antigen (CEA2), Cortisol, Folate, Free Triiodothyronine (FreeT3), Prostatic Antigen (PSA-Hyb), Progesterone, Thyroid Stimulating Hormone (TSH3), Testosterone, Total T3, Human Folicle Stimulating Hormone (hFSH), Human Luteinizing Hormone (hLH) on 05/27/2024. Findings included: 1-Review of Access 2 Analyzer Manual on pages 93 to 95 revealed on section "Test Result Flags" "If something occurs while a sample is running, the system associates a flag to the test result. Use the Sample details to read the flag description associated with a result. Select Troubleshoot F2 to find troubleshooting information about the flag. There are two types of test results Flags. Fatal Flags- no calculated result is given, Non-Fatal Flags a result was calculated but a condition exists for the result". And corrections are required. Listed of Non-Fatal Flags: CEX: Calibration expired, LEX Reagent Lot expired, PEX reagent Pack expired, QEX Quality Control lot expired, QCF Quality Control Failure. 2-Review of Quality Control (QC) instrument printouts for the Access 2 for testing date 05/27 /2024 revealed that the QC results printed on 05/29/2024 at 4:29 PM for the Biorad 1, 2 and 3 Q. The results showed flags for the following analytes: Control 1, 2 and 3: - CEA2 with CEX, PEX and QEX -Cortisol: QEX -Folate: QEX; FT3: CEX, PEX, QEX - PSA-Hyb: QEX - Progesterone QEX; TSH3: QEX -Testosterone: CEX, PEX, QEX -Total T3: QEX - hFSH: QEX - hLH: CEX, PEX, QEX. 3-Review of another set of printouts of the QC records with same time and date (05/27/2024) printed on 01/21 /2025 at 12:15 PM and had the Supervisor signature did not have any flag. 4-Review of American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE)

	Proficiency Testing (PT) samples (PT#6, PT#7, PT#8 and PT#10) tested on 05/27 /2024 and printed on 05/29/2024 at 4:29 PM, revealed that the FT3 test had the flags CEX and PEX. The laboratory reported the results. 5- During an interview on 04/23 /2025 at 11:24 AM with a laboratory assistant, she confirmed that there were two sets of results for the QC for 05/27/2024. During a phone call on 05/15/2025 at 09:05 AM the owner confirmed that the laboratory reported the FT3 results with the flag.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to perform maintenance for the CellDyn Emerald 22 and ACL Elite as specified by the manufacturer for period reviewed January through December of 2024 and January through April of 2025. Findings included: 1- Review of maintenance records for the CellDyn Emerald 22 serial number 310321-OD0292, initially revealed that the laboratory did not record the quarterly and semiannually maintenance recommended by the manufacturer in 2024 and 2025. The laboratory did not use the correct log as per manufacturer. 2- Review of the CellDyn Emerald 22 operator's manual PN 9141000 F Table E1. Maintenance Log procedure listed weekly, quarterly and semiannually maintenance that the laboratory did not follow. a. Weekly - Bleach cleaning b. Quarterly - Lubricate the Pistons, Inline Filter Cleaning, and Barcode Reader Cleaning c. Semiannually - Particle Air Filter Cleaning, Needle Replacement, O-ring Replacement. 3- Review of maintenance records ACL ELITE Pro serial number 06110501, revealed that the laboratory did not perform monthly Air filter check and monthly clean in June, July and August 2024 as per manufacturer Maintenance Log PN 774413 AA (Nov 2010) 4- Interview on 04/23/2025 at 2:10 PM the Laboratory Risk Management consultant admitted that the maintenance for the CellDyn Emerald 22 and ACL Elite Pro were not performed and recorded as per the manufacturer's frequency.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to document corrective action taken when the room temperature/humidity was out of range for the specialties of Serology, Hematology, Chemistry and Special Chemistry areas of the

	laboratory for 2024 and 2025. Findings included: 1-Record review of the Policy: Temperature Checks states in step 6, "If temperature's not meet the acceptance criteria, the supervisor must be notified for follow-up." 2-During a tour of the laboratory on 4/22/2025 at approximately 10:35 AM it was noted that the temperature /humidity logs in the specialty of Serology were outside the acceptable range, with no correction documented for February, May, June and September of 2024 and February of 2025. 4- Review of records for temperature/humidity in the specialty of Hematology, during the months of January, February, March, April, June, October, November, and December of 2024 showed no corrective action for days when temperature was outside the range. 5- Review of records for temperature/humidity, in the specialty of Chemistry during the month of February of 2024 showed no corrective action for days when temperature was outside of range. 6- Review of record for temperature/humidity, in the specialty of Special Chemistry during the months of February, March and April of 2025, and February of 2024 showed no corrective action for days when temperature was outside of range. 7- Review of the Temperature and Humidity Record form stated "NOTE: if temperature reading is not within expected range, document corrective action." 8- During interview on 04/24/2025 at approximately 4:30 PM, the laboratory Technical Consultant confirmed that the laboratory was not documenting the corrective action