Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1044073	01/09/2024
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	Recertification survey was conducted from 7/17/2023 to 01/09/2024. United Laboratory Services Corp clinical laboratory was not in compliance with 42 CFR Part 493, requirements for clinical laboratories. The following Conditions were not met: 5300 Preanalytic Systems 5400 Analytic Systems
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) 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. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview, the Laboratory Director and the Testing Personnel failed to sign the attestation form for PT for specialty of Chemistry, Diagnostic Immunology Hematology, and Microbiology in 2022. Findings included: Review of the Proficiency Testing Policy noted "The Medical Director and employees performing PT will sign off an attestation form of all survey before leaving the laboratory." The American Association of Bioanalysts (AAB) attestation form states "In addition to the analysts' signature, one of the following must sign once for all analytes reported on this form. Director or Technical Consultant (moderate complexity) or Technical Supervisor (high complexity)." 1. Review of the AAB PT records showed the attestation statements were not signed by the Laboratory Director for the following: 2022 2nd event for Hepatitis Markers, HIV (Human Immunodeficiency Virus), and Immunoproteins. 2022 3rd event for Antinuclear Antibody, Antistreptolysin O, Blood Cell Identification, Coagulation, COVID-19/SARS Antigen, C-Reactive Protein, Erythrocyte Sedimentation Rate, Fertility - Endocrinology, Glycohemoglobin, Helicobacter Pylori, Hematology with Diff C, Hepatitis Markers, HIV (Human Immunodeficiency Virus) Markers, Immunochemistry, Immunoprotein, Infectious Mononucleosis, Iron Binding, Lipids,

	Parasitology, Reticulocyte Count Manual, Rheumatoid Factor, Syphilis Serology, Therapeutic Drugs, Tumor Markers, and Urine Microalbumin. 2. Review of the AAB PT records showed the attestation statements were not signed by the Testing Personnel for the following: 2022 1st event for Blood Cell Identification, Hepatitis Markers, Immunochemistry, and Iron Binding. 2022 2nd event for Hepatitis Markers, HIV (Human Immunodeficiency Virus), Immunoproteins, and Urine Microalbumin. 2022 3rd event for Antinuclear Antibody, Antistreptolysin O, Basic Chemistry, Blood Cell Identification, Coagulation, Comprehensive Chemistry, COVID-19/SARS Antigen, C-Reactive Protein, Erythrocyte Sedimentation Rate, Fertility - Endocrinology, Glycohemoglobin, Helicobacter Pylori, Hematology with Diff C, Hepatitis Markers, HIV (Human Immunodeficiency Virus) Markers, Immunochemistry, Immunoprotein, Infectious Mononucleosis, Iron Binding, Lipids, Reticulocyte Count Manual, Rheumatoid Factor, Syphilis Serology, Therapeutic Drugs, Tumor Markers, and Urine Microalbumin. On 07/17/2023 at 2:05 PM, General Supervisor acknowledged that some of the attestations were not signed.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records, maintenance records, and interview, the laboratory failed to retain the hematology daily QC records for 19 (July 1, 4, 5, 6, 7, 9, 11, 12, 13, 14, 15, 16, 18, 19, 20, 21, 22, 23, 25 2022) of 20 (July 1, 4, 5, 6, 7, 8, 9, 11, 12, 13, 14, 15, 16, 18, 19, 20, 21, 22, 23, 25 2022) days of patient testing, and failed to retain the hematology patient's instrument test records for 16 (February 1, 2, 3, 4, 5, 7, 8, 9, 10, 11, 12, 14, 15, 16, 17, 18 2022) of 23 (February 1, 2, 3, 4, 5, 7, 8, 9, 10, 11, 12, 14, 16, 17, 18, 19, 21, 22, 23, 24, 25, 26, 28 2022) days of patient testing, Findings Included: 1. Review of the log for titled DxH800 Maintenance Log for July 2022 showed that maintenance on the hematology analyzer was performed on July 1, 4, 5, 6, 7, 8, 9, 11, 12, 13, 14, 15, 16, 18, 19, 20, 21, 22, 23, and 25 2022. The laboratory was not able to provide the daily QC printouts for July 1, 4, 5, 6, 7, 9, 11, 12, 13, 14, 15, 16, 18, 19, 20, 21, 22, 23, 25 2022. On 07/20/2023 at 3:30 PM, General Supervisor stated she was unable to find the hematology daily QC records. 2. Review of the logs for hematology titled QC Monthly Log and DxH800 Maintenance Log (hematology analyzer) for February showed daily QC was performed on February 1, 2, 3, 4, 5, 7, 8, 9, 10, 11, 12, 14, 15, 16, 17, 18, 19, 21, 22, 23, 24, 25, 26, and 28, 2022. Review of patient's CBC printouts for February 2022 revealed the patients instrument test records from February 1st to February 18th were missing. On 07/20 /2023 at 4:24 PM, General Supervisor stated she was unable to find the hematology patient's printouts.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall

	quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to run blood serum specimens within manufacturer's instructions for Antinuclear Antibody (ana) screen, Anti-double-stranded deoxyribonucleic acid antibodies (dsDNA) testing, Helicobacter pylori (H.pylori) testing, , Hsv-1 IgG, and Herpes Type II (HSV-2 Ig G) 12 (PT#1-12) out of 12 patients (PT) reviewed (D5311)
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on review patient test requisitions and interview, the laboratory failed to ensure the test requisition included the specimen collection time for 13 (#1 - #9, #12- #15) of 15 (#1 - #15 patients reviewed. Findings Included: Review of the patient test requisitions showed Patients #1 - #4 were collected on 2/22/2022, Patients #5 - #7 were collected on 2/28/2022, Patient #8 was collected on 01/05/2023, Patient #9 was collected on 01/06/2023, Patients #12 - #14 were collected on 05/18/2023, and Patient #15 was collected on 05/19/2023. No time of collection were recorded on the requisitions. On 07/26/2023 at 5:06 PM, General Supervisor acknowledged the test requisitions were missing the collection times.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to run blood

serum specimens within manufacturer's instructions for Antinuclear Antibody (ana) screen, Anti-double-stranded deoxyribonucleic acid antibodies (dsDNA) testing, Helicobacter pylori (H.pylori) testing, , Hsv-1 IgG, and Herpes Type II (HSV-2 Ig G) 12 (PT#1-12) out of 12 patients (PT) reviewed. Findings Included: Review of Ana Screen Test System procedure signed by laboratory director (LD) on 11/29/2021 package insert read, "Store sample at room temperature for no longer than 8 hours. If testing is not performed within 8 hours, sera may be stored between 2-8 Celsius (C) for no longer than 48 hours. If delay in testing is anticipated, store test sera at -20 C or lower." Review of DsDNA Test System procedure signed by laboratory director (LD) on 11/29/2021 package insert read, "Store sample at room temperature for no longer than 8 hours. If testing is not performed within 8 hours, sera may be stored between 2-8 Celsius (C) for no longer than 48 hours. If delay in testing is anticipated, store test sera at -20 C or lower." Review of H. Pylori Test System procedure signed by laboratory director (LD) on 11/29/2021 package insert read, "Store sample at room temperature for no longer than 8 hours. If testing is not performed within 8 hours, sera may be stored between 2-8 Celsius (C) for no longer than 48 hours. If delay in testing is anticipated, store test sera at -20 C or lower." Review of Hsv-1 IgG Test System procedure signed by laboratory director (LD) on 11/29/2021 package insert read, "Store sample at room temperature for no longer than 8 hours. If testing is not performed within 8 hours, sera may be stored between 2-8 Celsius (C) for no longer than 48 hours. If delay in testing is anticipated, store test sera at -20 C or lower." Review of HSV-2 Ig G Test System procedure signed by laboratory director (LD) on 11/29/2021 package insert read, "Store sample at room temperature for no longer than 8 hours. If testing is not performed within 8 hours, sera may be stored between 2-8 Celsius (C) for no longer than 48 hours. If delay in testing is anticipated, store test sera at -20 C or lower." Review of Herpes I (HSV-1) and Herpes II (HSV-2) testing worksheet revealed the following: A. PT# 1 blood specimen was collected on 5/27 /2023 for HSV-1 and HSV-2. B. PT#2 blood specimen was collected on 6/14/2023 for HSV-1 and HSV-2. C. PT#3 blood specimen was collected on 12/16/2022 for HSV-1 and HSV-2. Review of Dynex (DSX) HSV I and HSV II instrument printouts revealed the following: a. PT#3 blood specimen tested for HSV-1 and HSV-2 on 12/30/2022. b. PT #1 and PT#2 blood specimens tested for HSV-1 and HSV-2 on 6/22/2023. Review of Ana Screen testing worksheet revealed the following: A. PT#4 blood specimen was collected on 12/14/2021 for Ana Screen B. PT#5 blood specimen was collected on 12/15/2021 for Ana Screen. C. PT#6 blood specimen was collected on 6 /29/2023 for Ana Screen. D. PT#7 blood specimen was collected on 6/30/2023 for Ana Screen. E. PT#8 blood specimen was collected on 7/5/2023 for Ana Screen. F. PT#9 blood specimen was collected on 7/6/2023 for Ana Screen. Review of DSX Ana Screen instrument printouts revealed the following: a. PT#4 and PT#5 blood specimen tested for Ana Screen on 1/5/2022. b. PT #6, PT#7, PT#8, and PT#9 blood specimens tested for Ana Screen on 7/11/23. Review of H. Pylori testing worksheet revealed the following: A. PT#10 blood specimen was collected on 5/23/2023 for H. Pylori testing. B. PT#11 blood specimen was collected on 7/6/2023 for H. Pylori testing. C. PT#12 blood specimen was collected on 7/7/2023 for H. Pylori testing. Review of DSX H. Pylori testing instrument printouts revealed the following: a. PT#10 blood specimen tested for H. Pylori on 6/6/2023. b. PT#11 and PT#12 blood specimens were tested for H. Pylori on 7/11/23. On 7/26/2023 at 3:53PM, there was a freezer in the room which went from -10 to -30C. There were no blood tubes located in this freezer for long term storage of blood specimens. Review of 2023 Temperature Log Freezer an Area General (samples Freezer) revealed the following days temperatures above -20 C: a. 25 out of 31 days in January b. 23 out of 28 days in February c. 27 out of 31 days in March d. 25 out of 30 days in April e. 25 out of 31 days in May f. 25 out of 30 days in June g. 24 out of 31 days in July h. 23 out of 31 days in August i. 21 out of 30 days in

	September j. 20 out of 31 days in October k. 22 out of 30 days in November l. 22 out of 31 days in December On 7/18/2023 at 2PM Consultant confirmed the blood specimens were stored past their storage requirements for testing.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observation, record review and interview, the laboratory failed to complete a performance specification for infectious Mononucleosis latex testing before testing 2 out of 2 patients in 2022. (D5423) to run positive and negative controls for 2 out of 2 patients tested for infectious mononucleosis latex testing in 2022.(5449)
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on observation, record review and interview, the laboratory failed to complete a performance specification for infectious Mononucleosis latex testing before testing 2 out of 2 patients in 2022. Findings Included: Review of Performance Specifications for Infectious Mononucleosis latex test revealed the following laboratory had no performance specifications including accuracy, precision, analytical, sensitivity, reportable ranges for infectious mononucleosis latex test. Review of Infectious Mononucleosis(mono) results revealed the following: a. Patient 1 was collected on 5 /10/22 and resulted as negative for mono. b. Patient 2 was collected on 9/10/2022 and resulted as negative for mono. On 7/26/2023 at 2:30 PM, Consultant confirmed performance specifications or validation could not be located.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) 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) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview, the lab failed to run positive and negative controls for 2 out of 2 patients tested for infectious mononucleosis latex testing in 2022. Findings Included: Review of Infectious Mononucleosis (IM) latex test read, " use of positive and negative control will permit monitoring of reagent performance. Place one drop each of the IM positive and negative control onto separate test well. IM positive and Negative should be included in each test series." Review of IM Test control serology Quality Control Log revealed no positive and negative controls were done for May and September in 2022. Review of Infectious Mononucleosis(mono) results revealed the following: a. Patient 1 was collected on 5/10/22 and resulted as negative for mono. b. Patient 1 was collected on 9/10/2022 and resulted as negative for mono. On 7/26/2023 at 2:30 PM, Consultant confirmed IM positive and negative controls were not done for 2 patients.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the instrument printouts and interview, the Laboratory failed to perform daily quality controls (QC) prior to Patient test samples on the Cell-Dyn Emerald 22 AL Hematology analyzer for 2 of 2 months (February 2022, January 2023) reviewed, and on the ACL Elitepro Coagulation analyzer for 2 of 2 month (Novemenber 2022, March 2023) reviewed. 1. CBC (Complete Blood Count) 02/23 /22 - No controls were run, and 26 Patients were run at 9:14 AM, 9:38 AM, 9:39 AM, 10:59 AM, 11:00 AM, 11:32 AM, 12:19 PM, 1:08 PM (2 Patients), 1:09 PM, 1:10 PM, 9:02 PM, 9:08 PM, 9:29 PM, 9:30 PM (2 Patients), 9:31 PM, 9:32 PM (2 Patients), 9:33 PM, 9:34 PM, 9:35 PM (2 Patients), 9:36 PM, and 9:37 PM. 02/25/22 - Level 1 control was run at 12:50 PM, Level 2 control was run at 12:51 PM, and Level 3 control was run at 12:51 PM. 1 of 32 Patients run before running QC. The patient was run at 12:02 PM. 01/03/2023 - No controls were run, and 4 Patients were run at 10:06 AM, 11:25 AM, 11:27 AM, and 11:53 AM. 01/06/2023 -Level 1 control was run at 11:58 AM, Level 2 control was run at 12:00 PM, and Level 3 control was run at 12:01 PM. 2 of 25 Patients were run before running QC. Patients were run at 8:58 AM and 11:42 AM. 01/07/2023 - No controls were run, and 2 Patients run at 2:10 PM and 2:12 PM. 01/11/2023 - Level 1 control was run at 8:59 AM, Level 2 control was run at 9:00 AM, and Level 3 control was run at 9:02 AM. 11 of 35 Patients run before running QC. Patients were run at 8:33 AM, 8:34 AM, 8:36 AM, 8:37 AM, 8:39 AM, 8: 40 AM, 8:42 AM, 8:43 AM, 8:45 AM, 8:46 AM, and 8:49 AM 01/14/2023 - No controls were run, and 9 Patients run at 2:47 PM, 2:48 PM, 2:50 PM, 2:52 PM, 2:53 PM, 2:54 PM, 2:56 PM, 2:58 PM, and 3:55 PM. 01/18/2023 - Level 1 control was run at 3:02 PM, Level 2 control was run at 12:19 PM and 3:04 PM, and Level 3 control was run at 12:21 PM and 3:05 PM. 10 of 35 Patients run before running QC. Patients were run at 8:39 AM, 8:41 AM, 8:42 AM, 8:44 AM, 8:45 AM, 8:47 AM, 8:48 AM, 8:

	50 AM, 8:52 AM, and 8:53 AM. 01/21/2023 - No controls were run, and 12 Patients run at 1:54 PM, 1:55 PM, 1:57 PM, 1:58 PM, 2:00 PM, 2:01 PM, 2:41 PM, 2:06 PM, 2:07 PM, 2:09 PM, 2:30 PM, and 2:50 PM. 01/24/2023 - Level 1 control was run at 9:00 AM, Level 2 control was run at 9:01 PM, and Level 3 control was run at 9:03 PM. 10 of 42 patients run before running QC. Patients were run at 8:15 AM, 8:17 AM, 8:28 AM, 8:29 AM, 8:31 AM, 8:32 AM, 8:34 AM, 8:35 AM, 8:37 AM and 8:38 AM. 01/26/2023 - Level 1 control was run at 10:49 AM, Level 2 control was run at 10:42 AM, and Level 3 control was run at 10:44 AM. 2 of 2 Patients were run before running QC. Patients were run at 8:19 AM, and 8:21 AM. 01/28/23 - No controls were run, and 14 Patients were run at 5:14 PM, 5:15 PM, 5:16 PM, 5:18 PM, 5:19 PM, 5:21 PM, 5:23 PM, 5:24 PM, 5:26 PM, 5:27 PM, 5:29 PM, 5:30 PM, 5:32 PM, and 5:33 PM. 2. Reticulocyte Count 02/23/22 - No controls were run, and 11 Patients were run at 10:26 AM, 10:28 AM, 10:29 AM, 10:45 AM, 10:46 AM, 10:47 AM, 10:48 AM, 10:49 AM, 10:51 AM, and 10:52 AM. 3. PT (Prothrombin Time) and PTT (Partial Thromboplastin Time) 11/05/2022 - No controls were run, and 1 Patients PT/PTT was run at 2:47 PM/3:06 PM. 11/05/2022 - No controls were run, and 1 Patients PT/PTT was run at 2:27 PM/2:36 PM. 11/05/2022 - No controls were run, and 1 Patients PT/PTT was run at 10:07 AM/10:21 PM 03/09/2023 - No controls were run, and 1 Patients PT/PTT was run at 7:59 AM/7:54 AM. 03/11/2023 - No controls were run, and 1 Patients PT/PTT was run at 1:32 PM/1:25 PM. 03/17/2023 - No controls were run, and 5 Patients PT/PTT were run at 7:52 AM/7:48 AM, 11:31 AM/11:26 AM (2 Patients), and 1:57 PM/1:53 PM (2 Patients). 03/21/2023 - Two levels of controls for PT/PTT were run at 12:55 PM/12:51 PM and 1 of 2 patients was run at 8:12 AM/8:08 AM. 03/23/2023 - Two levels of controls for PT/PTT were run at 7:46 PM/7:42 PM and 4 of 5 patients were run at 7:38 AM/7:33 AM(4 Patients). On 07/26/2023 at 3:10 PM, General Supervisor acknowledged that patient specimens were run before daily qc was run and on days where no qc was run.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on review of worklist's and interview, the laboratory failed to identify the personnel who performed the testing for Chemistry for 1 of 19 days, Hematology for 20 of 20 days, Immunology for 5 of 5 days, and Microbiology for 3 of 19 days in May 2023. Findings Included: The worklist's included a list of the patients run, the date, and a place for the tech who performed the test to initial. Review of the Chemistry Worklist showed testing was performed on 19 days in May 2023 (1, 2, 3, 4, 8, 9, 11, 12, 15, 16, 17, 18, 19, 24, 25, 26, 29, 30, and 31). The worklist's failed to indicate who performed the testing on one day (05/11/2023). Review of the Hematology Worklist showed testing was performed on 20 days in May 2023 (1, 2, 3, 4, 5, 8, 9, 10, 11, 12, 15, 16, 17, 18, 22, 24, 25, 26, 29, and 30). The worklist's failed to indicate who performed the testing for all twenty days. Review of the Immunology Worklist showed testing was performed on 5 days in May 2023 (1, 2, 17, 19, and 26). The worklist's failed to indicate who performed the testing for all five days. Review of the

	Microbiology Worklist showed testing was performed on 19 days in May 2023 (1, 2, 4, 5, 8, 9, 10, 11, 12, 15, 16, 17, 18, 19, 22, 24, 25, 26, 29, and 31). The worklist's failed to indicate who performed the testing on three days (05/19/23, 05/24/23, 05/25 /2023). On 07/26/2023 at 3:32 PM, General Supervisor acknowledged that some of the worklists were missing the information on who performed the test.