Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D2081860	10/19/2022
Name of Provider or Supplier	**Street Address, City, State**	
Americahealth Inc Idaho Falls	1995 E 17th St, Idaho Falls, ID	

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
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 a review of the Centers for Medicare and Medicaid (CMS) Proficiency Testing (PT) data report (Report 155D), PT reports from the College of American Pathologists (CAP) and an interview with the operations manager on 10/19/2022, the laboratory failed to enroll in PT for the specialty of chemistry for 2022. The findings include: 1. Review of Report 155D and PT reports from CAP identified that the laboratory failed to enroll in PT for the sub-specialty of routine chemistry for the following analytes: albumin, alkaline phosphatase, alanine aminotransferase, aspartate aminotransferase, urea, calcium, chloride, creatinine, glucose, potassium, sodium, total bilirubin and total protein for 2022. 2. Review of Report 155D and PT reports from CAP identified that the laboratory failed to enroll in PT for the sub-specialty of endocrinology for the following analytes: thyroid-stimulating hormone, thyroxine, triiodothyronine, free thyroxine for 2022. 3. An interview with the operations manager on 10/19/2022 at 12:48 pm confirmed the above findings. 4. The laboratory reports performing 39,025 chemistry tests annually.
D2003	ENROLLMENT CFR(s): 493.801(a)(2)(ii)

	For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1) This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid (CMS) Proficiency Testing (PT) data report (Report 155D), PT reports from the College of American Pathologists (CAP) and an interview with the operations manager on 10/19/2022, the laboratory failed to verify the accuracy at least twice annually of tests not included in subpart I for the specialty of chemistry for 2022. The findings include: 1. A review of Report 155D and PT reports from CAP identified that the laboratory failed to verify the accuracy at least twice annually for the sub-specialty of routine chemistry for the analyte carbon dioxide in 2022. 2. A review of Report 155D and PT reports from CAP identified that the laboratory failed to verify the accuracy at least twice annually the sub-specialty of endocrinology for the following analytes: thyroglobulin antibody and thyroid peroxidase antibodies in 2022. 3. An interview with the operations manager on 10/19/2022 at 12:48 pm confirmed the above findings. 4. The laboratory reports performing 39,025 chemistry tests annually.
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 a review of proficiency testing (PT) documentation from the College of American Pathologists (CAP) and an interview with the operations manager on 10/19 /2022, the laboratory failed to have testing personnel and the laboratory director attest to the integration of PT samples with routine testing of patient samples in 2021 and 2022. The findings include: 1. A review of PT results from CAP for urine toxicology, qualitative, ethanol biomarkers and drugs of abuse identified that the laboratory failed to have the testing personnel and the laboratory director attest that the PT samples were tested with patient samples for all testing events in 2021 and 2022. 2. An interview with the operations manager on 10/19/2022 at 12:48 pm confirmed that the laboratory failed to have documentation of signed attestations available at the time of survey. 3. The laboratory reports performing 30,025 urine toxicology tests annually.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (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. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) documentation from the College of American Pathologists (CAP) and an interview with the operations manager on 10/19 /2022, the laboratory failed to retain PT documents in 2021 and 2022. The findings include: 1. A review of PT results from CAP for urine toxicology, qualitative, ethanol biomarkers and drugs of abuse identified that the laboratory failed retain documentation of raw testing data for all events in 2021 and 2022. 2. A review of PT results from CAP for urine toxicology, qualitative, ethanol biomarkers and drugs of abuse identified that the laboratory failed retain documentation of graded results for events one and two in 2022. 3. An interview with the operations manager on 10/19 /2022 at 12:48 pm confirmed that the laboratory failed to have documentation of raw data and graded results available at the time of survey. 4. The laboratory reports performing 30,025 urine toxicology tests annually.
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 a review of the Centers for Medicare and Medicaid (CMS) proficiency testing (PT) data report (Report 155D), graded results from the College of American Pathologists (CAP) and an interview with the operations manager on 10/19/2022, the laboratory failed to successfully participate and achieve an overall satisfactory score for two consecutive testing events in 2022 for the specialty of hematology. See D2131
D2131	HEMATOLOGY CFR(s): 493.851(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

	This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid (CMS) Proficiency Testing (PT) data report (Report 155D), graded PT results from the College of American Pathologists (CAP) and an interview with the operations manager on 10/19 /2022, the laboratory failed to achieve satisfactory performance for two (2) consecutive PT events for the specialty of hematology. The findings include: 1. A review of Report 155D and graded PT results from CAP identified that the laboratory failed to achieve satisfactory performance for events one (1) in 2022 and two (2) in 2022 for the specialty of hematology for the analytes: Analyte Year Event Score WBC 2022 1 0% WBC 2022 2 0% RBC 2022 1 0% RBC 2022 2 0% Hematocrit 2022 1 0% Hematocrit 2022 2 0% Hemoglobin 2022 1 0% Hemoglobin 2022 2 0% Platelet 2022 1 0% Platelet 2022 2 0% WBC differential 2022 1 0% WBC differential 2022 2 0% 2. An interview with the operations manager on 10/19/2022 at 12:48 pm confirmed that there was no additional PT documents. 3. The laboratory reports performing 5,000 CBC tests annually.
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on direct observations, lack of documentation and interviews with the operations manager and technical supervisor on 10/19/2022, the laboratory failed to provide evidence of initial training, competency assessments, quality control performance, calibration performance, instrument maintenance performance, proficiency testing performance, sample testing policies, policies for sample collection, processing and transport, proper reagent storage, discontinuing reagent use after expiration for comprehensive metabolic panels. See D5209, D5311, D5403, D5413, D5417, D5429, D5437 and D5447
D5020	ENDOCRINOLOGY CFR(s): 493.1212 If the laboratory provides services in the subspecialty of Endocrinology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on direct observations, lack of documentation and interviews with the operations manager and technical supervisor on 10/19/2022, the laboratory failed to provide evidence of initial training, competency assessments, quality control performance, calibration performance, instrument maintenance performance, proficiency testing performance, sample testing policies, policies for sample collection, processing and transport, proper reagent storage, discontinuing reagent use after expiration for thyroxine, triiodothyronine, free thyroxine, thyroid stimulating hormone, Thyroglobulin Antibody and Thyroid peroxidase antibody testing . See D5209, D5311, D5403, D5413, D5417, D5429, D5437 and D5447

D5022	TOXICOLOGY CFR(s): 493.1213 If the laboratory provides services in the subspecialty of Toxicology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on direct observations, lack of documentation and interviews with the operations manager and technical supervisor on 10/19/2022, the laboratory failed to provide evidence of initial training, quality control performance, calibration performance, instrument maintenance performance, policies for sample collection, processing and transport, storage of reagents at proper temperature, discontinuing reagent use after expiration for urine toxicology testing. See D5209, D5311, D5403, D5413, D5417, D5429, D5437 and D5447
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based on direct observations, lack of documentation and interviews with the operations manager and technical supervisor on 10/19/2022, the laboratory failed to provide evidence of initial training, competency assessments, quality control performance, calibration performance, instrument maintenance performance, instrument verification, proficiency testing performance, sample testing policies, policies for sample collection, processing and transport, proper reagent storage, discontinuing reagent use after expiration for complete blood counts. See D5209, D5311, D5403, D5413, D5417, D5421, D5429, D5437 and D5447
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 a review of competency assessments and an interview with the technical supervisor (TS) on 10/19/2022, the laboratory failed to have documentation of six month competency for one of three testing personnel. The findings include: 1. A review of competency assessments identified that the laboratory failed to have six month competency assessment for one testing personnel (TP1) testing on the Abbott Architect ci4100 and the CELL-DYN Ruby. 2. An interview with the TS on 10/19 /2022 at 3:06 confirmed that there was no six month competency assessment for TP1 for the Abbott Architect ci4100 and the CELL-DYN Ruby. 3. The laboratory reports performing 44,025 moderate and high complexity testing annually.

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 a record review of proficiency testing (PT) from College of American Pathologists (CAP) and an interview with the operations manager on 10/19/2022, the laboratory failed to review PT and evaluate results that were less than 100% for 2021 and 2022. The findings include: 1. A review of PT records from CAP for Ethanol biomarkers in 2021 identified that the laboratory failed to evaluate the results for the following; Ethyl glucuronide 67% and Ethyl sulfate 67% for event one, Ethyl glucuronide 0% and Ethyl sulfate 3% for event two. 2. A review of PT records from CAP for Ethanol biomarkers in 2022 identified that the laboratory failed to evaluate the results for the following; Ethyl glucuronide 67% and Ethyl sulfate 33% for event one. 3. A review of PT records from CAP for urine toxicology, qualitative in 2021 identified that the laboratory failed to evaluate the results for the following; UT-03 0%, UT-04 0% for event one, UT-07 0% for event two and UT-11 0%, UT-13 0% and UT-15 0% for event three. 4. A review of PT records from CAP for urine toxicology, qualitative in 2022 identified that the laboratory failed to evaluate the results for the following; UT-05 0% for event one, UT-10 0% for event two. 5. An interview with the operations manager on 10/19/2022 at 12:48 pm confirmed that there was no documentation of PT review. 6. The laboratory reports performing 30,025 urine toxicology tests annually.
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 a lack of documentation and an interview with the operations manager on 10 /19/2022, the laboratory failed to provide written procedures for the company's other urgent care and behavior health locations for specimen collection, specimen labeling, specimen storage and transport. The findings include: 1. A lack of documents available at the time of inspection identified that the laboratory failed to provide a written procedure to their locations that included sample collection, sample labeling, sample storage and transportation conditions for chemistry, hematology, virology and toxicology testing. 2. An interview with the operations manager on 10/19/2022 at 12: 58 confirmed that this facility was testing samples for the company's other urgent care and behavior health locations. 3. An interview with the operations manager on 10/19 /2022 at 12:48 pm confirmed that there were no written policies for their other facilities. 4. The laboratory reports performing 44,025 moderate and high complexity tests annually.

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 a lack of documentation and an interview with the operations manager on 10 /19/2022, the laboratory failed to have written procedures for testing performed available to the laboratory testing personnel. The findings include: 1. The laboratory failed to have procedures available for testing personnel to follow for complete blood count testing performed on the Cell-DYN Ruby. 2. The laboratory failed to have procedures available for testing personnel to follow for complete metabolic panel and thyroid panel testing performed on the Abbott Architect ci4100. 3. The laboratory failed to have procedures available for testing personnel to follow for influenza A/B and SARS-CoV-2 tests performed on the Quidel Solana. 4. An interview with the operations manager on 10/19/2022 at 12:48 pm confirmed the above findings. 5. The laboratory reports performing 44,025 moderate and high complexity tests annually.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a lack of documentation, a review of laboratory procedures and an interview with the operations manager on 10/19/2022, the laboratory failed to document room temperature and humidity in two of two testing rooms, temperatures for two of two refrigerators, a freezer and an incubator in 2021 and 2022. The findings include. 1. A lack of documentation identified that the laboratory failed to record temperatures for

	two laboratory refrigerators, a freezer, an incubator and room temperature and humidity in two testing rooms for 2021 and 2022. 2. A review of the policy "Standard Operating Procedures for Amerihealth Toxicology" stated that "the temperature will be checked and recorded for the refrigerator, freezer, room and humidity" identified that the laboratory failed to follow procedures for documenting room temperature, humidity, refrigerator and freezer temperatures. 3. An interview with the operations manager on 10/19/2022 at 12:48 confirmed that there was no documentation of temperatures and humidity at the time of survey. 4. The laboratory reports performing 44,025 moderate and high complexity tests annually.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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 direct observations and an interview with the operations manager on 10/19 /2022, the laboratory failed to discontinue the use of reagents, control materials and calibration materials when they had exceeded their expiration date. The findings include: 1. A direct observation of the refrigerator in the testing room identified thyroid stimulating hormone (TSH) controls lot 23225u100 expiration 1/4/2022, hematology CD-Cal lot 3KC0222 expiration 3/5/2022, free triiodothyronine (FT3) controls lot 2948UD00 expiration 4/8/2022, (Integrated Chip technology) ICT serum CAL lot 157011 expiration 2/3/2022, ICT serum CAL lot 157013 expiration 2/3/2022, ICT cleaning fluid lot 59682 expiration 7/30/2022, complete blood count (CBC)-3K hematology controls lots KK104H, KK104N, KK104L expiration 1/5/2022, CBC-3K hematology controls lots KK103H, KK103N, KK103L expiration 3/5/2022 and CELL-DYN 18 Plus Calibrator set lot 1235C expiration 10/6/2021 that the laboratory failed to discontinue use before they exceeded the expiration. 2. A direct observation of the Abbott Architect ci4100 reagent carousels identified the following reagents: total protein (TP) R1 lot 81830UN20 expiration 6/30/2022, alanine aminotransferase (ALT) R1 lot 59099UQ02 expiration 2/8/2022, albumin (ALBG) R1 lot 88031UN21 expiration 2/24/2023, aspartate aminotransferase (AST) R1 lot 68138UN21 expiration 2/8/2022, Urea R1 lot 26365UN21 expiration 4/16/2022, alkaline phosphatase (ALKP) R2 lot 44855UN21 expiration 5/6/2022, glucose (GLUC) R1 lot 58873UQ01 expiration 1/31/2022, calcium (CAL) R1 lot 3593UN21 expiration 7/21/2022, Urea R2 lot 26365UN21 expiration 4/16/2022, AST R2 lot 68138UN21 expiration 2/8 /2022, ALT R2 lot 59099UQ02 expiration 2/8/2022, ALKP R1 lot 44855UN21 expiration 5/5/2022, total bilirubin (BiliT) R1 and R2 lot 58700UQ01 expiration 6/30 /2022, carbon dioxide (CO2C) R1 lot 59085UQ01 expiration 3/31/2022, ICTD5 R1 lot 96870UN20 expiration 6/16/2022, Acid Wash lot 02016UN21 expiration 11/17 /2021, Detergent B (10%) lot 57192 expiration 1/30/2022 and Detergent A lot 57822 expiration 11/26/2021 that the laboratory failed to discontinue use before they exceeded the expiration. 3. A direct observation of the refrigerator in the specimen processing room identified one box of Copan UTM tubes lot B002259 expiration 3/31 /2022 that the laboratory failed to discontinue use before they exceeded the expiration. 4. A direct observation of the laboratory flammable cabinet identified five Kits (20 tests each) of Premier Biotech COVID-19 IgG/IgM rapid test cassettes lot COV20040073 expiration 4/30/2022, Acetic Acid lot MKCK9381 expiration 4/2 /2022, Ammonium formate lot MKCL5617 expiration 4/6/2022, Acetonitrile lot

	I1066891 003 expiration 12/31/2022 and Lisinopril lot LRAB3302 expiration 6/30 /2022 that the laboratory failed to discontinue use before they exceeded the expiration. 5. A direct observation of the CELL-DYN Ruby identified WBC-LYSE lot 23068UN20 in use expiration 4/30/22 and Diluent/Sheath lot 60651UN20 in use expiration 12/21/2021 for which the laboratory failed to discontinue use before exceeding the expiration. 6. An interview with the operations manager on 10/19/2022 at 1:13 pm identified that he knew of no other testing reagents. 7. The laboratory reports performing 44,025 moderate and high complexity tests annually.
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 review of the Centers for Medicare and Medicaid Services (CMS) 116 Application For Certification, Abbott Architect ci4100 verifications, direct observation, lack of documentation and interviews with the technical supervisor (TS) on 10/19/2022, the laboratory failed to verify the performance of new testing on the CELL-DYN Ruby, the Abbott Architect ci4100 and the Solana before performing patient testing. The findings include: 1. A review of the CMS 116 submitted by the laboratory and signed by the laboratory director on 12/6/2021 identified the laboratory added comprehensive metabolic panels, complete blood counts (CBC), thyroxine, triiodothyronine, free thyroxine, thyroid stimulating hormone, Thyroglobulin Antibody and Thyroid peroxidase antibodies effective 12/9/2021. 2. A review of Abbott Architect ci4100 verifications identified that the laboratory director failed to approve and sign (1/5/2022) the verification studies for comprehensive metabolic panels,thyroxine, triiodothyronine, free thyroxine, thyroid stimulating hormone, Thyroglobulin Antibody and Thyroid peroxidase antibodies prior to patient testing. 3. A lack of documentation identified that the laboratory failed to perform testing performance verifications on CBC testing performed on the CELL-DYN Ruby prior to patient testing. 4. A direct observation in the laboratory identified a Quidel Solana instrument and reagents for Influenza A/B and SARS-CoV-2 testing. A lack of documentation identified that the laboratory failed to perform testing performance verifications prior to patient testing. 5. An interview with the TS on 10/19/2022 at 1: 28 pm confirmed that there was no verification for the CBC testing and a second interview at 3:25 pm confirmed that there was no verification for testing on the Solana. 6. The laboratory reports performing 44,025 moderate and high complexity tests annually. 7. This is a repeat deficiency from the previous survey on 11/05/2020 for Premier BioTech SARS CoV 2 Serology testing.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document 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 a lack of maintenance logs and an interview with the operations manager on 10/19/2022, the laboratory failed to perform maintenance on all testing instruments as required by the manufacturer for 2021 and 2022. The findings include: 1. A lack of Cell-DYN Ruby maintenance logs identified that the laboratory failed to perform maintenance as required by the manufacturer since beginning testing in December of 2021. 2. A lack of Abbott Architect ci4100 maintenance logs identified that the laboratory failed to perform maintenance as required by the manufacturer since beginning testing in December of 2021. 3. A lack of AB Sciex 4500 LC/MS maintenance logs identified that the laboratory failed to perform maintenance as required by the manufacturer since the last inspection on 11/05/2020. 4. An interview with the operations manager on 10/6/2022 at 12:48 pm confirmed that the laboratory failed to have documentation of maintenance. 5. The laboratory reports performing 44,025 moderate and high complexity tests annually.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on a lack of documentation and an interview with the operations manager on 10/19/2022, the laboratory failed to document calibration performance following the manufacturers requirements or at least every six months for testing performed on the Abbott Architect ci4100 and the AB Sciex 4500. The findings include: 1. A lack of documentation identified that the laboratory failed to perform calibrations at least every six months for toxicology testing performed on the AB Sciex 4500 and for comprehensive metabolic panels, thyroxine, triiodothyronine, free thyroxine, thyroid stimulating hormone, Thyroglobulin Antibody and Thyroid peroxidase antibodies performed on the Abbott Architect ci4100. 2. An interview with the operations manager on 10/19/2022 at 12:48 pm confirmed that the laboratory failed to have documentation of calibrations. 3. The laboratory reports performing 44,025 moderate and high complexity tests annually.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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 quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a lack of documentation and an interview with the operations manager on 10 /19/2022, the laboratory failed to have documentation of quality control (QC) each day of patient testing for 2021 and 2022. The findings include: 1. A lack of QC documentation for comprehensive metabolic panels, thyroxine, triiodothyronine, free thyroxine, thyroid stimulating hormone, Thyroglobulin Antibody and Thyroid peroxidase antibodies identified that the laboratory failed to perform at least two levels of QC each day of testing since beginning testing on 12/9/2021. 2. A lack of QC documentation for complete blood counts (CBC) identified that the laboratory failed to perform at least two levels of QC each day of testing since beginning testing on 12/9/2021. 3. A lack of QC documentation for urine toxicology testing identified that the laboratory failed to perform at least two levels of QC each day of testing since the last inspection on 11/5/2020. 4. A lack of QC documentation for influenza and SARS-COV-2 testing on the Solana identified that the laboratory failed to perform at least two levels of QC each day of testing since beginning testing. 5. An interview with the operations manager on 10/19/2022 at 12:48 PM confirmed that the laboratory failed to have documentation of QC testing. 6. The laboratory reports performing 44,025 moderate and high complexity tests annually.
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 a review of the Centers for Medicare and Medicaid (CMS) Proficiency Testing (PT) data report (Report 155D), PT reports from the College of American Pathologists (CAP), direct observations, a lack of documentation and an interviews with the operations manager on 10/19/2022, the laboratory director failed to ensure that new testing verifications were performed, that testing personnel were providing accurate and reliable patient results, that PT was tested and reviewed for all analytes, that testing personnel had appropriate education and training, and that the laboratory had a procedure manual for personnel to follow. See D6086, D6087, D6088, D6091, D6101 and D6106
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services (CMS) 116 Application For Certification, Abbott Architect ci4100 verifications, a direct

	observation, a lack of documentation and interviews with the technical supervisor (TS) on 10/19/2022, the laboratory director failed to ensure that the laboratory verified the performance specifications of new testing on the CELL-DYN Ruby and the Quidel Solana before performing patient testing. See D5421 The findings include: 1. A review of the CMS 116 submitted by the laboratory identified the laboratory added comprehensive metabolic panels, complete blood counts (CBC), thyroxine, triiodothyronine, free thyroxine, thyroid stimulating hormone, Thyroglobulin Antibody and Thyroid peroxidase antibodies effective 12/9/2021 and by direct observation, identified the laboratory added Quidel Solana testing. 2. A lack of documentation identified that the laboratory failed to perform testing performance specification verifications on CBC testing performed on the CELL-DYN Ruby and Influenza A/B and SARS-CoV-2 testing on the Quidel Solana prior to patient testing. 3. An interview with the TS on 10/19/2022 at 1:28 pm confirmed that there was no performance specification verification for the CBC testing and a second interview at 3: 25 pm confirmed that there was no performance specification verification for testing on the Solana. 4. The laboratory reports performing 44,025 moderate and high complexity tests annually.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on a lack of documentation, direct observations, and an interview with the technical supervisor on 10/19/2022, the laboratory director failed to ensure that testing personnel were performing testing in accordance with manufacturers recommendations to ensure accurate and reliable patient results. The findings include: 1. Based on a lack of documentation the laboratory failed to record temperatures for two laboratory refrigerators, a freezer, an incubator and room temperature and humidity in two testing rooms. See D5413 2. Direct observations of the laboratory refrigerators identified chemistry and hematology quality controls, reagents, calibrators and one box of Copan UTM tubes past expiration. Direct observations of the CELL-DYN Ruby and the Abbott Architect ci4100 reagent carousels identified reagents past expiration. By direct observation of the flammable cabinet identified urine toxicology testing reagents past expiration. See D5417 3. Lack of Cell-DYN Ruby, Abbott Architect ci4100 and AB Sciex 4500 LC/MS maintenance logs identified that the laboratory failed to perform maintenance as required by the manufacturers. See D5429 4. Lack of documentation identified that the laboratory failed to perform calibrations at least every six months for testing on the AB Sciex 4500 and Abbott Architect ci4100. See D5437 5. Lack of QC documentation for comprehensive metabolic panel, thyroid panel, complete blood counts, urine toxicology testing, influenza and SARS-COV-2 testing identified that the laboratory failed to perform at least two levels of QC each day of patient testing. See D5447 6. Review of competency assessments identified that the laboratory failed to have six month competency assessment for one testing personnel (TP1). See D5209
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 a review of the Centers for Medicare and Medicaid (CMS) Proficiency Testing (PT) data report (Report 155D), PT reports from the College of American Pathologists (CAP) and an interview with the operations manager on 10/19/2022, the laboratory director failed to ensure that the laboratory was enroll in PT for the specialty of chemistry for 2022. The findings include: 1. A review of Report 155D and PT reports from CAP identified that the laboratory failed to enroll in PT for the sub-specialty of routine chemistry and endocrinology for 2022. See D2000, D2003 2. An interview with the operations manager on 10/19/2022 at 12:48 pm confirmed the above findings. 3. The laboratory reports performing 44,025 moderate and high complexity tests annually.
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 a record review of proficiency testing (PT) from College of American Pathologists (CAP), a lack of documentation and an interview with the operations manager on 10/19/2022, the laboratory director failed to ensure that the laboratory reviewed PT and performed corrective actions for identified issues in 2021 and 2022. The findings include: 1. A review of PT records from CAP for Ethanol biomarkers and urine toxicology, qualitative in 2021 and 2022 identified that the laboratory failed to evaluate the PT scores for any incorrect results. See D5211 2. An interview with the operations manager on 10/19/2022 at 12:48 pm confirmed that there was no documentation of PT review. 3. The laboratory reports performing 30,025 urine toxicology tests annually.
D6101	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(11) The laboratory director must employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart. This STANDARD is not met as evidenced by: Based on direct observations, a lack of documentation and interviews with the operations manager and technical supervisor (TS) on 10/19/2022, the laboratory director failed to ensure that two of three testing personnel had the appropriate education and training to accurately perform and report patient testing, The findings include: 1. A direct observation of testing identified two new testing personnel's initials. A lack of educational documents identified that the laboratory failed to have documentation of educational requirements for two testing personnel that began testing after the previous inspection on 11/5/2022. See D6171 2. A lack of training

	documentation identified that the laboratory failed to have documentation of initial training for two of two testing personnel (TP1 & TP2) performing testing on the Abbott Architect ci4100 and the CELL-DYN Ruby before patient testing began on 12 /9/2021. 3. A lack of training documentation identified that the laboratory failed to have documentation of training for one new testing person (TP3) with a start date of 4 /26/2022 for urine toxicology testing. 4. An interview with the TS on 10/19/2022 at 3: 06 pm identified that he was unaware of TP3 and had no educational or training documentation for TP2 and TP3 or training documentation for the Abbott Architect ci4100 and the CELL-DYN Ruby for TP1. 5. The laboratory reports performing 44,025 moderate and high complexity testing annually.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on a lack of documentation and an interview with the operations manager on 10 /19/2022, the laboratory director failed to ensure the laboratory had written procedures for all testing that it performed available to the laboratory testing personnel. The findings include: 1. Lack of documents available at the time of inspection identified that the laboratory failed to have a written procedures available for testing personnel performing tesing on the Cell-Dyn Ruby, Abbott Architect ci4100 and the Quidel Solana. See D5403 2. Lack of documents available at the time of inspection identified that the laboratory failed to have a written procedure available for the company's other locations collecting and sending samples that include sample collection, labeling, storage and transportation conditions for chemistry, hematology, virology and toxicology testing. See D5311 3. An interview with the operations manager on 10/19 /2022 at 12:48 pm confirmed the above findings. 4. The laboratory reports performing 44,025 moderate and high complexity tests annually.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services (CMS) 116 Application For Certification, CMS Proficiency Testing (PT) data report (Report 155D), PT reports from the College of American Pathologists (CAP), Abbott Architect ci4100 verifications, direct observations, a lack of documentation and interviews with the technical supervisor (TS) on 10/19/2022, the TS failed to ensure that the laboratory verified the performance of new testing before performing patient testing, failed to ensure that the laboratory enrolled and participated in PT for all analytes they are testing, failed to ensure that the laboratory had acceptable QC before resulting patient test results, failed to perform training and competency assessments on testing personnel. See D6115, D6116, D6117 and D6120

D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services (CMS) 116 Application For Certification, Abbott Architect ci4100 verifications, a direct observation, lack of documentation and interviews with the technical supervisor (TS) on 10/19/2022, the TS failed to ensure that the laboratory verified the performance specifications of new testing on the CELL-DYN Ruby, the Abbott Architect ci4100 and the Solana before performing patient testing. See D5421 The findings include: 1. A review of Abbott Architect ci4100 performance specification verifications identified that the laboratory director failed to approve and sign the verifications prior to patient testing. 2. A lack of documentation identified that the laboratory failed to perform testing specification performance verifications on testing performed on the CELL-DYN Ruby and Quidel Solana prior to patient testing. 3. An interviews with the TS on 10/19/2022 at 1:28 pm and 3:25 pm confirmed that there were no specification verifications performed prior to patient testing. 4. The laboratory reports performing 44,025 moderate and high complexity tests annually.
D6116	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(3) The technical supervisor is responsible for enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered. This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid (CMS) Proficiency Testing (PT) data report (Report 155D), PT reports from the College of American Pathologists (CAP) and an interview with the operations manager on 10/19/2022, the technical supervisor failed to ensure the laboratory enrolled and participated in PT for 2022. The findings include: 1. A review of Report 155D and PT reports from CAP identified that the laboratory failed to enroll in PT for the sub-specialties of routine chemistry and endocrinology for 2022. See D2000, D2003 2. A review of Report 155D and PT reports from CAP identified that the laboratory failed to participate in PT for the specialty of hematology for 2022. See D2016 3. An interview with the operations manager on 10/19/2022 at 12:48 pm confirmed the above findings. 4. The laboratory reports performing 44,025 moderate and high complexity tests annually.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results.

	This STANDARD is not met as evidenced by: Based on a lack of documentation and an interview with the operations manager on 10/19/2022, the technical supervisor failed to ensure that the laboratory had acceptable quality control (QC) each day of patient testing for 2021 and 2022. The findings include: 1. A lack of QC documentation for comprehensive metabolic panel, thyroxine, triiodothyronine, free thyroxine, thyroid stimulating hormone, Thyroglobulin Antibody, Thyroid peroxidase antibodies, complete blood count, urine toxicology, influenza A/B and SARS-COV-2 testing identified that the laboratory failed to document acceptable QC each day of testing. See D5447 2. An interview with the operations manager on 10/19/2022 at 12:48 PM confirmed that the laboratory failed to have documentation of QC testing. 3. The laboratory reports performing 44,025 moderate and high complexity tests annually.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on direct observations, review of competency assessments, a lack of documentation and an interview with the technical supervisor (TS) on 10/19/2022, the technical supervisor failed to perform training and competency assessments for three of three testing personnel. The findings include: 1. A direct observation of reagents for the Abbott Architect ci4100 and the CELL-DYN Ruby identified a second testing personnel's initials (TP2). A direct observation of mobile phase for urine toxicology testing on the AB Sciex 4500 identified initials for a third testing personnel (TP3). 2. A lack of training documentation identified that the laboratory failed to have documentation of initial training for two of two testing personnel (TP1 & TP2) performing testing on the Abbott Architect ci4100 and the CELL-DYN Ruby before patient testing began on 12/9/2021. 3. A lack of training documentation identified that the laboratory failed to have documentation of training for one new testing person (TP3) with a start date of 4/26/2022 for urine toxicology testing. 4. A review of competency assessments identified that the laboratory failed to have a six month competency assessment for one testing personnel (TP1) for testing on the Abbott Architect ci4100 and the CELL-DYN Ruby. 5. An interview with the TS on 10/19/2022 at 3:06 pm confirmed the above findings. 6. The laboratory reports performing 44,025 moderate and high complexity testing annually.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.

	This CONDITION is not met as evidenced by: Based on direct observations, a lack of documentation and interviews with the operations manager and technical supervisor (TS) on 10/19/2022, the laboratory failed to have documentation of the minimum educational requirements for two of three testing personnel performing chemistry, endocrinology, hematology and urine toxicology testing. See D6171
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1,

	1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on direct observations, lack of documentation and interviews with the operations manager and technical supervisor (TS) on 10/19/2022, the laboratory failed to have documentation of educational requirements for two of three testing personnel. The findings include: 1. Direct observation of reagents for the Abbott Architect ci4100 and the CELL-DYN Ruby identified a second testing personnel's initials (TP1). Direct observation of mobile phase for urine toxicology testing on the AB Sciex 4500 identified initials for a third testing personnel (TP3). 2. Lack of educational documents identified that the laboratory failed to have documentation of educational requirements for two testing personnel (TP2 and TP3) that began testing after the previous inspection on 11/5/2022. 3. Interviews with the operations manager on 10/19/2022 at 2:16 pm and 3:06 pm identified the two new testing people: TP2 with a starting date of 8/16/2021 and end date of 1/7/2022 and TP3 with a start date of 4/26/2022. 4. An interview with the TS on 10/19/2022 at 3:06 pm identified that he was unaware of TP3 and had no educational documentation for the two new testing personnel. 5. The laboratory reports performing 44,025 moderate and high complexity testing annually.