Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D1042991	03/31/2022
Name of Provider or Supplier	**Street Address, City, State**	
Lab Usa, Inc	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. Due to repeat deficiencies cited herein, the following Condition level deficiencies were deemed to be not met: CFR 493.801 Condition:Enrollment and testing of samples (Proficiency Testing) CFR 493.1443 Condition: Laboratory Director .
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: . Based on record review and interview with Technical Supervisor 3 (TS3) on 3/31/22 as well as an American Proficiency Institute (API) representative by telephone on 4/1 /22, the laboratory failed to enroll in an approved proficiency testing (PT) program for each Chemistry specialty and subspecialty as evidenced by the following: a) A review of API PT records on 3/31/22 for calendar years 2020 and 2021 revealed no scores for routine chemistry analytes for the first and second testing events of 2021. b) Technical Supervisor 3 confirmed in an interview on 3/31/22 at 10:00 A.M. that the PT service was not able to provide samples for chemistry for the first testing event of 2021. However the API proficiency testing representative stated that the ideal cutoff date was 11/1/2021. She further stated that the lab did not enroll until 2/11/22 at which

	time the chemistry core module was sold out. c) The laboratory performs 288,576 chemistry tests annually. This deficiency was cited at the last CLIA inspection performed on 11/13/19. .
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: A review of American Proficiency Institute (API) and College of American Pathologists (CAP) PT records for calendar years 2020 and 2021 (6 testing events). The review revealed that signed attestation statements and/or coding forms provided by the PT program were not available for the following events: 1. API Hematology - first testing event 2021. 2. CAP Urine Toxicology 2021 testing events UT-B, and UT-C. 3. Sars - COV2 - both testing events (A and B)for 2021. Technical Supervisor 3 confirmed in an interview on 3/31 /22 at 10:30 AM that not all attestation statements as well as coding form documentation was being retained. This deficiency was cited at the last CLIA inspection performed on 11/13/19. .
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 3/31/22, the laboratory failed to review and evaluate all unacceptable PT results obtained on proficiency testing performed as specified in subpart H of this part as evidenced by the following: a) A review of the American Proficiency Institute (API) PT records for calendar years 2020 and 2021 (6 testing events). The review revealed that the laboratory failed to review and evaluate and investigate the following unacceptable testing event scores: 1. API testing event 3 for Vitamin D - score of 50% obtained. 2. API testing event 3 for Hemoglobin AIC - score of 50% obtained. Technical Supervisor 3 interviewed on 3/31/22 at 10:34 AM confirmed that the laboratory failed to review and evaluate the unacceptable PT analytes listed above. .
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE

	CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to verify the accuracy of any test or procedure it performs that is not included in subpart I of this part at least semiannually as evidenced by the following: a) The laboratory performs toxicology (drugs of abuse) by liquid chromatography/mass spectroscopy (LC/MS). The lab is enrolled in College of American Pathologists (CAP) proficiency testing for the qualitative testing performed. However, the laboratory had no system in place to verify the accuracy of quantitative drug testing performed at least semi-annually. b) According to Technical Supervisor 3 interviewed on 3/31/22 at 9:15 a.m. the laboratory had no system in place to verify the accuracy of quantitative drug testing semiannually. c) The laboratory performs approximately 21,774 quantitative toxicology 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 record review and interview, the laboratory failed to to perform validation studies to ensure that it can obtain performance specifications comparable to those established by the manufacturer for re-introduced test system as evidenced by the following: Endocrinology testing: a) In February of 2021 the laboratory restarted performing the following Endocrinology tests after a years hiatus of not performing them: 1. Thyroid Stimulating Hormone (TSH) 2. Total T4 3. Total T3 4. Free T4 5. Free T3 b) In an interview on 3/31/22 at 10:30 AM Technical Supervisor #2 stated that no validation of the test method had been performed prior to utilizing it for patient testing and reporting after a years hiatus of not performing them. c) The laboratory performs approximately 5,359 Endocrinology tests annually. .
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

	This STANDARD is not met as evidenced by: Based on observation, the laboratory failed to maintain documentation to verify function checks on all laboratory equipment as evidenced by the following: Biosafety hood -Virology * On the day of the survey at 10:55 AM in the presence of the laboratory director, and technical supervisor 3 it was observed that the biosafety hood had no certification documentation displayed to confirm that the airflow was adequate. The laboratory could provide no documentation at the time of the survey to confirm that the biosafety hood was operating correctly. .
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 calibration verification as appropriate as evidenced by the following: a) A review of quality control records for calendar years 2020, 2021, and 2022 was performed. The review revealed that calibration verifications of at least 3 points were not performed once every six months for twenty four (24) of twenty four (24) chemistry analytes performed. A review of calibration verification documentation revealed that the laboratory had performed them on 4/5/21 and then on 1/24/22. There were no calibration verifications performed during the second half of 2021. b) Technical supervisor 3 interviewed on 3/31/22 at 11:30 AM confirmed that calibration verifications of at least 3 points had not been performed at least once every six months for routine chemistry analytes. c) The laboratory performs approximately 110,253 routine chemistry tests annually. This deficiency was cited at the last CLIA inspection performed on 11/13/19. .
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 the fact that four of the deficiencies cited during this CLIA recertification survey had been cited at the previous CLIA survey (refer to D2000, D2015, D5211, and D5439), the Laboratory Director failed to provide overall management and direction in accordance with 493.1407 of this subpart and did not ensure that deficiencies cited were corrected and remained corrected through the implementation of appropriate monitoring mechanisms. a) The Laboratory Director failed to ensure that the laboratory was enrolled in an approved proficiency testing (PT) program for each Chemistry specialty and subspecialty. Refer to D2000. b) The Laboratory Director failed to ensure that the laboratory maintained documentation of all proficiency testing records. Refer to D2015. c) The Laboratory Director failed to ensure that all unacceptable PT results obtained on proficiency testing performed were reviewed and evaluated. Refer to D5211. d) The Laboratory Director failed to ensure that the laboratory performed calibration verifications on Routine Chemistry methods at least once every six months. Refer to D5439.