Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2151207	04/08/2020
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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of the federal proficiency testing data report and review of the comparative evaluation summery from American Proficiency Institute (API) proficiency testing (PT) program, the laboratory failed to successfully participate in the API PT program for chemistry testing, in which the laboratory is certified under CLIA, (Refer to D2096)
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f)

	Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of the federal proficiency testing data report and review of the performance summery from the American Proficiency Institute proficiency testing program, the laboratory failed to successfully participate in the API PT program for routine chemistry. The following analyte was noted as failed in the first event of 2020 and the third event 2019. Findings: 1. American Proficiency Institute 2020 1st event sodium, NA 60% 2. American Proficiency Institute 2019 3rd event sodium, NA 40%
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 review of the federal proficiency testing data report and review of the comparative evaluation summery from American Proficiency Institute (API) proficiency testing (PT) program , the laboratory director failed to ensure the laboratory successfully participate in the API PT program for chemistry testing, in which the laboratory is certified under CLIA. (Refer to D2096)
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of the federal proficiency testing data report and review of the comparative evaluation summery from American Proficiency Institute (API) proficiency testing (PT) program, the laboratory director failed to ensure that an approved corrective action plan was followed when the laboratory failed to successfully attain a score of 80% in the API PT program for chemistry testing. The following analyte was noted as failed in the first event of 2020 and the third event 2019. Findings: 1. American Proficiency Institute 2020 1st event sodium, NA 60% 2. American Proficiency Institute 2019 3rd event sodium, NA 40%