Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2021915	08/15/2019
Name of Provider or Supplier	**Street Address, City, State**	
Lab Trust, Llc	400 River Highlands Blvd, Suite 10, Covington, LA	

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 Certification Survey was performed on August 15, 2019 at LabTrust, LLC, CLIA ID # 19D2021915. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
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 record review and interview with personnel, the laboratory failed to ensure the Laboratory Director reviewed the performance evaluation of proficiency and blind sample testing results for the first event of 2019. Findings: 1. Review of proficiency and blind sample testing records for 2018 and 2019 revealed the laboratory did not have documentation of evaluation of results by the Laboratory Director for the following: a) American Proficiency Institute (API) 2019 Chemistry-Miscellaneous-1st Event b) Blind Sample Event 1 2019 2. Review of the laboratory's "Proficiency Testing Checklist" revealed 2. In interview on August 15, 2019 at 2:21 pm, the Quality Assurance Coordinator stated the Laboratory Director reviewed the identified documents' results, but did not sign. The Quality Assurance Coordinator confirmed the laboratory did not have the Laboratory Director's signature on the evaluation form /results indicating review.
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 observation and interview with personnel, the laboratory failed to ensure reagents did not exceed their expiration date. Findings: 1. Observation during laboratory tour on August 15, 2019 revealed the following expired items: RICCA Acetonitrile, Lot # 4601C13, 4 liters, Expiration date: January 2019, Quantity: three (3) bottles 2. In interview on August 15, 2019, the Technical Supervisor and Quality Assurance Coordinator confirmed the identified items were expired.
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: I. Based on record review and interview with personnel, the laboratory failed to have complete precision studies for the Waters Analyzer # 2 utilized for Urine Drug Confirmation testing. Findings: 1. Review of the laboratory's validation studies for the Waters Analyzer # 2 revealed the laboratory did not include operator variance in the precision studies completed in February 2019. 2. In interview on August 15, 2019 at 11:29 am, the Quality Assurance Coordinator stated there is a back up person who performs sample preparation if the primary person is out. The Quality Assurance Coordinator confirmed the laboratory did not include operator variance in their precision studies. 3. In further interview on August 15, 2019, the Technical Supervisor stated one testing personnel performed sample preparation for the validation studies. II. Based on record review and interview with personnel, the laboratory failed to ensure the extended specimen stability study was approved by the Laboratory Director. Findings. 1. Review of the laboratory's "Extended Stability Studies," performed in March 2019, revealed the laboratory did not have documentation of the Laboratory Director's approval/signature. 2. In interview on August 15, 2019, the Quality Assurance Coordinator confirmed the laboratory did not have documentation of the Laboratory Director's approval/signature for the extended stability studies prior to the surveyor being onsite.
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 record review and interview with personnel, the laboratory failed to perform monthly maintenance on the Aqua Solutions Water Purification System per policy. Findings: 1. Review of the laboratory's policy and procedure manual revealed the following maintenance tasks for the water system: "Monthly: Test Hand-held conductivity monitor" 2. Review of the Aqua Solutions Water Purification manual under maintenance section revealed "measuring the TDS of the RO purified water" as a task. 3. Review of the laboratory's maintenance records for 2018 and 2019 revealed the laboratory did not have documentation of performance of monthly maintenance for the water purification system. 4. In interview on August 15, 2019 at 4:34 pm, the Technical Supervisor stated the laboratory has not performed the monthly maintenance for the water system as indicated in their policy.
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 record review and interview with personnel, the Laboratory Director failed to establish complete performance specifications for Urine Drug Confirmation testing. Refer to D5423 I and D5423 II.
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 observation, record review, and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed the test methods as required for accurate and reliable results. Refer to D5417.
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 record review and interview with personnel, the Laboratory Director failed to ensure the proficiency and blind sample testing results were evaluated. Refer to D5211.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure required maintenance was performed to ensure acceptable levels of performance. Refer to D5433.
D6112	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451 The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Technical Supervisor failed to provide technical and scientific oversight for the laboratory. Findings: 1. The laboratory failed to ensure reagents did not exceed their expiration date. Refer to D5417. 2. The laboratory failed to perform monthly maintenance on the Aqua Solutions Water Purification System per policy. Refer to D5433.
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 record review and interview with personnel, the Technical Supervisor failed to ensure the laboratory established complete performance specification studies for Urine Drug Confirmation testing. Findings D5423 I and D5423 II.