Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D1026323	12/27/2018
Name of Provider or Supplier	**Street Address, City, State**	
Medcare Express-North Charleston Llc	8740 Rivers Ave, N Charleston, SC	

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: During a PT desk review performed on 12/27/2018, based on review of CASPER report 155D and graded reports from American Academy of Family Physicians (AAFP), the laboratory failed to successfully participate in proficiency testing for the regulated analytes white blood cell differential (WBC Diff), red blood cell (RBC), and hematocrit (HCT) for two consecutive proficiency testing events reviewed (2017, Event C and 2018, Event 1). See D2130.
D2130	HEMATOLOGY CFR(s): 493.851(f)

	Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: During a PT desk review performed on 12/27/2018, based on review of CASPER report 155D and graded reports from AAFP, the laboratory failed to achieve satisfactory performance for WBC Diff, RBC, and HCT in two consecutive testing events (2017, Event C and 2018, Event A). Findings include: 1. Review of the CASPER report 155D revealed of the following proficiency testing scores: a. 2017, Event C WBC Diff: 76% RBC: 60% HCT: 0% b. 2018, Event A WBC Diff: 28% RBC: 20% HCT: 20% 2. The scores were confirmed upon review of the graded report from AAFP.