Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1044073	08/11/2021
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	A recertification survey was conducted on 07/19/2021 to 08/11/2021, United Laboratory Services Corp clinical laboratory was found not in compliance with 42 CFR 493, Requirements for Clinical Laboratories. Based on the survey findings an Immediate Jeopardy situation was identified and the laboratory was notified of the Immediate Jeopardy on 08/11/2021 at 1:47 PM. The laboratory failed to follow Qiagen QuantiFERON - Tuberculosis (TB) Gold Plus (QFT-Plus) manufacturer instructions to ensure the quality of the blood specimens prior to testing for TB. The laboratory failed to reject specimens not incubated for 16 to 24 hours per manufacturer specimen guidelines for QFT-Plus. (D 5311)The laboratory failed to validate Advia Centaur human immunodeficiency virus (HIV) antigen (Ag) / antibody (Ab) Combo (CHIV) assay from 04/06/2020 to present and Bio-Rad Recombinant and Synthetic Peptides (GS) HIV-1/HIV-2 PLUS O Enzyme Immunoassay (EIA) from 02 /27/21 to present for use in the detection of HIV-1 and HIV-2 antibodies (D 5421). The laboratory failed to validate the Stanbio Rapid Plasma Reagin (RPR) Quicktest for use without humidifying covers, temperature ranges and revolutions per minute (rpm) outside of the Food and Drug Administration (FDA) approved manufacturer guidelines for Syphilis testing from December 2019 to present (D 5423). The laboratory failed to follow the Bio-Rad GS HIV-1/HIV-2 PLUS O EIA manufacturer's instructions for valid positive and negative controls to detect HIV-1 and HIV-2 antibodies from January 2020 to present (D 5481). The following conditions were cited: -D 2000- Enrollment and Testing of Samples -D 2016-Successful Participation -D 5200-General Laboratory Systems -D 5300-Preanalytic Systems -D 5400-Analytic Systems -D 6076- Laboratory Director
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner

	as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on record review and interview with General Supervisor (GS) A, the laboratory failed to enroll in a Proficiency Testing (PT) program approved by the Department of Health and Human Services (HHS) and Centers for Medicare and Medicaid Services (CMS) for anti-Human immunodeficiency antibody test (anti-HIV) and for Rubella antibody test for 2021. Findings included: -Review of test menu included in the CMS 116-form revealed that the laboratory is currently performing anti-HIV and Rubella antibody test. -Review of Casper report 96 Clinical Laboratory Improvement Amendments (CLIA) Application and Survey Summary report pulled on 07/12/2021 revealed the absence of anti-HIV and anti Rubella antibodies test results during 1st event of 2021. -Review of American Association of Bioanalysts (AAB) PT records revealed that the laboratory failed to enroll anti-HIV and Rubella antibody tests for 2021. During an interview on 07/20/2021 at 9:30 a.m. the GS A confirmed that the facility failed to enroll in PT for 2021 for the analytes of reference.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of laboratory proficiency testing records for 2019 and 2020, the laboratory did not have a successful performance for Activated Partial Thromboplastin Time (APTT). (See D 2130)
D2047	PARASITOLOGY CFR(s): 493.829(a) 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 record review and interview with General Supervisor A (GS A), the laboratory failed to get at least 80 % in proficiency testing for 1 out of 6 Parasitology events reviewed from 2019 to 2021. Findings included: Review of American Association of Bioanalysts (AAB) proficiency testing records from 2019 (3rd event) to 2021 (2nd event) revealed that the laboratory failed Parasitology, 2nd event of 2021 with a 60 % score resulting in a unsatisfactory event result. During an interview on 07 /26/2021 at 2:30 PM, the GS A confirmed that the laboratory failed the event of reference.
D2066	SYPHILIS SEROLOGY CFR(s): 493.835(a) 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 record review and interview with General Supervisor (GS) A, the laboratory failed to score at least 80% in proficiency testing for 1 (3rd event of 2019) out of 6 (2019 3rd event, 2021 2nd event) events for Syphilis Serology reviewed. Findings included: Review of American Association of Bioanalysts (AAB) proficiency testing records revealed a score of 60% for 3rd event of 2019 resulting in a unsatisfactory score for the Syphillis Serology subspecialty. During an interview on 07/26/2021 at 3: 30 PM, the GS A confirmed the failed proficiency testing score in Syphilis Serology.
D2075	GENERAL IMMUNOLOGY CFR(s): 493.837(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 interview with General Supervisor (GS) A, the laboratory failed to score at least 80 % in proficiency testing for Rheumatoid antibody test in 3rd event of 2019, anti-Human immunodeficiency antibody (anti-HIV) in 3rd event of 2020 and complement C3 protein (C3) in second event of 2021. Findings included: Review of proficiency testing records for American Association of Bioanalysts (AAB) revealed that the laboratory had unsatisfactory scores for the following analytes of the immunology specialty in the events listed below: - 60 % score in the Rheumatoid antibody test in the 3rd event of 2019 - 60 % score in the anti-HIV antibody test in the 3rd event of 2020 - 60 % score of C3 test in the 2nd event of 2021. During an interview on 07/26/2021 at 3:30 PM, the GS A confirmed the failed proficiency testing scores of the analytes referenced.
D2099	ENDOCRINOLOGY CFR(s): 493.843(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 record review and interview, the laboratory failed to obtain a score of at least 80 % in proficiency testing (PT) for 1 out of 6 events reviewed (3rd event 2019 to 2nd event 2021) of the Endocrinology subspecialty. Findings included: Record review for American Proficiency Institute (API) PT, revealed that the laboratory received a score of 60 % in Cortisol and 20 % in Thyroxine test for the 1st Event of 2020 resulting in a score of 70 % for Endocrinology. During an interview on 07/26 /2021 at 1:30 PM, the General Supervisor A confirmed the laboratory received an unsatisfactory score for the subspecialty of Endocrinology in the PT event of reference.
D2123	HEMATOLOGY CFR(s): 493.851(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to participate in proficiency testing (PT) for the 2nd event of 2021 for fibrinogen test. Findings included: Review of American Association of Bioanalysts (AAB) proficiency testing (PT) records revealed that the laboratory received a 0 % score for fibrinogen in the 2nd event of 2021. During an interview on 08/03/2021 at 12:30 PM, the General Supervisor A confirmed that the laboratory failed to notify the PT agency the laboratory was not testing fibrinogen at the time of the event of reference.
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory had unsatisfactory score results for the 1st and 3rd events of 2020 for the Activated Partial Thromboplastin Time (APTT) resulting in an unsuccessful result for this analyte Findings included: - Review of American Proficiency Institute (API) proficiency testing results in 2020, showed that the laboratory had analyte unsatisfactory score for APTT of 60 % score for the 1st and 3rd event of 2020 resulting in an unsuccessful result for this analyte. - The laboratory tested 1793 patients from 03/13/2020 to 07/21/2021. During an interview on 07/19/2021 at 2:00 PM, with General Supervisor A, she confirmed that the laboratory failed the events of reference for APTT.

D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to perform blind testing at least twice a year for the nonregulated Qiagen QuantiFERON-Tuberculosis (TB) Gold Plus (QFT-Plus) test for 2 (2020 and 2021) out of 2 years to determine the accuracy and reliability of TB testing.(See D 5217)
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to do a competency assessment for 1 out of 2 General Supervisors (GS) in 2021. Findings included: -Review of CMS 209 Laboratory Personnel Report dated and signed by the Laboratory Director (LD) on 07/19/2021 revealed the following: a) There were 2 GS. b) GS A, who oversees the Chemistry and Hematology section and GS B that it is the LD and oversees the Microbiology Section. -Review of personnel policy signed by the LD on 3/02/2021, revealed that the policy failed to include an evaluation for General Supervisor. -Review of Laboratory Employee records revealed that there were no records of competency assessment for GS A hired on March 2021. During an interview on 07/26/2021 at 12:30 PM with GS A, she confirmed that the laboratory's personnel policy failed to have a competency assessment for the General Supervisor.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to perform blind testing at least twice a year for the nonregulated Qiagen QuantiFERON-Tuberculosis (TB) Gold Plus (QFT-Plus) test for 2 (2020 and 2021) out of 2 years to determine the accuracy and reliability of TB testing. Findings included: Review of 2019-2021 College of American Pathologists (CAP) revealed QFT-Plus blind testing was performed twice a year in 2019. For 2020 and 2021, there was no documentation that QFT-Plus blind testing was performed twice annually for the 2 years. Review of 2020-2021 American

	Association of Bioanalysts (AAB) proficiency testing record revealed there was no written documentation of blind testing for QFT-Plus performed twice a year in 2020 and 2021. During an interview on 08/06/2021 at 1:47 PM, the owner confirmed the laboratory failed to perform blind testing at least twice a year for QFT-Plus test for 2 out of 2 years.
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 record review, and interview, the laboratory failed to follow Qiagen QuantiFERON- Tuberculosis(TB) Gold Plus (QFT-Plus) manufacturer's instructions to ensure the quality of blood specimens prior to testing for TB. The laboratory failed to reject QFT-Plus specimens not incubated for 16 to 24 hours per manufacturer guidelines. (see D 5311)
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 record review, and interview, the laboratory failed to follow Qiagen QuantiFERON- Tuberculosis (TB) Gold Plus (QFT-Plus) manufacturer's instructions to ensure the quality of blood specimens prior to testing for TB. The laboratory failed to reject QFT-Plus specimens not incubated for 16 to 24 hours per manufacturer guidelines. Findings included: Review of QFT-Plus Instructions for Use stated "Tubes must be transferred to a 37 Celsius (C) 1C incubator within 2 hours. If QFT-Plus Blood Collection Tubes are not incubated at 37 C directly after blood collection and shaking, invert the tubes to mix 10 times (10x) prior to incubator at 37 C. Incubate the QFT-Plus Blood collection tubes upright at 371 C for 16 to 24 hours. In order to obtain valid results from the QFT-Plus assay, the operator needs to perform specific tasks within set times. Prior to harvesting plasma, samples in QFT-Plus Blood Collection Tubes must have been incubated at 37 C for 16-24 hours." QFT-Plus Blood Collection Tubes also contain the following controls: Nil (the negative control) and mitogen (the positive control). Review of 2020-2021 QuantiFERON Incubation list revealed 20 out 30 QFT-plus specimens had no written documentation of incubator temperatures and exit incubator times from 02/12/2020 to 05/12/2020. 30 out 30 QFT-plus specimens did not have written incubator enter and exit times from 01/08/21 to 04

	/30/21. Review of QFT-Plus Patient Records revealed the following patient specimens removed from the incubator before the 16 to 24 hour timeframe: 1. Patient 1 QFT - Plus specimen had no written documentation of incubator entry time and was removed from the incubator 3:00 AM on 03/19/2020. 2. Patient 2 QFT -Plus specimen arrived at 10:41 PM on 03/19/2020 and was removed from the incubator 6:30 AM on 03/20 /2020. Total incubation time was 7 hours. The number of patients tested on QFT-Plus for tuberculosis was 275 from January 2020 to July 2021. During an interview on 08 /11/2021 at 1:47 PM, the owner confirmed the laboratory failed to follow QFT-Plus manufacturer's instructions to ensure the quality of blood specimens prior to testing for TB and to reject specimens not incubated within 16 to 24 hours.
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 record review and interview, the laboratory failed to validate Advia Centaur human immunodeficiency virus (HIV) antigen(Ag)/antibody(Ab) Combo (CHIV) assay from 04/06/2020 to present and Bio-Rad Recombinant and Synthetic Peptides (GS) HIV-1/HIV-2 PLUS O Enzyme Immunoassay (EIA) from 02/27/21 to present for use in the detection of HIV-1 and HIV-2 antibody. (See D 5421) Based on observation, record review and interview, the laboratory failed to validate the Stanbio Rapid Plasma Reagin (RPR) Quicktest for use without humidifying covers, temperature ranges and revolutions per minute (rpm) outside of the Food and Drug Administration (FDA) approved manufacturer guidelines for Syphilis testing from December 2019 to present. (See D 5423) Based on record review and interview, the laboratory failed to follow the Bio-Rad GS HIV-1/HIV-2 PLUS O EIA manufacturer instructions for valid positive and negative controls to detect HIV-1 and HIV-2 antibodes from January 2020 to present. (See D 5481)
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values.

	(12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory's written procedure manual was incomplete at the time of the survey from 07/19/2021 to 08/11/2021. Findings include: 1) Review of the procedure manual signed by the laboratory director (LD) on 03/02/2021, showed the written procedure manual did not include procedures for the following tests that were listed in the test menu of the laboratory: -anti-Human immunodeficiency antibody (anti-HIV) detection with Biorad. -Rubella antibody detection from Zeus. - Rapid Plasma Reagin (RPR) Syphilis Testing from Stanbio. -QuantiFERON-Tuberculosis (TB) Gold Plus from Qiagen. -Microscan instrument for identification and sensitivity test for Bacteria. 2) Review of the procedure manual revealed that there was no record of changes in test methods used for Rapid Plasma Reagin (RPR) Syphilis Testing when the laboratory changed from Teco manufacturer to Stanbio manufacturer. During an interview on 07/27/2021 at 11:00 AM, the General Supervisor A acknowledged that the procedure manual failed to include the policies listed above and failed to record the change of RPR test brands in use.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to have a validation for Advia Centaur human immunodeficiency virus (HIV) antigen (Ag)/antibody (Ab) Combo (CHIV) assay from 04/06/2020 to present and Bio-Rad Recombinant and Synthetic Peptides (GS) HIV-1/HIV-2 PLUS O Enzyme Immunoassay (EIA) for the 02/27/21 to present for use in the detection of HIV-1 and HIV-2 antibodies. Findings included: Review of Advia Centaur CHIV validation revealed the laboratory had no documentation of a validation for Advia Centaur instrument used in CHIV testing from 04/06/2020 to present available onsite. Review Bio-Rad GS HIV-1/HIV-2 Plus O EIA validation revealed the laboratory had discontinued the use of the Bio-Rad GS HIV-1/HIV-2 Plus O EIA during the introduction of the Advia Centaur CHIV in July 2020. The laboratory started to use the Biorad instrument again in 02/27/2021. Upon further review the laboratory lacked documentation of a validation or a comparison validation from the previous method prior to reusing the instrument. Review of 2020 HIV proficiency testing (PT) record revealed Bio-Rad GS HIV-1/HIV-2 Plus O EIA was used in the first PT event of 2020 and Advia Centaur CHIV was used in the 2nd and 3rd PT event of 2020. Review of HIV Patient Log revealed the number of HIV

	tests were 1012 from January 2020 to July 2021. During an interview on 08/05/2021 at 12:00 PM, the owner stated the validations were performed but failed to provide documentation to prove the validations were completed.
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 validate the Stanbio Rapid Plasma Reagin (RPR) Quicktest for use without humidifying covers, temperature ranges and revolutions per minute (rpm) outside of the Food and Drug Administration (FDA) approved manufacturer guidelines for Syphilis testing from December 2019 to present. Findings included: Review of Stanbio RPR Quicktest Syphilis package insert stated antigen suspension and controls are used at 23-29 Celsius(C) room temperature. RPR cards are rotated for 8 minutes at 100 rpm on mechanical rotator with humidifying cover. A rotator is used at 1002 rpm. During an observation on 07/23/2021 at 12:30 PM, a technologist was performing the rotation of Stanbio RPR test cards without a humidity cover on the rotator. Review of December 2019 - July 2021 RPR Quality Control records revealed the laboratory did not follow the package insert instructions as follows: 1. Temperatures were below 23-29 C for 15 out of 15 testing days in December 2019. 2. Temperatures were below 23-29 C for 16 out of 16 testing days in January 2020. 3. Temperatures were below 23-29 C for 14 out of 14 testing days in February 2020. 4. Temperatures were below 23-29 C for 17 out of 17 testing days in March 2020. 5. Temperatures were below 23-29 C for 10 out of 10 testing days in April 2020. 6. Temperatures were below 23-29 C for 9 out of 10 testing days in May 2020. 7. Temperatures were below 23-29 C for 4 out of 7 testing days in October 2020. 8. RPR card were rotated above 1002 rpm for 27 and 29 in November 2020. 9. RPR card were rotated above 1002 rpm on December 15, 2020. 10. RPR card were rotated above 1002 rpm on 6 out of 12 testing days in March 2021 and temperatures were below 23-29 C for 12 out of 12 testing days in March 2021. 11. Temperatures were below 23-29 C for 11 out of 11 testing days in April 2021. 12. Temperatures were below 23-29 C for 7 out of 7 testing days in May 2021. 13. Temperatures were below 23-29 C for 9 out of 8 testing days in June 2021. 14. Temperatures were below 23-29 C for 1 out of 1 testing days in July 2021. Review of RPR Patient Log revealed the number of patients tested on Stanbio RPR Quicktest for syphilis was 994 from January 2020 to July 2021. During an interview on 08/05/2021 at 12:00 PM, the owner confirmed the laboratory failed to validate the Stanbio Rapid Plasma Reagin (RPR) Quicktest for use outside of the FDA approved manufacturer guidelines for Syphilis testing from December 2019 to present.
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 record review and interview, the laboratory failed to follow the Bio-Rad Recombinant and Synthetic Peptides (GS) human immunodeficiency virus (HIV)-1 /HIV-2 PLUS O Enzyme Immunoassay (EIA) manufacturer's instructions for valid positive and negative controls to detect HIV-1 and HIV-2 antibodies from January 2020 to present. Findings included: Review Bio-Rad GS HIV-1/HIV-2 Plus O EIA instructions for use stated "A run is valid if the following criteria are met : -The absorbance values of the individual negative controls are greater than 0.000 AU and less than or equal to 0.150 AU. One negative control value may be discarded. If two or more negative controls are out of limit, the assay must be repeated. -The absorbance value of the HIV-1 positive control must be greater than or equal to 0.700 AU. -The absorbance value of the HIV-2 positive control must be greater than or equal to 0.700AU. -The absorbance value of the HIV-1 Group O positive control must be greater than or equal to 0.700 AU If any of these criteria have not been met, the assay is invalid and must be repeated." Review of Bio-Rad GS HIV-1/HIV-2 Plus O EIA plate testing runs revealed the following : 1. On 01/17/2020 a plate was manually run with 3 positive controls lower than 0.700AU. The plate was not labeled as failed run. 41 test results were reported. 2. A plate was run on 01/10/2020 with 3 positive controls lower than 0.700AU. The plate was not label a failed run. 73 patient test results were reported. 3. A plate was manually run on 01/16/2020 with 3 positive controls lower than 0.700AU. The plate was not labeled a failed run. 47 test results were reported. 4. A plate was manually run on 03/19/2020 with 3 positive controls lower than 0.700AU. The plate was not labeled a failed run. 53 test results were reported. 5. A plate was manually run on 04/03/2020 with 1 positive control lower than 0.700AU. The plate was not labeled a failed run. 34 test results were reported. 6. A plate was run on 06/18/2020 using Advia Centaur XP with 3 positive controls lower than 0.700AU. The plate was not labeled a failed run. 26 test results were reported. 7. A plate was run on 08/03/2020 using Advia Centaur XP with 3 positive controls lower than 0.700AU. The plate was not labeled a failed run. 26 test results were reported. 8. A plate was manually run on 03/09/2021 with 1 positive control lower than 0.700AU. The plate was not labeled a failed run. 18 test results were reported. 9. A plate was manually run on 04/16/2021 with 3 positive controls lower than 0.700AU. The plate was not labeled as failed run. 10 test results were reported. 10. A plate was manually run on 04/30/2021 with 3 positive controls lower than 0.700AU. The plate was not labeled a failed run. 10 test results were reported. 11. A plate was manually run on 05 /21/2021 with 3 positive controls lower than 0.700AU. The plate was not labeled a failed run. 10 test results were reported. 12. A plate was manually run on 07/07/2021 with 3 negative controls greater than 0.150 AU. The plate was not labeled a failed run. 12 test results were reported. Review of Patients Laboratory Test Menu revealed the number of patients tested for HIV were 1012 from January 2020 to July 2021. During an interview on 08/11/2021 at 1:00 PM, the owner confirmed the laboratory failed to follow the Bio-Rad GS HIV-1/HIV-2 Plus O EIA manufacturer's instructions for valid positive and negative controls to detect HIV-1 and HIV-2 antibodies from January 2020 to present.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT

	CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on lack of quality assurance (QA) documentation and owner interview, the laboratory failed to follow the Quality Assessment (QA) plan to identify and correct problems in analytic systems for 2 (2020 and 2021) out of 2 years reviewed . Findings included: -Review of procedure manual signed by the laboratory director (LD) on 03 /02/2021, revealed that the laboratory had a QA policy and QA plan. The laboratory had to keep records of the QA activity. -The QA failed to identify and correct the following deficiencies: a) No proficiency testing enrollment for the anti-Human immunodeficiency antibody (anti-HIV) and Rubella antibody test detection for 2021. b) No accuracy verification for Quantiferon Tuberculosis Gold Plus in test in 2020 and 2021. Refer to D 5217. c) Analytical failures in the establishment and verification of performance for Antigen/Antibody Combo (CHIV) assay and Bio-Rad Recombinant and Synthetic Peptides (GS) human Immunideficiency virus (HIV)-1 /HIV-2 Plus O Enzyme Immunoassay (EIA). See D 5421. d) The laboratory failed to follow manufacturer instructions for Stanbio Rapid Plasma Reagin (RPR) Quicktest. See D 5423. e) The laboratory failed to follow Biorad GS HIV-1/HIV-2 Plus O EIA manufacturer instructions for valid positive and negative controls. See D 5481 - No documentation found of the QA activity for 2020 and 2021. During an interview on 08 /04/2021 at 2:30 PM, with the owner, she confirmed that the laboratory failed to follow their QA plan.
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to correct patient test reports listed as negative or positive for syphilis with the unvalidated Stanbio Rapid Plasma Reagin (RPR) Quicktest on 01/29/2020 and 01/30/2020. Findings included : Refer to D 5423 Review of January 2020 Stanbio RPR results log displayed the following test results : 1. On 01/29/2020 patient #1 specimen tested with Stanbio RPR was positive for syphilis. 2. On 01/29/2020 patient #2 specimen tested with Stanbio RPR was positive for syphilis . 3. On 01/30/2020 patient #3 specimen tested with Stanbio RPR was positive for syphilis. 4. On 01/30/2020 patient #4 specimen tested with Stanbio RPR was positive for syphilis. 5. On 01/30/2020 patient #5 specimen tested with Stanbio RPR was positive for syphilis. Review of January 2020 RPR Patient test report displayed the following patient results: 1. Patient #1 test report for Stanbio RPR was negative for syphilis on 01/29/2020. 2. Patient #2 test report for

	Stanbio RPR was negative for syphilis on 01/29/2020. 3. Patient #3 test report for Stanbio RPR was negative for syphilis on 01/30/2020. 4. Patient #4 test report for Stanbio RPR was negative for syphilis on 01/30/2020. 5. Patient #5 test report for Stanbio RPR was negative for syphilis on 01/30/2020. During an interview on 08/06 /2021 at 12:00 PM, the laboratory supervisor confirmed the laboratory failed to correct patient test reports listed as negative or positive for syphilis with the unvalidated Stanbio RPR Quicktest on 01/29/2020 and 01/30/2020.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory director failed to ensure the laboratory enrolled in a Proficiency Testing (PT) program approved by the Department of Health and Human Services (HHS) and Centers for Medicare and Medicaid Services (CMS) for anti-Human immunodeficiency antibody test (anti-HIV) and for Rubella antibody test for 2021. (see D 6088) Based on record review and interview, the laboratory director failed to ensure the laboratory followed the Bio-Rad Recombinant and Synthetic Peptides (GS) human immunodeficiency virus (HIV)-1 /HIV-2 PLUS O Enzyme Immunoassay (EIA) manufacturer instructions for valid positive and negative controls to detect HIV-1 and HIV-2 from January 2020 to present. (see D 6093) Based on record review and interview, the laboratory director failed to ensure the laboratory followed the Quality Assessment (QA) plan to identify and correct problems in analytic systems for 2 out of 2 years reviewed (2020 and 2021). (see D 6094) Based on record review and interview, the laboratory director failed to ensure the laboratory validated Advia Centaur human immunodeficiency virus (HIV) antigen(Ag)/antibody(Ab) Combo (CHIV) assay from 04/06/2020 to present, Bio-Rad Recombinant and Synthetic Peptides (GS) HIV-1/HIV-2 PLUS O Enzyme Immunoassay (EIA) from 02/27/21 to present for use in the detection of HIV-1 and HIV-2 antibodies and Stanbio Rapid Plasma Reagin (RPR) Quicktest for use without humidifying covers, temperature ranges and revolutions per minute (rpm) outside of the Food and Drug Administration (FDA) approved manufacturer guidelines for Syphilis testing from December 2019 to present. (see D 6095)
D6088	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4) The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director failed to ensure the laboratory enrolled in a Proficiency Testing (PT) program approved by the Department of Health and Human Services (HHS) and Centers for Medicare and Medicaid Services (CMS) for anti-Human immunodeficiency antibody test (anti-HIV) and Rubella antibody test for 2021. Findings included: Review of American Association of Bioanalysts (AAB) PT records revealed that the laboratory failed to

	enroll anti-HIV and Rubella antibody test for 2021. During an interview on 08/11 /2021 at 1:00 PM, the owner confirmed the laboratory director failed to ensure the laboratory enrolled in a PT program approved by the HHS and CMS for anti-HIV and for Rubella antibody test for 2021.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on the review of the laboratory's proficiency testing scores, the laboratory director failed to ensure that the laboratory performed proficiency testing in such a manner as to achieve and maintain successful participation in proficiency testing for the analyte, partial thromboplastin time (APTT), in the specialty of hematology. Findings included: The review of the American Proficiency Institute (API) proficiency testing records and the Centers for Medicare & Medicaid Services (CMS) 155 report on July 19 2021 showed that the laboratory received unsatisfactory proficiency testing scores of 60% in 1st and 3rd event of 2020. See D 2130 During an interview on 08/11/2021 at 1:55 PM, the owner confirmed the laboratory director failed to ensure the laboratory had a succesful result in APTT due to the failure of the APTT analyte, in the specialty of hematology during the events of reference.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director failed to ensure the laboratory followed the Bio-Rad Recombinant and Synthetic Peptides (GS) human immunodeficiency virus (HIV)-1/HIV-2 PLUS O Enzyme Immunoassay (EIA) manufacturer instructions for valid positive and negative controls to detect HIV-1 and HIV-2 antibodies from January 2020 to present. Findings include: Refer to D 5481 During an interview on 08/11/2021 at 2:05 PM, the owner confirmed the laboratory director failed to ensure the laboratory followed the Bio-Rad GS HIV-1/HIV-2 PLUS O EIA manufacturer instructions for valid positive and negative controls to detect HIV-1 and HIV-2 antibodies from January 2020 to present.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by:

	Based on record review and interview, the laboratory director failed to ensure Quality Assessment (QA) identified and corrected problems in analytic systems for 2 (2020 and 2021) out of 2 years reviewed. Findings included : -See D 5791 During an interview on 08/11/2021 at 2:15 PM, the owner confirmed the laboratory director failed to ensure the laboratory followed the QA plan to identify and correct problems in analytic systems for 2 (2020 and 2021) out of 2 years reviewed.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director failed to ensure the laboratory validated Advia Centaur human immunodeficiency virus (HIV) antigen(Ag) /antibody(Ab) Combo (CHIV) assay from 04/06/2020 to present, Bio-Rad Recombinant and Synthetic Peptides (GS) HIV-1/HIV-2 PLUS O Enzyme Immunoassay (EIA) from 02/27/2021 to present for use in the detection of HIV-1 and HIV-2 antibodies and the Stanbio Rapid Plasma Reagin (RPR) Quicktest for use without humidifying covers, temperature ranges and revolutions per minute (rpm) outside of the Food and Drug Administration (FDA) approved manufacturer guidelines for Syphilis testing from December 2019 to present. Findings included: Refer to D 5421 Refer to D 5423 During an interview on 08/11/2021 at 1:00 PM, the owner confirmed the laboratory director failed to ensure the laboratory validated Advia Centaur CHIV assay, Bio-Rad Recombinant GS HIV-1/HIV-2 PLUS O EIA and Stanbio RPR Quicktest.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on record review and interview, the Technical Supervisor (TS) failed to do an initial competency assessment for 3 out of 4 testing personnel in 2021. Findings included: -Review of CMS 209 Laboratory Personnel Report dated and signed by the Laboratory Director (LD) on 07/19/2021 revealed there were 4 testing personnel (TP) A, B, C and D. -Review of Laboratory Employee records revealed that there were no initial evaluations for TP B, C and D hired on March 2021. During an interview on 07 /26/2021 at 12:30 PM with the GS A, she confirmed that the TS failed to do initial competency assessments for the personnel listed above.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case,

	prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on record review and interview, the Technical Supervisor failed to do an annual competency assessment for 1 out of 4 testing personnel during 2020 and 2021. Findings included: -Review of CMS 209 Laboratory Personnel Report dated and signed by the Laboratory Director (LD) on 07/19/2021 revealed there were 4 testing personnel (TP) A, B, C and D. TP A was working in the laboratory in 2020 and 2021. -Review of Laboratory Employee records revealed that there were no records of competency assessments for TP A in 2020 and 2021. During an interview on 07/26 /2021 at 12:32 PM with GS A, she confirmed that the TS failed to do annual competency assessments for TP A in the period of reference.