Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2008492	05/01/2018
Name of Provider or Supplier	**Street Address, City, State**	
Express Biomedical Lab Llc	13921 Old Chocolate Bayou Rd, Houston, TX	

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	The laboratory was found out of compliance with the CLIA regulations. The conditions not met were: D5016 - 42 C.F.R. 493.1210 Condition: Routine chemistry; D5300 - 42 C.F.R. 493.1240 Condition: Preanalytic systems; D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems; D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director; D6033 - 42 C.F.R. 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant; D6063 - 42 C.F.R. 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel; D8100 - 42 C.F.R. 493.1771 Condition: Inspection requirements applicable to all CLIAcertified and CLIA-exempt laboratories. This was not an active laboratory. There was no evidence of patient testing at this site from the time the laboratory received their certificate of registration on 5/19/16 through day of survey on 5/1/18 per 42 CFR 493.1 Basis and Scope and 42 CFR 493.2 Definitions.
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 a review of the manufacturer's instructions, test reports and staff interview, the laboratory failed to meet the applicable requirements in the specialty of chemistry. Findings were: 1. The the laboratory failed to perform a complete verification study on the Alfa Wassermann chemistry analyzers (accuracy, precision, reportable range and reference intervals) Refer to D5421 2. The laboratory failed to define the correct acceptable criteria for accurate and reliable test system operation consistent with the manufacturer's instructions. Refer to D5413 3. The laboratory failed to document manufacturer required maintenance on the Alfa Wassermann ACE Alera Clinical

	Chemistry System. Refer to D5429 4. The laboratory failed to have documentation of performing six month calibration verification for the Alfa Wassermann ACE Alera chemistry analyzer. Refer to D5439
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on record review and confirmed in interview, the laboratory failed to have written instructions available to the laboratory's clients that included information on specimen storage and preservation and conditions for transportation for chemistry testing on the Alfa Wassermann ACE Alera chemsitry analzyer. Findings were: 1. Review of records revealed the laboratory did not include written instructions for facilities that used that laboratory as a referral laboratory for specimen testing. There was no documentation of requirements for: a) Specimen storage and preservation. b) Condition for specimen transport. 2. During an interview on 5/1/2018 at 1000 hours in the laboratory, the laboratory director confirmed the above findings. He was unaware he needed a client services manual.
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 observation and an interview of the lab director, the laboratory failed to ensure that an approved procedure manual was available for the Alfa Wassermann ACE Alera chemsitry analzyer. Findings were: 1. A request for the procedure manual revealed no approved procedure manual was available for review for Alfa Wassermann ACE Alera chemsitry analzyer. 2. An interview of the lab director on 05 /01/18 at 1040 hours in the laboratory confirmed he had not signed nor dated the procedures.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

	This STANDARD is not met as evidenced by: A. Based on a review of the manufacturer's instructions, laboratory's environmental chart, laboratory policy, and interview of facility personnel, the laboratory failed to define the correct acceptable criteria for accurate and reliable test system operation consistent with the manufacturer's instructions for the Alfa Wassermann ACE Alera chemistry analyzer. (Temperature and Humidity Range) Findings were: 1. A review of the operating manuals for ACE Alera Clinical Chemistry System PN701298 (Rev 4 01/13) ACE Alera systems specifications are as follow: Ambient Room temperature 15 - 27 C Humidity 20 - 80 % 2. Review of the laboratory policy General Maintenance Program revealed "all general laboratory equipment must be monitored to assure acceptable performances...Record temperatures on a daily basis." 3. Review of the laboratory temperature logs available for review from the time the laboratory received their certificate of registration on 5/19/16 through day of survey on 5/1/18 revealed 36 of 170 days when the temperature was documented and no humidity was documented on any of the days. 4. An interview with the lab director on 05/01/18 at 0930 hours in the laboratory confirmed the above findings. B. Based on a review of the manufacturer's instructions, laboratory's refrigerator temperature log, and interview of facility personnel, the laboratory failed to define the correct acceptable criteria for accurate and reliable test system operation for the refrigerator consistent with the manufacturer's instructions. (Temperature Range) Findings were: 1. A review of the ACE AST Reagent (REF SA1047) revealed under reagent storage and stability that unopened reagent is stable until the expiration date when stored at 2-8 C. 2. A review of the ACE Cholesterol Reagent (REF SA1010) revealed under reagent storage and stability that unopened reagent is stable until the expiration date when stored at 2-8 C. 3. A review of the package insert for ACE Bun/Urea reagent (REF SA2024) under reagent storage and stability that unopened reagent is stable until the expiration date when stored at 2-8 C. 4. Review of the laboratory refrigerator temperature log available for review revealed 9 days when the temperature was documented. The laboratory was asked for documentation of the refrigerator temperature of the other 161 days the laboratory was open from the time the laboratory received their certificate of registration on 5/19/16 through day of survey on 5/1/18. No documentation was provided. date temperature (C) 05/01/17 10 05/02 /17 10 05/03/17 10 05/04/17 10 05/04/17 10 10/09/17 10 11/09/17 10 12/07/17 10 12 /28/17 10 5. An interview with the lab director on 05/01/18 at 0930 hours in the laboratory confirmed the above findings. He acknowledged that the laboratory did not document the temperature every day nor was the refrigerator set at the correct temperature.
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 observations, review of laboratory records, and confirmed in interview, the laboratory failed to ensure the laboratory did not use expired materials for chemistry quality control testing with the Alfa Wassermann chemistry analyzer. Findings were: 1. Random review of the laboratory refrigerator on 5/1/18 at 0945 hours revealed the following expired reagents. Alk Phos (REF SA2002) lot F4023 exp 01/31/18 ALT

	(REF SA1046) lot F4020, exp 11/30/17 LDL (REF SA3018) lot F3957, exp 08/31/17 Cholesterol (REF SA 1010) lot F3944, exp 04/30/17 BUN/CREA (REF SA2024) lot F3964, exp 07/31/17 Lipid Control (REF C287) lot F3861, exp 12/31/16 2. Random review of the laboratory back room where the Alfa Wasserman chemistry analyzer was kept on 5/1/18 at 1015 hours revealed the following expired reagents. System Diluent (REF SA1021) lot 754488, exp 05/17 ISE Cleaning and Sodium Electrode Conditioner (REF SA1028) lot F3898, exp 10/31/17 BD Vacutainer (REF 366703) lot 5041967, exp 08/2016 3. An interview with the lab director on 5/1/18 at 1100 hours confirmed the above findings. He acknowledged that the laboratory still used the expired reagents for controls and/or maintenance because he's unable to purchase fresh reagents, but no patient testing performed.
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 a review of the chemistry verification studies, and verified by interview, the laboratory failed to perform a complete verification study on the Alfa Wassermann ACE Alera chemistry analyzer. (linearity, accuracy, precision, normal patient range) Findings were: Linearity 1. A review of the laboratory verification records for the Alfa Wassermann revealed the laboratory analzyed Audit Micro Controls linearity samples on 06/23/16 and 07/02/16 for the following analytes: CO2 (Carbon Dioxide) Cl (Chorine) Sodium Cholesterol Potassium Triglyceride ALP (Alkaline phosphatase) Calcium ALT (alanine aminotransferase) BUN (blood urea nitrogen) AST (aspartate aminotransferase Creatinine Total Bilirubin Total Protein Glucose Albumin HDL (High-density lipoproteins) No documentation of the linearity assessment from this data was available for review by the end of survey on 05/01/18. Accuracy 2. Review of the laboratory verification records for the Alfa Wassermann revealed the laboratory analyzed correlation samples from another laboratory on 05/10/17 for the same analytes above. No documentation of the accuracy assessment from this data was available for review by the end of survey on 05/01/18. a) An interview with the lab director on 05/01/18 at 1010 hours in the laboratory confirmed the correlation samples were from another CLIA certified laboratory. b) A random review of the available package inserts for the Alfa Wassermann reagents revealed the following specimen stability: i) A review of the ACE AST Reagent (REF SA1047) revealed under specimen collection, storage and handling that specimen stable for 28 days at 4 C and 1 year at -20C. ii) A review of the ACE Cholesterol Reagent (REF SA1010) revealed under specimen collection, storage and handling that specimen is stable for 7 days at 4-8 C and 3 months at -20C. ii) A review of the package insert for ACE Bun/Urea reagent (REF SA2024) revealed under specimen collection, storage and handling that specimen stable for 7 days refrigerated (4-8C) or frozen (-20C) for 1 year c) Review of the patient reports from the other laboratory revealed the top portion of the report were excluded. The date and time and the location of the laboratory could not be determined. The laboratory was asked for the documentation to ensure the correlation

	specimens were analyzed within the specimen stability of each of the analytes. No documentation was provided by the end of survey on 05/01/18. Precision/ Normal Patient range 3. A review of the Alfa Wassermann verification studies revealed no documentation of a normal patient range and precision study. 4. An interview with the lab director on 05/01/18 at 1015 hours confirmed the above findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of the laboratory's equipment maintenance records, review of manufacturer operator's manual and interview of facility personnel, the laboratory failed to document manufacturer required maintenance on the Alfa Wassermann ACE Alera chemistry System. Findings were: 1. Review of the Alfa Wassermann ACE Alera Chemistry System Operator's Manual (P/N 701298 Rev 4 01/13) revealed "periodic maintenance procedures must be performed on the ACE Alera System in order to assure consistent efficient performance" "The required preventative maintenance procedures for the system are summarized below: Daily Remove Condensation from Reagent Compartment Clean Wash Bath and Probe Pathway Clean Exterior of Probe Check Probe Alignment Clean and Conditioin ISE Weekly Clean ISE Sample Port Inspect Air Filters and Clean if necessary Clean Exterior Surface of Instrument Washplate Assembly Cleaning Procedures Monthly Rinse Probe and Fluid Lines with Bleach Clean Cap Assemblies Calibrate Table offset, Sample Delay, and Optics Clean ISE Reference Housing Biannual Replace ISE Pump Tubing" 2. Review of the avalilable laboratory maintenance logs from February 2017 - April 2017; July 2017 - August 2017; February 2018 - April 2018 revealed 43 of 170 days when the daily maintenance was documented as performed; 10 of 36 days when the weekly maintenance was documented as performed; and 2 of 8 monthly maintenance was documented as performed. 3. The laboratory was asked for the documentation of the other days when maintenance was not documented. No documentation was provided by the end of survey on 05/01/18. 4. An interview with the lab director on 05/01/18 at 1035 hours in the laboratory confirmed the above findings.
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 review of the laboratory policies, calibration verification records from 2016 and 2017, and staff interview, the laboratory failed to have documentation of performing six-month calibration verification for the Alfa Wassermann ACE Alera chemistry analyzer. The findings were: 1. Review of the laboratory policy Linearity Testing (reportable range) calibration verification policy revealed "calibration verification is necessary to verify that an analyte' s calibration is still valid, and confirms that testing provides continued accurate results throughout the previously established range...Calibration verification is performed every six months." 2. A review of the laboratory's calibration verification records from 2016 and 2017 revealed the laboratory had documentation of performing calibration verification for the following analytes on 06/23/16 and 07/02/16. CO2 (Carbon Dioxide) Cl (Chorine) Sodium Cholesterol Potassium Triglyceride ALP (Alkaline phosphatase) Calcium ALT (alanine aminotransferase) BUN (blood urea nitrogen) AST (aspartate aminotransferase Creatinine Total Bilirubin Total Protein Glucose Albumin HDL (High-density lipoproteins) 3. The laboratory was asked for documentation of performing the calibration verification for the second half of 2016 and the first and second half of 2017. No documentation was provided. 4. An interview with the laboratory director on 05/01/18 at 1045 hours in the laboratory confirmed the laboratory did not perform the required calibration verifications.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records from 2016 to 2018, and staff interview, the laboratory failed to have a quality control procedure that monitored the accuracy and precision of the Alfa Wassermann ACE Alera chemistry analyzer over time. Findings were: The findings were: 1. An attempted review of the laboratory's records from June 2016 to April 2018 revealed no documentation of monitoring quality control results over time to detect shifts and trends. 2. The

	laboratory was asked to provide documentation of monitoring quality control results of the above months. No documentation was provided by the end of survey on 05/01 /18. 3. An interview with the lab director on 05/01/18 at 1025 hours confirmed the above findings.
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 direct observation, review of instrument verification records, review of patient final reports, and confirmed in interview of facility personnel, the laboratory director failed to provide overall management and direction of the laboratory. Findings were: 1. Review of the laboratory policy Laboratory Director Job Description Moderate Complexity revealed "the General duties and responsibilities: "1. Administers and supervises the technical and scientific operation of the clinical laboratory. "a. oversee and implement quality control for all methodologies b. oversees preventative maintenance and calibration verification programs on all instrumentation c. Ensure that the laboratory participates in an approved Proficiency testing program for all regulated analytes and reviews the performance in this program. Ensures that all unregulated analytes are validated on a regular basis. d. Reviews and approves all new procedures and any procedural changes e. Reviews and approves all procedure manuals on a yearly basis. f. Oversees general quality of technical performance of clinical laboratory personnel. g. Advises administration of personnel deficiencies, including staffing needs and requirements for personnel qualification h. Supervises in-service and continuing education to all technical personnel. " 2. The laboratory director failed to ensure that testing systems developed and used for the Alfa Wassermann ACE Alera chemistry analyzer performed in the laboratory provided quality laboratory services for all aspects of test performance. Refer to D6007 3. The laboratory director failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in all laboratory systems. Refer to D6021 4. The laboratory director failed to ensure that all personnel had the appropriate education required to perform moderate complexity testing. Refer to D6029 5. The laboratory was asked for documentation of the above duties performed from the time the laboratory received their certificate of registration on 5/19/16 through day of survey on 5/1/18. No documentation was provided by the end of survey on 05/01/18. 6. An interview with the lab director on 05/01/18 at 1030 hours in the laboratory confirmed the above findings. He stated he has been unable to purchase supplies to perform testing for the laboratory. He also stated he could not order proficiency testing because he was unaware if his CLIA number was valid.
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) 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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on a review of laboratory analytic systems it was revealed that the laboratory director failed to ensure that testing systems developed and used for the Alfa Wassermann ACE Alera chemistry analyzer performed in the laboratory provided quality laboratory services for all aspects of test performance. Refer to D5317, D5421, D5441
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of laboratory records and interview of facility personnel it was revealed that the laboratory director failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in all laboratory systems. refer to D5291, D5391, D5791, and D5891
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) 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 review of personnel records and interview of laboratory personnel, the laboratory director failed to ensure that all personnel had the appropriate education required to perform moderate complexity testing. (refer to D6065)
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on a review of personnel records, policies and procedures and interview of facility personnel found that the laboratory director failed to specify in writing the responsibilities and duties of each person responsible for testing patient specimens from preanalytic to result reporting that identified which examinations and procedures each individual is authorized to perform on the Alfa Wasserman ACE Alera chemistry analyzer. Findings were: 1. A review of personnel records revealed that 2 of 2 testing persons did not have documentation of authorization to perform testing on the Alfa Wassermann ACE Alera chemistry analyzer. 2. The facility was asked to provide 2 of 2 documentation signed by the laboratory director that specified which examinations and procedures each individual is authorized to perform; no documentation was provided at the time of survey on 05/1/18. 3. In an interview of the lab director on 05 /01/18 at 1050 hours in the laboratory confirmed the above findings.
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, review of laboratory records, manufacturer ' s instructions, quality control records and interview it was revealed that the technical consultant failed to provide the required technical oversight for the laboratory. (refer to D6040, D6046)
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the 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 a review of the laboratory's test system records and interview of facility personnel it was revealed that the technical consultant failed to ensure verification studies were performed on the Alfa Wassermann ACE Alera chemistry analyzer. (Refer to D5421)
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES

	CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records and interview, the Technical consultant failed to evaluate the competency of 2 of 2 testing personnel. Findings were: 1. Review of the laboratory's personnel records revealed no documentation for 2 of 2 testing personnel of a competency assessment that included the following criteria: Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; Monitoring the recording and reporting of test results; Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; Direct observation of performance of instrument maintenance and function checks; Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; Assessment of problem solving skills; 2. In interview with the lab director on 05/01/18 at 1030 hours in the laboratory confirmed the above findings. He was unaware he needed to perform competencies for the testing personnel.
D6056	CLINICAL CONSULTANT CFR(s): 493.1415 The laboratory must have a clinical consultant who meets the qualification requirements of 493.1417 of this part and provides clinical consultation in accordance with 493.1419 of this part. This CONDITION is not met as evidenced by: Based on review of the laboratory CMS209, laboratory records, and confirmed in interview, the facility failed to have documentation available for review to qualify the clinical consultant for his position as clinical consultant of a moderate complexity laboratory. Refer to D6057 Key: CMS- Centers for Medicare & Medicaid Services
D6057	CLINICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1417 The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493. 1405(b)(1), (2), or (3)(i); or (b) Be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine and possess a license to practice medicine, osteopathy or podiatry in the State in which the laboratory is located. This STANDARD is not met as evidenced by: Based on review of the laboratory CMS209, laboratory records, and confirmed in interview, the facility failed to have documentation (medical license and/or medical degree) available for review to qualify the clinical consultant for his position as clinical consultant of a moderate complexity laboratory. Findings were: 1. Review of

	the laboratory policy Clinical Consultant Job Description revealed "each clinical laboratory must have a clinical consultant who is qualified to provide consultations and opinions regarding clinical diagnosis and treatment of clients' patients." 2. Review of the CMS209 signed by the laboratory director on 5/1/18 revealed no Clinical Consultant documented. 3. An interview with the laboratory director on 5/1/18 at 1130 hours in the laboratory revealed that the laboratory did acquire a clinical consultant, but that the lab director has not been in "contact with him for some time." The laboratory was asked to provide the education credentials for the clinical consultant. No documentation was provided. Key: CMS- Centers for Medicare & Medicaid Services
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on a review of the Laboratory Personnel Report, personnel records and staff interview, it was revealed that the 2 of 2 testing personnel did not have the appropriate education credentials required to perform moderate complexity testing (refer to D6065).
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of personnel records and interview of facility personnel, it was revealed that the facility failed to ensure all personnel had the appropriate education required to perform moderate complexity testing on the Alfa Wassermann ACE Alera chemistry analyzer. Findings were: 1. A review of personnel records revealed that 2 of 2 testing personnel did not have documentation available, at the time of the survey, for proof of a high school diploma or equivalent. 2. An interview with lab director on 05/01/18 at 0930 hours in the laboratory confirmed the above findings.
D8100	INSPECTION REQUIREMENTS CFR(s): 493.1771

	Each laboratory issued a CLIA certificate must meet the requirements in 493.1773 and the specific requirements for its certificate type, as specified in 493.1775 through 493.1780. All CLIA-exempt laboratories must comply with the inspection requirements in 493.1773 and 493.1780, when applicable. This CONDITION is not met as evidenced by: Based on review of the laboratory records and confirmed in interview, the laboratory failed to meet the requirements in 493.1773. Refer to D8103
D8103	BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(b)(c)(d) (b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part. This STANDARD is not met as evidenced by: Under section 42 CFR 493.55 (c) Application format and contents "...(2) states the application must be signed by an owner or authorized representative of the laboratory who attests that the laboratory will be operated in accordance with the requirements established by the Secretary under section 353 of the Public Health Service Act; and...". In addition, this statement is also on the 116 application which "determine the laboratory's eligibility or continued eligibility for its certificate or continued compliance with the CLIA regulations". The laboratory owner and laboratory director failed to adhere to this requirement. This location was not an active laboratory. During a tour of the facility on 05/01/18 at 0915 hours, it was determined that the location had an Alfa Wassermann chemistry analyzer in the back of the laboratory space and expired reagents and controls in the refrigerator. The laboratory was not ready to perform patient testing as of the date of the survey on 05/01/18. State agency received an application for Registration Certificate of Compliance on 04/03/2017. The application stated the following tests would be tested: subspecialties of general chemistry for an annual total volume of 1500; and waived PT (Protime) for an annual volume 500. history: A certificate of registration with COLA (Commission on Office Laboratory Accreditation) with specialty of toxicology was approved on 06/11/10. Facility withdrew their accreditation on 03/2011, but was reinstated with COLA on 06 /27/12 A COLA inspection was performed on 03/15/13 and COLA required them to cease testing because there were no personnel who could perform high complexity testing. Facility ceased testing. Facility reactivated with certificate of registration with

	COLA on 05/17/16 for specialty of routine chemistry. An application was received on 4/3/17 for a change of certificate to a certificate of compliance. The change to certificate of compliance was processed on 5/3/17. The certificate of registration was effective from 05/17/16 - 05/16/18. On 05/26/17, the lab director sent an initial application for a certificate of waiver for another laboratory Texas Analytical Laboratories. State agency inquired about the application because there was already a laboratory in the same location. On 08/09/17, lab director called the State Agency and stated that Express Biomed was financially in trouble and he withdrew himself as Director and asked to close CLIA number. He stated will be send a new application for Texas Analytical laboratories. State agency received an initial application on 12/19 /17 for Express Biomedical Labs sub of Texas Analytical Laboratories for a certificate of registration for CAP with specialty of routine chemistry. State agency responded via email on 12/20/17 for a list of tests and to confirm the phone number. State agency attempted to call the phone number on the application and revealed there was a nonworking number on application. Again state agency contacted the facility because there was already a laboratory at the same location. On 01/18/18, state agency received a letter stating that Express Biomed could not be ready for a COLA inspection due to health reasons. State agency contacted the lab director to inquire about the letter. On 2/6/18, the facility faxed another CMS116 application for a change in name for Express Biomed to Express Biomedical Labs, sub of Texas analytical Labs. It was for a certificate of compliance. The laboratory was asked for documentation of the transfer of ownership. No documentation was provided. On 04 /09/18, state agency received two CMS116 applications for a closure for Express Biomed and an initial application for Express Biomedical Labs, sub of Texas analytical Lab.