Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2151207	10/24/2019
Name of Provider or Supplier	**Street Address, City, State**	
Express Way Medical Laboratories	6600 York Road, Suite 207, Baltimore, MD	

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
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of the written procedure manual and interview with the laboratory director (LD) acting as the technical consultant (TC), the laboratory did not perform corrective action procedures for failed proficiency testing (PT). Findings: 1. The laboratory failed the 2019 chemistry 3rd event with a 40% score. 2. The laboratory did not perform corrective action procedures nor an investigation into the failure. 3. The laboratory has a PT corrective action tool that was not utilized for the failure investigation. 4. The TC stated that she does not know why an investigation and corrective action procedures were not performed.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.

	This STANDARD is not met as evidenced by: Based on review of the written procedure manual and interview with the testing person (TP), the laboratory did have written procedures to ensure optimal integrity of patient samples throughout all phases of laboratory testing. Findings: 1. On the patient final reports the laboratory would use the last five digits of the patient social security number as one of the patient identifier. 2. In October 2019 the final report for "patient A" did not have the last five digits of the social security number on the final report. Instead the laboratory used the last four of the patient Medicaid number. 3. The TP stated that she used the last four of the patient Medicaid number because the social security number was not documented on the sample requisition. 4. The TP confirmed that the laboratory did not have written procedures to ensure optimal integrity of patient samples throughout all phases of laboratory testing.
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 review of the written procedure manual and interview with the testing person (TP), the laboratory did not have written procedures for all areas of the laboratory when performing patient testing. Finding: 1. The laboratory did not have a venipuncture procedure when collecting samples for hematology and chemistry testing. 2. The laboratory did not have specimen labeling procedures with the appropriate identifiers to ensure optimal integrity of patient testing throughout all phases of laboratory testing that included the date of specimen collection, time of collection, and the collector's name. 3. The laboratory did not have a transportation procedure after the collection of patient specimens that included storage of collected specimens and validation of the storage method for transporting patient samples. 4. The TP confirmed that written procedures for all areas of the laboratory when performing patient testing were not available.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals

	(normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: I. Based on review of the validation records and interview with the analyzer consultant, the laboratory's procedure manual failed to include instructions for entering the verified reportable range of the chemistry analyzer. Findings: 1. The validation records that were reviewed show the upper and lower limits that were verified by the installer of the chemistry analyzer. 2. The analyzer consultant that was present on the day of the survey was asked to verify that the upper and lower limits had been installed into the analyzer profile for each analyte. The analyzer consultant stated that none of the values had been entered into the analyzer. 3. During the survey on 10/24/19 at 2:30 pm the analyzer consultant confirmed that the upper and lower limits that were verified by the installer of the chemistry analyzer had not been entered into the profile for each analyte performed and reported. II. Based on review of the quality control (QC) printouts, policy and procedure manuals, and interview with the laboratory director, the laboratory's procedure manual did not include an interpretation of the abbreviations flags that were printed next to chemistry QC results. Findings: 1. The laboratory's QC printouts included abbreviations such as "LH", "SD", "LL", and "NR" Neither the printout nor the policy and procedure manual identified the meaning of the abbreviations used. 2. During the survey on 10 /24/19 at 2:30 PM the laboratory director confirmed that the abbreviations printed on the QC printouts were not identified in the policy and procedure manuals. III. Based on review of the final patient report, policy and procedure manuals, and interview with the laboratory director and testing person, the laboratory's procedure manual did not include instructions for documenting repeat analysis of patient test results on the final report and when to repeat patient test results. Findings: 1. Review of a patient report on 09/03/19 showed that the chloride (Cl), blood urea nitrogen (BUN), Calcium (Ca), total bilirubin (TBil) and triglycerides (Trig) were repeated and both results were listed on the final report. For each of these results the abbreviation "NR" (normal range) was noted in the column labeled "Flags." 2. When interviewed the testing person stated that she repeated any valued outside of the low and high range and reported both values. 3. The policy and procedure manuals did not define when it was appropriate to repeat a test result, when to report the first value once it was verified and how to document that a value was verified by repeat analysis. 4. During the survey on 10/24/19 at 2:30 pm the laboratory director confirmed that the final reports included two results for CL, BUN, Ca, Tbili and Trig that were not classified as alert values but were within the normal range and that the final report failed to notify the client that the results were verified by repeat analysis.
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 review of the patient final report and interview with the testing person (TP), the laboratory did not provide a disposition statement on the patient final report when samples were repeated. Findings: 1. Review of five patient reports from the year 2019 showed repeated results for analytes that were not within the normal range and reported to the requesting physician. . 2. The TP stated that sometimes patient results were not within the normal range and she repeated analytes that were out of range. . 3. The TP did not give a written statement on the patient report for the original result and the repeated result on the same final report. 4. The TP stated that the provider did not ask why there were two results for analytes that were not in range and she did not think to provide a disposition statement. II. Based on review of the final report and interview with the testing person (TP), the laboratory did not establish procedures for completing the collection time on the final report. Findings: The collection time was not completed and left blank on the patient final report. The TP stated that there was no way to enter the collection time on the final report because the reporting database was not setup to enter the time.
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 record review and interview, the laboratory director failed to ensure that the chemistry methodologies performed in the laboratory provided accurate and reliable test results (D6013); failed to ensure that the maintenance logs were being completed as required (D6020); failed to ensure that the quality assessment (QA) plan included instructions for documenting repeat analysis of patient test results on the final report and when to repeat patient test results (D6021); failed to ensure that remedial reactions were taken and documented when the ISE daily start up failed (D6024); and failed to specify in writing, the responsibilities and duties of each person engaged in the performance of the preanalytic, analytic and post analytic phases of testing, that identifies which examination and procedure each individual is authorized to perform, and whether supervisory or director review is required prior to reporting patient test results (D6032).
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 review of the standard operating procedure manual (SOPM) and interview with the laboratory director, the laboratory director failed to ensure that the chemistry methodologies performed in the laboratory provided accurate and reliable test results. Findings: 1. The method validation section of the SOPM states "Each laboratory should demonstrate that it can obtain performance specifications comparable to EasyRA specifications following performance characteristics." The specifics characteristics were listed as accuracy, precision, reportable range, normal patient values, comparison of methods, and linearity. 2. The laboratory director failed to provide a written protocol that listed specifics to be followed for each of the specific characteristics listed above; number of quality controls and patients to be tested; limits of acceptability; and corrective actions when limits were not met. 3. The correlation studies showing the results of the specimens tested in-house and sent to the reference laboratory were not given correlating identification numbers. When the summary was reviewed the surveyor could not identify the corresponding results of each specimen. There was also no protocol for acceptability between the two sets of results. 4. The laboratory director reviewed and signed off on validation results that did not have a defined protocol for acceptability. 5. During the survey on 10/24/19 at 2:30 pm the laboratory director confirmed that there was no written validation protocol for the chemistry analyzer listing the specifics of acceptability.
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 review of the operators manual for the chemistry analyzer, worksheet for documenting the "Daily Cleaning and Inspection Log", and interview with the analyzer consultant and testing person, the laboratory director failed to ensure that the maintenance logs were being completed as required. Findings: 1. Review of the "Daily Cleaning and Inspection Log" for the months of May through September 2019 showed that the monthly cleaning of the air filter was not being performed by the testing person. When interviewed the analyzer consultant stated that the operator's manual failed to define the required frequency of cleaning the air filter. 2. Review of the "Daily Cleaning and Inspection Log" for the months of May through September 2019 showed that the weekly precision check and Levy-Jennings (L-J) graphs were being documented as being performed daily by the testing person. The testing person is not qualified to review the L-J graphs. When interviewed the testing person stated that she was just checking the boxes each day. 3. Review of the "Daily Cleaning and Inspection Log" for the months of May through September 2019 showed that the daily wiping of the cooling plate was not being performed each day of testing by the testing person. When interviewed the testing person stated that she was not performing and checking the boxes each day. 4. The "Daily Cleaning and Inspection Log" from May through September were reviewed by the laboratory director on a monthly basis but

	the errors in the lack of documentation and excessive documentation were not addressed in the quality assessment reviews or reviewed with the testing person.
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 review of the final patient report, policy and procedure manuals, and interview with the laboratory director and testing person, the laboratory director failed to ensure that the quality assessment (QA) plan included instructions for documenting repeat analysis of patient test results on the final report and when to repeat patient test results. Findings: 1. Review of a patient report on 09/03/19 showed that the chloride (Cl), blood urea nitrogen (BUN), Calcium (Ca), total bilirubin (TBil) and triglycerides (Trig) were repeated and both results were listed on the final report. For each of these results the abbreviation "NR" (normal range) was noted in the column labeled "Flags." 2. When interviewed the testing person stated that she repeated any valued outside of the low and high range and reported both values. 3. The policy and procedure manuals did not define when it was appropriate to repeat a test result, when to report the first value once it was verified and how to document that a value was verified by repeat analysis. 4. During the survey on 10/24/19 at 2:30 pm the laboratory director confirmed that the final reports included two results for CL, BUN, Ca, Tbili and Trig that were not classified as alert values but were within the normal range and that the final report failed to notify the client that the results were verified by repeat analysis.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on review of the ion selective electrode (ISE) documentation and interview with the laboratory director, the laboratory director failed to ensure that remedial reactions were taken and documented when the ISE daily start up failed. Findings: 1. The daily ISE start up documentation showed that the ISE failed to meet limits of acceptability on 05/15/19 through 05/23/19. 2. The quality assessment review for the month of May 2019 failed to include an assessment and resolution of the problem and

	what happened to the patients during that time period. 3. During the survey on 10/24 /19 at 2:30 pm the laboratory director confirmed that remedial reactions had not been taken and documented when the ISE daily start up failed.
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 review of the procedure manual and interview with the laboratory director, the laboratory director failed to specify in writing, the responsibilities and duties of each person engaged in the performance of the preanalytic, analytic and post analytic phases of testing, that identifies which examination and procedure each individual is authorized to perform, and whether supervisory or director review is required prior to reporting patient test results. Findings: The laboratory director confirmed that the laboratory's approved procedure manual did not specify in writing the duties and responsibilities of the laboratory director, clinical consultant, technical consultant and testing personnel.
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 review of the hematology operators' manual and interview with the laboratory director acting as the technical consultant (TC), the TC failed to establish written procedures for performing the hematology analyzer validation (D6040); failed to perform corrective action procedures for failed proficiency testing (D6043); failed to perform direct observations of the testing person (D6047) and (D6050).
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 review of the hematology operators' manual and interview with the laboratory director acting as the technical consultant (TC), the TC failed to establish written procedures for performing the hematology analyzer validation. Findings: 1. The hematology analyzer operators' manual had written validation procedures that were not utilized by the laboratory when the validation was performed. 2. The laboratory instead performed the validation utilizing the procedures that were in the hematology analyzer which is an updated version for performing the analyzer validation. 3. Review of the validation data showed that dilution procedures were performed when the white blood cells were validated on the analyzer, 4. The validation data did not have an explanation for the dilution and procedures were not written when the dilution was performed. 5. The TC stated that she did not know that written validation procedures needed to be done
D6043	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(5) (b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications; This STANDARD is not met as evidenced by: Based on review of the written procedure manual and interview with the laboratory director (LD) acting as the technical consultant (TC), the TC failed to perform corrective action procedures for failed proficiency testing (PT). Findings: Refer to D2094
D6047	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by: Based on review of training and competency procedures and interview with the technical consultant (TC), the TC failed to perform direct observations of the testing person. Findings: 1. The TC failed to perform direct observations of the testing person performing patient testing, sample preparation, and specimen processing. 2. Review of training and competency procedures showed that the TC failed to complete the direct observation "DO" box on the training form.
D6050	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iv) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks. This STANDARD is not met as evidenced by:

	Based on review of training and competency procedures and interview with the technical consultant (TC), the TC failed to perform direct observations of the testing person. Findings: 1. The TC failed to perform direct observations of the testing person performing instrument maintenance and function check procedures. 2. Review of training and competency procedures showed that the TC failed to complete the direct observation "DO" box on the training form.