Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	29D2049463	02/05/2019
Name of Provider or Supplier	**Street Address, City, State**	
Citilab	3909 S Maryland Pkwy Ste 400, Las Vegas, NV	

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	This Statement of Deficiencies was created as a result of an on-site CLIA recertification survey conducted at your facility on February 5, 2019. The findings and conclusions of any investigation by the Division of Public and Behavioral Health shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws.
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 proficiency testing records for laboratory testing years 2017 and 2018 and an interview with the laboratory owner, the laboratory failed to enroll in a Health and Human Services (HHS) approved proficiency testing program for all testing specialties and subspecialties for testing year 2018. Findings include: 1. The laboratory failed to enroll in a HHS approved proficiency testing program for testing year 2018 for the moderate complexity test PT and INR laboratory testing. 2. The laboratory continued to perform patient PT and INR testing through April 2, 2018. This was confirmed by the laboratory owner on February 5, 2019 at approximately 10: 00 AM. The laboratory performed approximately 160 Hematology laboratory tests annually.

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 a review of the American Proficiency Institute (API) proficiency testing records for testing year 2017 and 2018 and an interview with the laboratory owner, the laboratory failed to participate in the API third event 2017 for Hematology and Coagulation. Findings include: 1. The laboratory failed to participate in the API 2017 third event for Hematology and Coagulation. 2. The laboratory was performing non-waived patient PT and INR Hematology testing through April 2, 2018. This was confirmed by the laboratory owner on February 5, 2019 at approximately 10:00 AM. The laboratory performed approximately 160 Hematology laboratory tests 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 review of proficiency testing records for testing year 2017 and 2018 and an interview with the laboratory owner, the laboratory failed to evaluate the results obtained from proficiency testing performed and to determine corrective action. Findings include: 1. The laboratory failed to review, evaluate and provide corrective action for the third event 2018 proficiency testing for Vitamin D which revealed a score of 80% for the event. 2. The laboratory director approved policy for proficiency testing review states that any outliers (less than 100%) will be immediately investigated to determine the cause of the unacceptable result and that all investigative action must be documented on the proficiency test result form. This was confirmed by the laboratory owner on February 5, 2019 at approximately 10:30 AM. The laboratory performs approximately 2210 Chemistry tests annually.
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 a review of proficiency testing records for testing years 2017 and 2018 and

	an interview with the laboratory owner, the laboratory failed to, at least twice annually, verify the accuracy of all laboratory tests performed. Findings include: 1. The laboratory failed to verify accuracy at least twice annually during testing year 2018 for Vitamin D. 2. The laboratory did not perform the first event of proficiency testing for Vitamin D since they began patient testing on 7/16/18. The laboratory failed the second event 2018 with a score of 40%. The third and last proficiency test for Vitamin D passed with a score of 80%. 3. The laboratory did not request or pursue additional proficiency testing events to meet the requirement of twice a year verification of accuracy. This was confirmed by the laboratory owner on February 5, 2019 at approximately 10:30 AM. The laboratory performs approximately 2210 Chemistry tests annually.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a review of laboratory maintenance records for test systems and an interview with the laboratory owner, the laboratory failed to follow maintenance requirements for all laboratory test systems. Findings include: The laboratory failed to perform maintenance on the laboratory centrifuge which had a maintenance due date of 7/18. This was confirmed by the laboratory owner on February 5, 2019 at approximately 11:30 AM. The laboratory performs approximately 2210 laboratory 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 random audit of quality control results from 2/7/17 through 1/26/19 for Hematology and Chemistry and an interview with the laboratory owner, the laboratory failed to perform at two controls of different concentrations each day that patient specimens were assayed. Findings include: The laboratory failed to perform at least two levels of quality control with different concentrations on 11/06/18 for Vitamin D testing before reporting patient test results. This was confirmed by the laboratory owner on February 5, 2019 at approximately 11:30 AM. The laboratory performs approximately 2210 Chemistry tests annually.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403

	The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a review of proficiency testing records, a review of quality control records, a review of quality assessment reports and an interview with the laboratory owner, the director failed to ensure that the laboratory maintained a quality assessment program that would identify failures in the quality of the laboratory (refer to D6021).
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of the laboratory director approved policy and procedure manual for quality assessment, a review of the quarterly documentation of quality assessment and an interview with the laboratory owner, the laboratory director failed to ensure that the quality assessment performed could assure the quality of the patient laboratory services provided. Findings include: 1. The laboratory director failed to assure that the quality assessment performed would identify issues with laboratory proficiency testing. There were issues regarding the failure of twice a year verification of accuracy for analytes, the failure to review all proficiency testing results and document corrective action and failure to enroll in proficiency testing for all analytes that were not identified with the current quality assessment system. 2. The laboratory director failed to assure that the quality assessment performed would identify issues with laboratory system maintenance. The laboratory failed to have maintenance performed on the laboratory centrifuge by 7/18 which was not identified by the current quality assessment system. 3. The laboratory director failed to assure that the quality assessment performed would identify issues with daily quality control. The laboratory performed and issued results for patient Vitamin D testing on 11/06/18 with no quality control performed. The current quality assessment system did not identify this issue. This was confirmed by the laboratory owner on February 5, 2019 at approximately 12:00 PM. The laboratory performs approximately 2210 Chemistry tests annually.