Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2119690	06/06/2018
Name of Provider or Supplier	**Street Address, City, State**	
Express Laboratory Solutions, Llc	2706 Hessmer Ave, Metairie, 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 COMPLAINT SURVEY was performed at Express Laboratory Solutions, LLC - CLIA # 19D2119690 on June 6, 2018. Express Laboratory Solutions was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1210 CONDITION: Routine Chemistry 42 CFR 493.1213 CONDITION: Toxicology 42 CFR 493.1403 CONDITION: Laboratories performing moderate complexity testing; Laboratory Director 42 CFR 493.1409 CONDITION: Laboratories performing moderate complexity testing; Technical Consultant 42 CFR 493.1441 CONDITION: Laboratories performing high complexity testing; Laboratory Director 42 CFR 493.1447 CONDITION: Laboratories performing high complexity testing; Technical Supervisor 42 CFR 493.1487 CONDITION: Laboratories performing high complexity testing; Testing personnel NOTE: The laboratory failed to notify the State of Louisiana and/or Center for Medicare and Medicaid Services (CMS) of a change of address of the laboratory. The laboratory moved from its location at 3434 Houma Blvd, Suite 301, Metairie, LA to its current location at 2706 Hessmer Avenue, Suite B, Metairie, LA in mid June 2017. CMS requires that notification of change of location be done within 30 days of the change.
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to ensure the quality of testing in the specialty of Routine Chemistry. Findings: 1. The laboratory failed to ensure that patient urine samples that are turbid for Urine Drug Screen (UDS) testing are centrifuged before analysis as required by the manufacturer, for eleven (11) of eleven (11) patients observed. Refer to D5311. 2. The

	laboratory failed to establish a laboratory policy and procedure manual that contained complete policies and procedures. Refer to D5401. 3. The laboratory failed to establish and verify performance specifications for accuracy, precision, reportable and reference ranges (normal values) and analytical sensitivity and specificity for the Thermoscientific Indiko Plus Analyzer for Creatinine (Creat), General Oxidant, Specific Gravity, and pH. Refer to D5423. 4. The laboratory failed to perform calibration/calibration verification procedures on the Thermoscientific Indiko Plus Analyzer [utilized for Urine Drug Screen (UDS) testing] at least every 6 months. Refer to D5439. 5. The laboratory failed to establish a written quality assurance plan to identify and correct quality issues in Routine Chemistry. Refer to D5391 and D5791.
D5022	TOXICOLOGY CFR(s): 493.1213 If the laboratory provides services in the subspecialty of Toxicology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to ensure the quality of testing in the specialty of Routine Chemistry. Findings: 1. The laboratory failed to ensure that patient urine samples that are turbid for Urine Drug Screen (UDS) testing are centrifuged before analysis as required by the manufacturer, for eleven (11) of eleven (11) patients observed. Refer to D5311. 2. The laboratory failed to establish a laboratory policy and procedure manual that contained complete policies and procedures. Refer to D5401. 3. The laboratory failed to establish and verify performance specifications for accuracy, precision, reportable and reference ranges (normal values) for the Thermoscientific Indiko Plus Analyzer for Amphetamine (Amph), Barbiturate (Barb), Benzodiazepine (Benzo), Cocaine Metabolite (COC), Ethyl Alcohol (ETOH), Methadone (Meth), Opiates (OPI), Oxycodone (Oxy), Cannabinoids (THC), and Phencyclidine (PCP). Refer to D5421. 4. The laboratory failed to perform calibration/calibration verification procedures on the Thermoscientific Indiko Plus Analyzer [utilized for Urine Drug Screen (UDS) testing] at least every 6 months. Refer to D5439. 5. The laboratory failed to establish a written quality assurance plan to identify and correct quality issues in Routine Chemistry. Refer to D5391 and D5791.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on observation, record review and interview with personnel, the laboratory failed to ensure that patient urine samples that are turbid for Urine Drug Screen (UDS)

	testing are centrifuged before analysis as required by the manufacturer, for eleven (11) of eleven (11) patients observed. Findings: 1. Observation by surveyors during the tour of the laboratory on June 6, 2018 revealed: a) The laboratory maintained a Thermoscientific Indiko Plus analyzer for testing Amphetamine (Amph), Barbiturate (Barb), Benzodiazepine (Benzo), Cocaine Metabolite (COC), Ethyl Alcohol (ETOH), Methadone (Meth), Opiates (OPI), Oxycodone (Oxy), Cannabinoids (THC), Phencyclidine (PCP), Creatinine (Creat), General Oxidant, Specific Gravity, and pH. b) The laboratory failed to have a centrifuge. c) The following patient urine samples were being stored in the refrigerator, were turbid and were tested and reported without centrifuging the samples prior to analysis: On June 1, 2018 Patients 10, and 11. On June 4, 2018 Patients 9. On June 5, 2018 Patients 8. On June 6, 2018 Patients 1 - 7. 2. Review of the Thermoscientific package inserts for Amph, Barb, Benzo, ETOH, Meth, OPI, THC, and PCP revealed under the "Specimen Collection and Handling: It is recommended that highly turbid specimens be centrifuged before analysis." 3. Review of the Thermoscientific package inserts for COC and Oxy revealed under the "Specimen Collection and Preparation: Centrifuge high turbid specimens before analysis." 4. Interview with personnel 2 (Technical Consultant/Technical Supervisor) and 4 on June 6, 2018 revealed they were unaware that turbid urine samples had to be centrifuged prior to analysis. Personnel 2 and 4 confirmed the patients cited above were tested and reported without being centrifuged prior to testing.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory's system failed to monitor, assess, and correct problems, identified with the preanalytic system for Routine Chemistry and Toxicology. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory had a Quality Assurance Policy however, the monitors failed to identify any that the laboratory failed to ensure that patient urine samples that are turbid for Urine Drug Screen (UDS) testing are centrifuged before analysis as required by the manufacturer, for eleven (11) of eleven (11) patients observed. Refer to D5311. 2. Interview with personnel 2 (Technical Consultant /Technical Supervisor) on June 6, 2018 confirmed the above findings.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual and interview with personnel, the laboratory failed to ensure the laboratory policy and procedure manual contained complete policies and procedures. Findings: 1. Review of the laboratory

	policy and procedure manual revealed the laboratory failed to have policies and procedures for: Performance specifications to include: a) Detailed policies and procedures for testing personnel that instructed testing personnel what to do for studies for accuracy, precision (day-to-day, run-to-run, and within-run variation, as well as operator variance), reportable and reference ranges and analytical sensitivity and specificity. a) Acceptability criteria for each of the studies for accuracy, precision, reportable and reference ranges and analytical sensitivity and specificity. a) Policies and procedures for when data from the studies for precision, accuracy, reportable range, reference range, analytical sensitivity and analytical specificity fail to meet acceptability criteria. Description of the course of action to take if the Siemens Viva E Analyzer becomes inoperable. 2. Interview with personnel 2 (Technical Consultant /Technical Supervisor) on June 6, 2018 confirmed the policy and procedure manual was incomplete
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 observations, record review and interview with personnel, the laboratory failed to establish and verify performance specifications for accuracy, precision, reportable and reference ranges (normal values) for the Thermoscientific Indiko Plus Analyzer for Amphetamine (Amph), Barbiturate (Barb), Benzodiazepine (Benzo), Cocaine Metabolite (COC), Ethyl Alcohol (ETOH), Methadone (Meth), Opiates (OPI), Oxycodone (Oxy), Cannabinoids (THC), and Phencyclidine (PCP). Findings: 1. Observation by surveyors during the tour of the laboratory on June 6, 2018 revealed the laboratory maintained a Thermoscientific Indiko Plus analyzer for testing Amphetamine (Amph), Barbiturate (Barb), Benzodiazepine (Benzo), Cocaine Metabolite (COC), Ethyl Alcohol (ETOH), Methadone (Meth), Opiates (OPI), Oxycodone (Oxy), Cannabinoids (THC), Phencyclidine (PCP), Creatinine (Creat), General Oxidant, Specific Gravity, and pH. 2. Review of the FDA web site for test complexity revealed for the Thermoscientific Indiko Plus: Amph, Barb, Benzo, COC, ETOH, Meth, OPI, Oxy, THC, and PCP were all classified as moderate complex tests. 3. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory failed to have written policies and procedures for accuracy, precision (day-to-day, run-to-run, and within-run variation, as well as operator variance), reportable and reference ranges and analytical sensitivity and specificity. Further the Laboratory Policy and Procedure Manual failed to give detailed instructions on what to do for each of the studies and what the acceptability criteria would be for each study. The procedure also failed to include who was responsible for the studies, who performed the studies, who evaluated the studies and when the studies were completed that they were to be reviewed and signed off by the Laboratory Director prior to implementing patient testing. 4. Review of Installation records for the Thermoscientific Indiko Plus Analyzer revealed the instrument was installed in June 2017. Further review of the installation records revealed the Thermoscientific Technical Representative performed

	studies for accuracy, simple precision, linearity, and analytical sensitivity and specificity studies. Further review of installation records revealed the laboratory performed Calibrations, Carryover Study and a Method Comparison Study; however the studies performed by the laboratory failed to identify what or if they were utilizing any of that data for establishment and verification studies. The laboratory failed for Amph, Barb, Benzo, COC, ETOH, Meth, OPI, Oxy, THC, and PCP to include studies for: a) Accuracy b) Studies for Precision for day-to-day, run-to-run, and within-run variation, as well as operator variance c) Studies for reportable range d) Studies for reference ranges. 5. Review of a random selection of patient records for urine Amph, Barb, Benzo, COC, ETOH, Meth, OPI, Oxy, THC, and PCP testing that utilized the Thermoscientific Indiko Plus Analyzer from from June 1, 2018 through June 6, 2018 revealed the laboratory failed to verify performance specification prior to patient testing for the following patients: On June 1, 2018 Patients 10, and 11. On June 4, 2018 Patients 9. On June 5, 2018 Patients 8 and 12. On June 6, 2018 Patients 1 - 7. Review of the Task 1 and 3 Form submitted to surveyors on June 6, 2018 revealed the laboratory performed the following annual test volumes for: 8400 - Amph, 8400 - Barb, 8400 - Benzo, 8400 - COC, 8400 - ETOH, 8400 - Meth, 8400 - OPI, 8400 - Oxy, 8400 - THC, and 8400 - PCP . 6. Interview with personnel 2 (Technical Consultant/Technical Supervisor) on June 6, 2018 confirmed the Thermoscientific Technical Representative was responsible for the initial setup of the instrument and performed the studies. Personnel 2 confirmed patient testing was being done without the laboratory verifying performance specifications for accuracy, precision, reportable and reference ranges.
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 observations, record review and interview with personnel, the laboratory failed to establish and verify performance specifications for accuracy, precision, reportable and reference ranges (normal values) and analytical sensitivity and specificity for the Thermoscientific Indiko Plus Analyzer for Creatinine (Creat), General Oxidant, Specific Gravity, and pH. Findings: 1. Observation by surveyors during the tour of the laboratory on June 6, 2018 revealed the laboratory maintained a Thermoscientific Indiko Plus analyzer for testing Amphetamine (Amph), Barbiturate (Barb), Benzodiazepine (Benzo), Cocaine Metabolite (COC), Ethyl Alcohol (ETOH), Methadone (Meth), Opiates (OPI), Oxycodone (Oxy), Cannabinoids (THC), Phencyclidine (PCP), Creatinine (Creat), General Oxidant, Specific Gravity, and pH. 2. Review of the FDA web site for test complexity revealed for the Thermoscientific Indiko Plus: Creat, General Oxidant, Specific Gravity and pH had not gone through the FDA process for classification and would then be considered a Laboratory

	Developed Test or High Complexity. 3. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory failed to have written policies and procedures for accuracy, precision (day-to-day, run-to-run, and within-run variation, as well as operator variance), reportable and reference ranges and analytical sensitivity and specificity. Further the Laboratory Policy and Procedure Manual failed to give detailed instructions on what to do for each of the studies and what the acceptability criteria would be for each study. The procedure also failed to include who was responsible for the studies, who performed the studies, who evaluated the studies and when the studies were completed that they were to be reviewed and signed off by the Laboratory Director prior to implementing patient testing. 4. Review of Installation records for the Thermoscientific Indiko Plus Analyzer revealed the instrument was installed in June 2017. Further review of the installation records revealed the Thermoscientific Technical Representative performed studies for accuracy, simple precision, linearity, and analytical sensitivity and specificity studies. Further review of installation records revealed the laboratory performed Calibrations, Carryover Study and a Method Comparison Study; however the studies performed by the laboratory failed to identify what or if they were utilizing any of that data for establishment and verification studies. The laboratory failed for Creat, General Oxidant, Specific Gravity and pH to include studies for: a) Accuracy b) Studies for Precision for day-to-day, run-to-run, and within-run variation, as well as operator variance c) Studies for reportable range d) Studies for reference ranges. e) Complete studies for analytical sensitivity and specificity. 5. Review of a random selection of patient records for urine Creat, General Oxidant, Specific Gravity and pH testing that utilized the Thermoscientific Indiko Plus Analyzer from from June 1, 2018 through June 6, 2018 revealed the laboratory failed to establish and verify performance specification prior to patient testing for the following patients: On June 1, 2018 Patients 10, and 11. On June 4, 2018 Patients 9. On June 5, 2018 Patients 8 and 12. On June 6, 2018 Patients 1 - 7. Review of the Task 1 and 3 Form submitted to surveyors on June 6, 2018 revealed the laboratory performed the following annual test volumes for: 8400 - Creat, 8400 - General Oxidant, 8400 - Specific Gravity, and 8400 - pH. 6. Interview with personnel 2 (Technical Consultant/Technical Supervisor) on June 6, 2018 confirmed the Thermoscientific Technical Representative was responsible for the initial setup of the instrument and performed the studies. Personnel 2 revealed she was unaware the tests for Creat, General Oxidant, Specific Gravity and pH were considered high complexity. Personnel 2 confirmed patient testing was being done without the laboratory having established performance specifications for accuracy, precision, reportable and reference ranges, and analytical sensitivity and specificity.
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 observation, record review, and interview with laboratory personnel, the laboratory failed to perform calibration/calibration verification procedures on the Thermoscientific Indiko Plus Analyzer [utilized for Urine Drug Screen (UDS) testing] at least every 6 months. Findings: 1. Observation by surveyors during the tour of the laboratory on June 6, 2018 revealed the laboratory maintained a Thermoscientific Indiko Plus analyzer for testing Amphetamine (Amph), Barbiturate (Barb), Benzodiazepine (Benzo), Cocaine Metabolite (COC), Ethyl Alcohol (ETOH), Methadone (Meth), Opiates (OPI), Oxycodone (Oxy), Cannabinoids (THC), Phencyclidine (PCP), Creatinine (Creat), General Oxidant, Specific Gravity, and pH. 2. Review of Installation records for the Thermoscientific Indiko Plus Analyzer revealed the instrument was installed in June 2017. 3. Review of Quality Control /Calibration Records for the Thermoscientific Indiko Plus revealed the laboratory performs a 1 point or 2 point calibration with each new lot or shipment or when there are quality control issues. 4. Review of the Laboratory's Policy and Procedure manual revealed the laboratory failed to have a written Calibration Verification policy and procedure. Further review of Laboratory Policy and Procedure Manual revealed the laboratory performs two (2) levels of controls each 24 hours of patient testing. 5. Interview with personnel 2 (Technical Consultant/Technical Supervisor) on June 6, 2018 revealed she was unaware of Calibration Verification and confirmed that the laboratory does not perform calibration verification every 6 months. Personnel 2 also confirmed the laboratory performs two (2) levels of controls each 24 hours of patient testing. 6. Review of a random selection of patient records for Urine Drug Screen testing that utilized the Thermoscientific Indiko Plus Analyzer from from June 1, 2018 through June 6, 2018 revealed the laboratory reported the following patients without performing a 6 month calibration verification procedure: On June 1, 2018 Patients 10, and 11. On June 4, 2018 Patients 9. On June 5, 2018 Patients 8 and 12. On June 6, 2018 Patients 1 - 7. Review of the Task 1 and 3 Form submitted to surveyors on June 6, 2018 revealed the laboratory performed the following annual test volumes for: 8400 - Amph, 8400 - Barb, 8400 - Benzo, 8400 - COC, 8400 - ETOH, 8400 - Meth, 8400 - OPI, 8400 - Oxy, 8400 - THC, 8400 - PCP, 8400 - Creat, 8400 - General Oxidant, 8400 - Specific Gravity, and 8400 - pH.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by:

	Based on observation, record review, and interview with personnel, the laboratory's Quality Assurance monitors failed to identify and correct quality issues in Analytic Systems. Findings: 1. A review of patient test records and quality control records indicated problems as follows: a) The laboratory failed to ensure that patient urine samples that are turbid for Urine Drug Screen (UDS) testing are centrifuged before analysis as required by the manufacturer, for eleven (11) of eleven (11) patients observed. Refer to D5311. b) The laboratory failed to establish a laboratory policy and procedure manual that contained complete policies and procedures. Refer to D5401. c) 3. The laboratory failed to establish and verify performance specifications for accuracy, precision, reportable and reference ranges (normal values) for the Thermoscientific Indiko Plus Analyzer for Amphetamine (Amph), Barbiturate (Barb), Benzodiazepine (Benzo), Cocaine Metabolite (COC), Ethyl Alcohol (ETOH), Methadone (Meth), Opiates (OPI), Oxycodone (Oxy), Cannabinoids (THC), and Phencyclidine (PCP). Refer to D5421. d) The laboratory failed to establish and verify performance specifications for accuracy, precision, reportable and reference ranges (normal values) and analytical sensitivity and specificity for the Thermoscientific Indiko Plus Analyzer for Creatinine (Creat), General Oxidant, Specific Gravity, and pH. Refer to D5423. e) The laboratory failed to perform calibration/calibration verification procedures on the Thermoscientific Indiko Plus Analyzer [utilized for Urine Drug Screen (UDS) testing] at least every 6 months. Refer to D5439. 2. The laboratory had a Quality Assurance Policy that identified specific monitors that were routinely performed by the laboratory. However, the laboratory failed to include monitors that would correct the issues cited above. 3. Interview with personnel 2 (Technical Consultant/Technical Supervisor) on June 6, 2018 confirmed the above findings.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: I. Based on observation and record review, the laboratory failed to include the statement from the manufacturer that states "This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgement should be applied to any drug of abuse test results, particularly when preliminary positive results are used." Findings: 1. Observation by surveyors during the tour of the laboratory on June 6, 2018 revealed the laboratory maintained a Thermoscientific Indiko Plus analyzer for testing Amphetamine (Amph), Barbiturate (Barb), Benzodiazepine (Benzo), Cocaine Metabolite (COC), Ethyl Alcohol (ETOH), Methadone (Meth), Opiates (OPI), Oxycodone (Oxy), Cannabinoids (THC), Phencyclidine (PCP), Creatinine (Creat), General Oxidant, Specific Gravity, and pH. 2. Review of the Thermoscientific package inserts for Amph, Barb, Benzo,

ETOH, Meth, OPI, THC, and PCP revealed under the "Intended Use: This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgement should be applied to any drug of abuse test results, particularly when preliminary positive results are used." 3. Review of a random selection of patient records for Urine Drug Screen testing that utilized the Thermoscientific Indiko Plus Analyzer from from June 1, 2018 through June 6, 2018 revealed the laboratory failed to include the manufacturer's statement "This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgement should be applied to any drug of abuse test results, particularly when preliminary positive results are used." on the final report for the following patients: On June 1, 2018 Patients 10, and 11. On June 4, 2018 Patients 9. On June 5, 2018 Patients 8 and 12. On June 6, 2018 Patients 1 - 7. Review of the Task 1 and 3 Form submitted to surveyors on June 6, 2018 revealed the laboratory performed the following annual test volumes for: 8400 - Amph, 8400 - Barb, 8400 - Benzo, 8400 - COC, 8400 - ETOH, 8400 - Meth, 8400 - OPI, 8400 - Oxy, 8400 - THC, and 8400 - PCP . 4. Interview with personnel 2 (Technical Consultant/Technical Supervisor) on June 6, 2018 revealed she was unaware the laboratory needed to include the statement from the manufacturer on the patient final reports. Personnel 2 confirmed the patient final reports failed to contain the manufacturer's statement for reporting results as preliminary results and failed to include the rest of the manufacturer's statement. II. Based on observation and record review, the laboratory failed to include on the report for Urine Drug Screen tests a statement that states "The performance characteristics of this test were determined by Express Laboratory Solutions, LLC. It has not been cleared or approved by the U.S. Food and Drug Administration." Findings: 1. Observation by surveyors during the tour of the laboratory on June 6, 2018 revealed the laboratory maintained a Thermoscientific Indiko Plus analyzer for testing Amphetamine (Amph), Barbiturate (Barb), Benzodiazepine (Benzo), Cocaine Metabolite (COC), Ethyl Alcohol (ETOH), Methadone (Meth), Opiates (OPI), Oxycodone (Oxy), Cannabinoids (THC), Phencyclidine (PCP), Creatinine (Creat), General Oxidant, Specific Gravity, and pH. 2. Review of the Food and Drug Administration (FDA) website for CLIA Test categorization revealed the Thermoscientific Indiko Plus for Creat, General Oxidant, Specific Gravity and pH had not been categorized by the FDA; thus being classified as high complexity and as a laboratory developed test. 3. Review of a random selection of patient records for Urine Drug Screen testing that utilized the Thermoscientific Indiko Plus Analyzer from from June 1, 2018 through June 6, 2018 revealed the laboratory failed to include a disclaimer on the patient final report that states "The performance characteristics of this test were determined by Express Laboratory Solutions. It has not been cleared or approved by the U.S. Food and Drug Administration for the following patients: On June 1, 2018 Patients 10, and 11. On June 4, 2018 Patients 9. On June 5, 2018 Patients 8 and 12. On June 6, 2018 Patients 1 - 7. Review of the Task 1 and 3 Form submitted to surveyors on June 6, 2018 revealed the laboratory performed the following annual test volumes for: 8400 - Creat, 8400 - General Oxidant, 8400 - Specific Gravity, and 8400 - pH . 4. Interview with personnel 2 (Technical Consultant/Technical Supervisor) on June 6, 2018 revealed she was unaware the patient final reports had to include a disclaimer that stated the performance characteristics of these tests were determined by Express Laboratory Solutions. It has not been cleared or approved by the U.S. Food and Drug Administration. Personnel 2 confirmed that patient final reports failed to include the

	disclaimer.
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 observation, record review and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure that verification procedures are performed to accuracy, precision, reportable and reference ranges (normal values) for the Thermoscientific Indiko Plus Analyzer for Amphetamine (Amph), Barbiturate (Barb), Benzodiazepine (Benzo), Cocaine Metabolite (COC), Ethyl Alcohol (ETOH), Methadone (Meth), Opiates (OPI), Oxycodone (Oxy), Cannabinoids (THC), and Phencyclidine (PCP). Refer to D6013. 2. The Laboratory Director failed to ensure laboratory personnel performed testing as required for accurate and reliable results. Refer to D6014. 3. The Laboratory Director failed to ensure that quality control programs were established to assure the quality of laboratory testing. Refer to D6020. 4. The Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided. Refer to D6021. 5. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Refer to D6031.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) 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 observations, record review and interview with laboratory personnel, the Laboratory Director failed to ensure that verification procedures are performed to determine accuracy, precision, reportable and reference ranges for the Thermoscientific Indiko Plus Analyzer for Amphetamine (Amph), Barbiturate (Barb), Benzodiazepine (Benzo), Cocaine Metabolite (COC), Ethyl Alcohol (ETOH), Methadone (Meth), Opiates (OPI), Oxycodone (Oxy), Cannabinoids (THC), and Phencyclidine (PCP). Refer to D5421.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) 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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required for accurate and reliable results. Findings: 1. The laboratory failed to ensure that patient urine samples that are turbid for Urine Drug Screen (UDS) testing are centrifuged before analysis as required by the manufacturer, for eleven (11) of eleven (11) patients observed. Refer to D5311. 2. The laboratory failed to include the statement from the manufacturer that states "This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgement should be applied to any drug of abuse test results, particularly when preliminary positive results are used." Refer to D5805 I.
D6020	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 the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that the laboratory performed calibration/calibration verification procedures on the Thermoscientific Indiko Plus Analyzer [utilized for Urine Drug Screen (UDS) testing] at least every 6 months. Refer to D5439.
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 observation, record review and interview with laboratory personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided.

	Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory had a Quality Assurance Policy however, the monitors failed to identify any of the deficiencies identified with the preanalytic and analytic system as follows: a) The laboratory failed to ensure that patient urine samples that are turbid for Urine Drug Screen (UDS) testing are centrifuged before analysis as required by the manufacturer, for eleven (11) of eleven (11) patients observed. Refer to D5311. b) The laboratory failed to establish a laboratory policy and procedure manual that contained complete policies and procedures. Refer to D5401. c) The laboratory failed to establish and verify performance specifications for accuracy, precision, reportable and reference ranges (normal values) for the Thermoscientific Indiko Plus Analyzer for Amphetamine (Amph), Barbiturate (Barb), Benzodiazepine (Benzo), Cocaine Metabolite (COC), Ethyl Alcohol (ETOH), Methadone (Meth), Opiates (OPI), Oxycodone (Oxy), Cannabinoids (THC), and Phencyclidine (PCP). Refer to D5421. d) The laboratory failed to perform calibration/calibration verification procedures on the Thermoscientific Indiko Plus Analyzer [utilized for Urine Drug Screen (UDS) testing] at least every 6 months. Refer to D5439. 2. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory establish a Quality Assurance Plan that covered all phases of testing; however the laboratory failed to identify and correct the problems cited above. Refer to D5391 and D5791. 3. Interview with personnel 2 (Technical Consultant/Technical Supervisor) on June 6, 2018 confirmed the laboratory failed to identify the deficiencies cited above.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that the laboratory had a complete policy and procedure manual. Findings: 1. Review of the laboratory policy and procedure manual revealed the laboratory failed to have policies and procedures for: Performance specifications to include: a) Detailed policies and procedures for testing personnel that instructed testing personnel what to do for studies for accuracy, precision (day-to-day, run-to-run, and within-run variation, as well as operator variance), reportable and reference ranges and analytical sensitivity and specificity. a) Acceptability criteria for each of the studies for accuracy, precision, reportable and reference ranges and analytical sensitivity and specificity. a) Policies and procedures for when data from the studies for precision, accuracy, reportable range, reference range, analytical sensitivity and analytical specificity fail to meet acceptability criteria. Description of the course of action to take if the Siemens Viva E Analyzer becomes inoperable. 2. Interview with personnel 2 (Technical Consultant/Technical Supervisor) on June 6, 2018 confirmed the policy and procedure manual was incomplete.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409

	The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on observation, record review, and interview with personnel, the Technical Consultants failed to provide technical and scientific oversight for the laboratory. Refer to D6036.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on observation, record review and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight for the laboratory. Findings: 1. Review of the FORM CMS 209 submitted to the surveyor on June 6, 2018 revealed that personnel 2 fulfilled the duties for Technical Consultant. 2. Observation, record review and interview with personnel revealed the Technical Consultant failed to address the following problems identified in the laboratory: a) The laboratory failed to ensure that patient urine samples that are turbid for Urine Drug Screen (UDS) testing are centrifuged before analysis as required by the manufacturer, for eleven (11) of eleven (11) patients observed. Refer to D5311. b) The laboratory failed to establish a laboratory policy and procedure manual that contained complete policies and procedures. Refer to D5401. c) The laboratory failed to establish and verify performance specifications for accuracy, precision, reportable and reference ranges (normal values) for the Thermoscientific Indiko Plus Analyzer for Amphetamine (Amph), Barbiturate (Barb), Benzodiazepine (Benzo), Cocaine Metabolite (COC), Ethyl Alcohol (ETOH), Methadone (Meth), Opiates (OPI), Oxycodone (Oxy), Cannabinoids (THC), and Phencyclidine (PCP). Refer to D5421. d) The laboratory failed to perform calibration/calibration verification procedures on the Thermoscientific Indiko Plus Analyzer [utilized for Urine Drug Screen (UDS) testing] at least every 6 months. Refer to D5439. e) The laboratory failed to include the statement from the manufacturer that states "This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgement should be applied to any drug of abuse test results, particularly when preliminary positive results are used." Refer to D5805 I. 3. Interview with the Technical Consultant on June 6, 2018 confirmed she failed to identify the deficiency cited above.
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 observation, record review and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure that verification procedures are performed to determine accuracy, precision, reportable and reference ranges (normal values) and analytical sensitivity and specificity for the Thermoscientific Indiko Plus Analyzer for Creatinine (Creat), General Oxidant, Specific Gravity, and pH. Refer to D6086. 2. The Laboratory Director failed to ensure laboratory personnel performed testing as required for accurate and reliable results. Refer to D6087. 3. The Laboratory Director failed to ensure that quality control programs were established to assure the quality of laboratory testing. Refer to D6093. 4. The Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided. Refer to D6094. 5. The Laboratory Director failed to ensure that all personnel have the appropriate education and experience to accurately report patient test results. Refer to D6102. 6. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Refer to D6106.
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 observation, record review and interview with the Laboratory Director, the Laboratory Director failed to ensure the laboratory established studies for accuracy, precision reportable and reference ranges (normal values) and analytical sensitivity and specificity failed to establish and verify performance specifications for the Thermoscientific Indiko Plus Analyzer for Creatinine (Creat), General Oxidant, Specific Gravity, and pH. Refer to D5423.
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 record review and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required for accurate and reliable results. Findings: 1. The laboratory failed to ensure that patient urine samples that are turbid for Urine Drug Screen (UDS) testing are centrifuged before analysis as required by the manufacturer, for eleven (11) of eleven (11) patients observed. Refer to D5311. 2. The laboratory failed to include the statement from the manufacturer that states "This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgement should be

	applied to any drug of abuse test results, particularly when preliminary positive results are used." Refer to D5805 I. 3. The laboratory failed to include on the report for Urine Drug Screen tests a statement that states "The performance characteristics of this test were determined by Express Laboratory Solutions, LLC. It has not been cleared or approved by the U.S. Food and Drug Administration." Refer to D5805 II.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that the laboratory performed calibration/calibration verification procedures on the Thermoscientific Indiko Plus Analyzer [utilized for Urine Drug Screen (UDS) testing] at least every 6 months. Refer to D5439.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on observation, record review and interview with laboratory personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory had a Quality Assurance Policy however, the monitors failed to identify any of the deficiencies identified with the preanalytic and analytic system as follows: a) The laboratory failed to ensure that patient urine samples that are turbid for Urine Drug Screen (UDS) testing are centrifuged before analysis as required by the manufacturer, for eleven (11) of eleven (11) patients observed. Refer to D5311. b) The laboratory failed to establish a laboratory policy and procedure manual that contained complete policies and procedures. Refer to D5401. c) The laboratory failed to establish and verify performance specifications for accuracy, precision, reportable and reference ranges (normal values) and analytical sensitivity and specificity for the Thermoscientific Indiko Plus Analyzer for Creatinine (Creat), General Oxidant, Specific Gravity, and pH. Refer to D5423. d) The laboratory failed to perform calibration/calibration verification procedures on the Thermoscientific Indiko Plus Analyzer [utilized for Urine Drug Screen (UDS) testing] at least every 6 months. Refer to D5439. 2. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory establish a Quality Assurance Plan that covered all phases of testing; however the laboratory failed to identify and correct the problems cited above. Refer to D5391 and D5791. 3. Interview with personnel 2 (Technical Consultant/Technical Supervisor) on June 6, 2018 confirmed the laboratory failed to identify the deficiencies cited above.

D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on a review of personnel records, the Laboratory Director failed to ensure all personnel had the appropriate education and experience for performing high complexity testing. Findings: 1. The laboratory failed to have a current license issued by the State of Louisiana (R. S. 37:131 - 1329 "Louisiana Clinical Laboratory Personnel Law"), that would allow testing personnel to perform high complexity testing for one (1) of three (3) testing persons performing high complexity testing. Refer to D6170. 2. Interview with personnel 2 on June 6, 2018 confirmed the above findings
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that the laboratory had a complete policy and procedure manual. Findings: 1. Review of the laboratory policy and procedure manual revealed the laboratory failed to have policies and procedures for: Performance specifications to include: a) Detailed policies and procedures for testing personnel that instructed testing personnel what to do for studies for accuracy, precision (day-to-day, run-to-run, and within-run variation, as well as operator variance), reportable and reference ranges and analytical sensitivity and specificity. a) Acceptability criteria for each of the studies for accuracy, precision, reportable and reference ranges and analytical sensitivity and specificity. a) Policies and procedures for when data from the studies for precision, accuracy, reportable range, reference range, analytical sensitivity and analytical specificity fail to meet acceptability criteria. Description of the course of action to take if the Siemens Viva E Analyzer becomes inoperable. 2. Interview with personnel 2 (Technical Consultant/Technical Supervisor) on June 6, 2018 confirmed the policy and procedure manual was incomplete.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by:

	Based on review of personnel records and interview with personnel, the Technical Supervisor failed provide technical and scientific oversight for the laboratory. Refer to D6112.
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. Review of the CMS Form 209 submitted to surveyors on June 6, 2018 revealed that Personnel 4 was assigned as the Technical Supervisor to provide technical oversight of the laboratory. 2. Observation, record review and interview with personnel revealed the laboratory failed to have monitors that identified problems within the laboratory as follows: a) The laboratory failed to ensure that patient urine samples that are turbid for Urine Drug Screen (UDS) testing are centrifuged before analysis as required by the manufacturer, for eleven (11) of eleven (11) patients observed. Refer to D5311. b) The laboratory failed to establish a laboratory policy and procedure manual that contained complete policies and procedures. Refer to D5401. c) The laboratory failed to establish and verify performance specifications for accuracy, precision, reportable and reference ranges (normal values) and analytical sensitivity and specificity for the Thermoscientific Indiko Plus Analyzer for Creatinine (Creat), General Oxidant, Specific Gravity, and pH. Refer to D5423. d) The laboratory failed to perform calibration/calibration verification procedures on the Thermoscientific Indiko Plus Analyzer [utilized for Urine Drug Screen (UDS) testing] at least every 6 months. Refer to D5439. e) The laboratory failed to include the statement from the manufacturer that states "This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgement should be applied to any drug of abuse test results, particularly when preliminary positive results are used." Refer to D5805 I. f) The laboratory failed to include on the report for Urine Drug Screen tests a statement that states "The performance characteristics of this test were determined by Express Laboratory Solutions, LLC. It has not been cleared or approved by the U.S. Food and Drug Administration." Refer to D5805 II. 3. Interview with personnel 2 on June 6, 2018 confirmed the above findings.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by:

	Based on record review and interview with laboratory personnel, the laboratory failed to ensure testing personnel met the qualifications of education and licensure to perform high complexity testing. Findings: 1. The laboratory failed to have a current license issued by the State of Louisiana (R. S. 37:131 - 1329 "Louisiana Clinical Laboratory Personnel Law"), that would allow testing personnel to perform high complexity testing for one (1) of three (3) testing persons performing high complexity testing. Refer to D6170. 2. Interview with personnel 2 on June 6, 2018 confirmed the above findings
D6170	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(a) Each individual performing high complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required. This STANDARD is not met as evidenced by: Based on observation, record review and interview with laboratory personnel, the laboratory failed to have a current license issued by the State of Louisiana (R. S. 37: 131 - 1329 "Louisiana Clinical Laboratory Personnel Law"), that would allow testing personnel to perform high complexity testing for one (1) of three (3) testing persons performing high complexity testing. Findings: 1. Observation by surveyors during the tour of the laboratory on June 6, 2018 revealed the laboratory maintained a Thermoscientific Indiko Plus analyzer for testing Amphetamine (Amph), Barbiturate (Barb), Benzodiazepine (Benzo), Cocaine Metabolite (COC), Ethyl Alcohol (ETOH), Methadone (Meth), Opiates (OPI), Oxycodone (Oxy), Cannabinoids (THC), Phencyclidine (PCP), Creatinine (Creat), General Oxidant, Specific Gravity, and pH. 2. Review of the FDA web site for test complexity revealed for the Thermoscientific Indiko Plus: Amph, Barb, Benzo, COC, ETOH, Meth, OPI, Oxy, THC, and PCP were all classified as moderate complex tests. Further review of the FDA web site revealed that Creat, General Oxidant, Specific Gravity and pH had not gone through the FDA process for classification and would then be considered a Laboratory Developed Test or High Complexity. 3. Review of personnel records revealed: a) Personnel 3 maintained a Laboratory Assistant License; however the Louisiana State Board of Medical Examiners (LSBME) has determined the Laboratory Assistant License does not cover high complexity testing. b) Personnel 3 failed to maintain documentation of a current license that would cover high complexity testing. 4. Interviews with Personnel 2 and 3 on June 6, 2018 revealed they did not know that they were performing high complexity testing. Personnel 2 and 3 also revealed they were unaware the LSBME Laboratory Assistant License not covering high complexity testing. Personnel 2 and 3 confirmed personnel 3 was performing testing and that personnel 3 only had a Laboratory Assistant license that would not cover high complexity testing.