Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2056591	09/28/2021
Name of Provider or Supplier	**Street Address, City, State**	
Citilabs, Inc	6201 N California Ave, Suite 111, Chicago, IL	

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 record review, the Food and Drug Administration (FDA) CLIA Complexity website, and interview, the laboratory failed to enroll in an HHS approved proficiency testing (PT) program for Hepatitis B Surface Antigen (HBsAg) testing during the year of 2020 and 2021. Findings include: 1. The American Proficiency Institute (API)-PT documents for the years of 2019 to 2021, manufacturer's package insert, the FDA website, and procedures manual were reviewed. 2. The laboratory used an unapproved and uncleared FDA kit for testing HbsAg {SD Bioline HBsAg (ONE STEP)}. 3. Review of API-PT records found the laboratory compared the API-PT results of another laboratory (14D2075610) to its own test results in lieu of enrolling and participating in API's PT program. 4. Further review showed this comparison method was performed for events 1, 2 and 3 of 2020 and events 1 and 2 of 2021. 5. On a Recertification and Complaint survey conducted on 09/28/2021 at 2:00 PM, the LD confirmed the above findings.
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100

	Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on record review, the lack of documentation, and interview, the laboratory failed to retain the printouts of patient test results, quality control results (D3031) and proficiency testing (PT) sample results and PT program documents (D3037) for at least 2 years.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on direct observation, record review, lack of documentation, and interview, the laboratory failed to retain quality control and patient test records from the Chemistry and Hematology testing performed for at least 2 years. Findings include: 1. The laboratory's procedures manual, the Clinical Laboratory Improvement Amendments (CLIA) application signed on 09/28/2021 by the laboratory director (LD), quality control records, and 19 randomly selected patients' Laboratory Information System (LIS) reports from 03/10/2020 to 08/24/2021 were reviewed. 2. On 09/28/2021 at 12: 00 PM during a tour of the laboratory, the surveyor observed the following analyzers: *Envoy 500 Blood Chemistry analyzer; *Abacus 5 Hematology analyzer for Complete Blood Counts (CBC); and *Access 2 analyzer for Endocrinology testing. 3. The CLIA application test menu listed the following analytes tested by the above analyzers: ENVOY 500 Albumin Alanine aminotransferase (ALT/SGPT) Alkaline phosphatase (ALP) Aspartate aminotransferase (AST/SGOT) Bilirubin, total Calcium, total Chloride Cholesterol Cholesterol, HDL Creatinine Creatine Kinase, Isoenzymes (CK) Glucose (Non-Waived) Iron (Fe) Magnesium Potassium Sodium Total Protein Triglycerides Urea Nitrogen (BUN) Uric Acid ACCESS 2 Ferritin Folate Prostate Specific Antigen (PSA) Free Thyroxine (T4) Total Thyroxine (T3) Vitamin B12 Vitamin D ABACUS 5 White Blood Cells (WBC) Red Blood Cells (RBC) Hemoglobin Hematocrit Platelets 4. The procedures manual stated the following: *#5. The results are now ready to be verified as per laboratory policy to detect any error or abnormal or panic values, and then it is transmitted to Laboratory information system (LIS) interface or printed and given to laboratory coordinator to enter in the LIS system. 5. Review of 19 selected patients LIS reports revealed the following: *19 out of 19 patients test results were immediately transmitted into LIS. *Patients results were not printed from the analyzer for review prior to transmission. *The laboratory failed to print 19 out of 19 patients' test results from the analyzers on the day of survey. 6. The laboratory failed to generate QC printouts from the analyzers for the 11

	test dates the 19 selected patients were tested. 7. Review of the laboratory records found the laboratory lacked any documented proof patients' tests and QC results were verified prior to LIS transmission. 8. The laboratory failed to establish a written policy and procedure that instructs the retention of controls and patient test printouts for at least 2 years. 9. On a Recertification and Complaint Investigation survey conducted on 09/28/2021 at 2:00 PM, the laboratory director (LD) confirmed the above findings.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview, the laboratory failed to retain all proficiency testing records for at least 2 years. Findings include: 1. The laboratory's procedures manual and the American Proficiency Institute (API)-PT documents for the years of 2019 to 2021 were reviewed. 2. The laboratory was enrolled in API-PT program for Chemistry and Hematology testing. 3. The API-PT records revealed the following: *PT sample results for five out of five events were Laboratory Information System (LIS) generated final reports instead of analyzer generated test printouts. *API-PT program documents were not retained for three out of five events reviewed. 4. The laboratory failed to follow written procedures to retain the PT program documents and PT specimen test data for at least 2 years. 5. On a Recertification and Complaint Investigation survey conducted on 09/28/2021 at 2:00 PM, the laboratory director (LD) confirmed the above findings.
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, Food and Drug Administration website, and interviews, the laboratory failed to verify the accuracy of the Hepatitis C Antibody (Anti-HCV) testing performed, during the years of 2020 and 2021. Findings Include: 1. The quality control (QC) records, manufacturer's package insert, selected patient test records from 03/2020 to 11/2020, and procedures manual were reviewed. 2. The laboratory used an unapproved and uncleared FDA kit for testing Hepatitis C Antibody (SD Bioline HCV). 3. Review of laboratory records found the laboratory failed to establish a method to verify the accuracy of the HCV test system. 4. Six out of six selected patients were tested using the Anti-HCV kits during the time period reviewed. 5. On a Recertification and Complaint Investigation survey conducted on 09/28/2021 at 2:00 PM, the laboratory director (LD) confirmed the above findings.
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 record review, Food and Drug Administration website, lack of documentation, and interviews, the laboratory failed to establish the performance specifications for their Hepatitis B Surface Antigen (HbsAg) and Hepatitis C Antibody (Anti-HCV) laboratory developed tests (LDTs), affecting six out of 19 patients. Findings Include: 1. The quality control (QC) records, manufacturer's package inserts, selected patient test records from 03/2020 to 11/2020, and procedures manual were reviewed. 2. The laboratory used the following unapproved and uncleared FDA kits for testing HbsAg and Anti-HCV: *SD Bioline HCV and SD Bioline HBsAg (ONE STEP). 3. Review of QC records and manual revealed the laboratory lacked any documentation that the manufacturer's performance specifications were verified prior to testing patients. 4. The laboratory failed to establish and perform methods to provide evidence of each test system's: (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. accuracy, precision, analytical sensitivity, and analytical specificity of the procedure is adequate to meet the patients' needs as determined by the laboratory director and clinical consultant. 5. Six out of 19 patients selected for review were tested using the HbsAg and Anti-HCV kits. 6. On a Recertification and Complaint Investigation survey conducted on 09/28/2021 at 2:00 PM, the laboratory director (LD) confirmed the above findings.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on direct observation, record review, the Clinical Laboratory Improvement Amendments application (CMS 116), and interviews, the laboratory failed to ensure the information interfaced into the Laboratory Information System (LIS)was transmitted accurately, affecting quality control, proficiency testing, and patients' test results. Findings: 1. The procedures manual, the CLIA application signed on 09/28 /2021 by the laboratory director (LD), quality control records, and 19 randomly selected patients' LIS reports from 03/10/2020 to 08/24/2021 were reviewed. 2. On 09

	/28/2021 at 12:00 PM during a tour of the laboratory, the surveyor observed the following analyzers: *Envoy 500 Blood Chemistry analyzer; *Abacus 5 Hematology analyzer, and *Access 2 analyzer. 3. The CLIA application test menu listed the following analytes tested by the above analyzers: ENVOY 500 Albumin Alanine aminotransferase (ALT/SGPT) Alkaline phosphatase (ALP) Aspartate aminotransferase (AST/SGOT) Bilirubin, total Calcium, total Chloride Cholesterol Cholesterol, HDL Creatinine Creatine Kinase, Isoenzymes (CK) Glucose (Non-Waived) Iron (Fe) Magnesium Potassium Sodium Total Protein Triglycerides Urea Nitrogen (BUN) Uric Acid ACCESS 2 Ferritin Folate Prostate Specific Antigen (PSA) Free Thyroxine (T4) Total Thyroxine (T3) Vitamin B12 Vitamin D ABACUS 5 White Blood Cells (WBC) Red Blood Cells (RBC) Hemoglobin Hematocrit Platelets 3. The laboratory failed to retain the analyzers' quality controls (QC) tests, proficiency testing (PT) sample tests, and patients test to verify the LIS transmission accuracy. See D3000, D3031, and D3037. 4. The laboratory failed to establish policies and procedures to perform periodic electronic transmission checks and failed to provide any documentation verifying the accuracy of its LIS interface. 5. On a Recertification and Complaint Investigation survey conducted on 09/28/2021 at 2:00 PM, the laboratory director (LD) confirmed the above findings.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to ensure reference ranges or normal values are included in the final test report, affecting 10 out of 19 patients. Findings: 1. The Laboratory Information System (LIS) final reports of 19 randomly selected patients were reviewed. 2. Ten (10) of the 19 selected patients were tested for the following analytes: *Hepatitis B Surface Antigen (HBsAg) *Hepatits C antibody (Anti-HCV) *Rheumatoid Factor (RF) *Antistreptolysin O (ASO) *Antinuclear antibody (ANA) *C-reactive protein (CRP) *Helicobacter Pylori (H.Pylori) 3. The laboratory failed to indicate the "reference intervals" or "normal" values for the above analytes on the 10 LIS generated patient reports. 4. On a Recertification and Complaint Investigation survey conducted on 09/28/2021 at 2:00 PM, the laboratory director (LD) confirmed the above findings.
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 direct observation, record review, lack of documentation, and interviews,

	the laboratory failed to notify the authorized person ordering patients' test of reporting errors and failed to maintain duplicates of the original report for 5 out of 19 patients. Findings include: 1. The Laboratory Information System (LIS) final reports of 19 randomly selected patients, corrective action/ incident reports, and procedures manual were reviewed. 2. 5 out of 19 patients' final reports had been marked "REVISED". 3. On 09/28/21 at 1:15 PM during the survey, the surveyor observed the following on the laboratory's computer: *The LIS allowed any laboratory personnel to change results or patient information without supervisor approval. *The LIS did not retain the changed information, did not record who made the changes and when (date and time); and the LIS did not indicate what changes were made on the "REVISED" reports. 4. Review of Corrective action records and manual revealed the laboratory lacked any documentation of notification to providers of patient result revisions and the laboratory personnel failed to follow procedure to maintain the original of all corrected reports. 5. On a Recertification and Complaint Investigation survey conducted on 09/28/2021 at 2:00 PM, the laboratory director (LD) confirmed the above findings.
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, the Laboratory Personnel Report (CMS 209), the Food and Drug Administration (FDA) CLIA Complexity website, personnel records, and interview, the laboratory director (LD) failed to meets the qualification requirements of LD providing oversight for the high complexity testing performed in the laboratory (D6078).
D6078	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1443 The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and (b)(2)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and

	continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification. This STANDARD is not met as evidenced by: Based on record review, the Food and Drug Administration (FDA) CLIA Complexity website, the Laboratory Personnel Report (CMS 209), personnel records, and interview, the laboratory director (LD) failed to meets the qualification requirements of LD for the laboratory developed tests (LDT) performed in the laboratory. Findings Include: 1. The Laboratory Personnel Report (CMS 209), personnel records, manufacturer's package inserts and Food and Drug Administration (FDA) website were reviewed. 2. The laboratory used the following unapproved and uncleared FDA kits for testing HBsAg and HCV antibody: *SD Bioline HCV and SD Bioline HBsAg (ONE STEP) 3. The CMS 209 showed the employee listed as LD files has the following: *Foreign education credentials which were evaluated (in 02/26/2009) to be equivalent to a Bachelors of Science in Medical Technology; and *Over 4 years of supervisory experience. 4. On a Recertification and Complaint survey conducted on 09 /28/2021 at 2:00 PM, the LD confirmed the above findings.
D8100	INSPECTION REQUIREMENTS CFR(s): 493.1771 Each laboratory issued a CLIA certificate must meet the requirements in 493.1773 and the specific requirements for its certificate type, as specified in 493.1775 through 493.1780. All CLIA-exempt laboratories must comply with the inspection requirements in 493.1773 and 493.1780, when applicable. This CONDITION is not met as evidenced by: Based on record review, lack of documentation, and interviews, the laboratory failed to provide the CMS agent with, upon request, all information and data needed to make a determination of the laboratory's compliance or complaint substantiation (D8103).
D8103	BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(b)(c)(d) (b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or

	a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview, the laboratory failed to MEET the general requirements of the inspection process. Findings Include: 1. The procedures manual, the American Proficiency Institute (API)-PT documents for the years of 2019 to 2021, quality control records, and 19 randomly selected patients' Laboratory Information System (LIS) generated reports from 03/10/2020 to 08/24 /2021 were reviewed. 2. On 09/28/2021 beginning at 9:45 AM, the surveyor requested the following printouts from the laboratory's three analyzers: *Proficiency testing results *QC results and *Patient results. 3. Review of the procedures manual revealed printing of patients and QC results as part of the laboratory's analytic process. See D3031. 4. The laboratory failed to provide the requested documents, as required, thus impeding the Complaint Investigation and Recertification process. 4. On a Recertification and Complaint Investigation survey conducted on 09/28/2021 at 2:00 PM, the laboratory director (LD) confirmed the above findings.