Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 22D1042991	**(X3) Date Survey Completed** 11/13/2019
Name of Provider or Supplier Lab Usa, Inc	**Street Address, City, State** 108r Merrimack Street, Haverhill, MA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	**Summary Statement of Deficiencies**
D0000	A CLIA recertification survey was conducted for the Lab USA, Inc. laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. .
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: . Based on record review and interview with Technical Supervisor 3 (TS3) on 11/13 /19, the laboratory failed to enroll in an approved proficiency testing (PT) program for each Chemistry specialty and subspecialty as evidenced by the following: The surveyors reviewed the American Proficiency Institute (API) PT records on 11/13/19 for calendar years 2018 and 2019. The review revealed that the laboratory enrolled late for the API PT program in 2019 and failed to participate in 2019 Chemistry - Core Chemistry - 1st Event. TS3 confirmed in an interview on 11/13/19 at 10:00 A.M. that the Technical Surpervisor 2 failed to order the PT kits for Chemistry - Core Chemistry - 1st Event for 2019 in a timely manner and therefore PT was not performed. The laboratory performs 375,624 chemistry 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 proficiency testing (PT) review and interview with Technical Supervisor 3 (TS3) on 11/13/19, the laboratory did not document and maintain a copy of all PT records as evidenced by the following: The surveyors reviewed American Proficiency Institute (API) and College of American Pathologists (CAP) PT records for calendar years 2018 and 2019 (30 testing events). The review revealed that signed attestation statements provided by the PT program were not available for the following events: 11 out of 30 attestation statements were not signed by the analyst: 1. API Chemistry Core 2018 Events 1, 2, and 3. 2. API Hematology, Coagulation, Urinalysis 2018 Events 1, 2, and 3. 3. API Microbiology, Dermatophyte, Mycology, Mycobacteriology 2018 Events 1, 2, and 3. 4. API Immunology, Immunohematology 2018 Event 2. 5. API Chemistry Miscellaneous 2018 Event 2. 17 out of 30 attestation statements were not signed by the laboratory director: 1. API Chemistry Core 2018 Events 1, 2, and 3. 2. API Hematology, Coagulation, Urinalysis 2018 Events 1, 2, and 3. 3. API Microbiology, Dermatophyte, Mycology, Mycobacteriology 2018 Events 1, 2, and 3. 4. API Immunology, Immunohematology 2018 Events 1, 2, and 3. 5. API Chemistry Miscellaneous 2018 Events 1 and 2. 6. CAP Urine Toxicology 2018 Events UT-A, UT-B, and UT-C. TS3 confirmed in an interview on 11/13/19 at 10:34 AM that not all attestation statements were signed by the analyst and laboratory director. .
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 proficiency testing (PT) review and interview with Technical Supervisor 3 (TS3) on 11/13/19, the laboratory director failed to effectively review and evaluate PT results obtained on proficiency testing performed as specified in subpart H of this part as evidenced by the following: The surveyors reviewed American Proficiency Institute (API) PT records for calendar years 2018 and 2019 (30 testing events). The review revealed that the laboratory director failed to review and evaluate 14 out of 30 final reports for the following testing events: 1. API Chemistry Core 2018 Events 1, 2, and 3. 2. API Hematology, Coagulation, Urinalysis 2018 Events 1, 2, and 3. 3. API Microbiology, Dermatophyte, Mycology, Mycobacteriology 2018 Events 1, 2, and 3. 4. API Immunology, Immunohematology 2018 Events 1, 2, and 3. 5. API Chemistry

	Miscellaneous 2018 Events 1 and 2. TS3 interviewed on 11/13/19 at 10:34 AM confirmed that the laboratory director failed to review and evaluate the API PT results for 2018. .
D5219	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2) At least twice annually, the laboratory must verify the accuracy of any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: . Based on record review and interview with Technical Supervisor 3 (TS3) on 11/13 /19, the laboratory failed to twice annually ensure the accuracy of the Ethyl Glucuronide (EtG) diagnostic test as evidenced by the following: The surveyor asked TS3 on 11/13/19 for documentation of twice annual accuracy checks for the EtG diagnostic test for 2018 and 2019. TS3 provided only documentation for one accuracy check performed in 2018 and no documentation for accuracy checks performed in 2019. The laboratory last performed an accuracy check for EtG on 4/30/18. TS3 confirmed in an interview on 11/13/19 at 11:05 A.M. that the laboratory failed to perform twice annual accuracy checks for EtG in 2018 and 2019. The laboratory performs 7,182 EtG tests annually. .
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the deficiencies cited herein, the laboratory failed to meet the the applicable analytic systems requirements in 493.1251 through 493.1283 as evidenced by the following: The laboratory failed to perform calibration verifications of at least 3 points once every six months in 2018 and 2019 for Fentanyl and Alcohol. This is a repeat deficiency. Refer to D5439. .
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test

	system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to perform and document calibration verifications as appropriate as evidenced by the following: Surveyors reviewed quality control records on 11/13/19 for calendar years 2018 and 2019. The review revealed that calibration verifications of at least 3 points were not performed once every six months for two (2) of thirty eight (38) chemistry analytes requiring calibration verifications tested on the Beckman AU680 analyzer. The only documented calibration verification for Fentanyl was performed on 11/7/19 and for Alcohol was performed on 11/4/19. Technical Supervisor 3 confirmed though interview on 11/13/19 at 11:30 AM that calibration verifications of at least 3 points had not been performed at least once every six months in 2018 and 2019 for Fentanyl and Alcohol. The laboratory performs 10,512 Fentanyl and 13,718 Alcohol tests annually. This is a repeat deficiency. .
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: . Based on record review and interview, the Technical Consultant (TC) failed to evaluate and document the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tested patient specimens as evidenced by the following: Surveyors reviewed personnel training and competency records for calendar 2017, 2018, and 2019 on 11/13/19. The review revealed that a semiannual competency evaluation was not documented for one (1) newly hired testing person (TP) performing moderate complexity testing. The TC confirmed in an interview on 11/13/19 at 10 AM that semiannual competency evaluations for the new TP were not documented.