Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	48D0702841	05/16/2018
Name of Provider or Supplier	**Street Address, City, State**	
Doctor's Clinical Laboratory	1010 10st Estate Thomas, St Thomas, VI	

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: 1. Based on review of PT records and interview with the laboratory director, the laboratory failed to successfully participate in RPR Serology for second and 3rd events of 2016. The findings include: a. For QTR 2, 2016 the laboratory obtained 60% and for QTR3, 2016, the laboratory obtained 20%. b. The laboratory director stated the Styrofoam underneath the cover for the rotator had been replaced. c. She stated the laboratory successfully participated in QTR 1 and 2 in 2017, obtaining 100% in each event. d. The CLIA lab consultant discussed with the laboratory director that CMS had given a blanket waiver in PT participation for QTR3, 2017 by labs in USVI and in Puerto Rico due to natural disaster. 2. Based on review of PT records and interview

	with the laboratory director, the laboratory failed to participate in QTR1, 2017 for the specialty of Hematology. The findings include: a. The laboratory director stated that AAB PT program did not send the samples because the laboratory had enrolled in the wrong CBC module. b. The laboratory director stated the laboratory no longer performed manual cell differential, and should have enrolled in Module A for automated differential, rather than Module G, which include manual cell differential. c. The laboratory consultant discussed with the laboratory director that CMS had given a blanket waiver in PT participation for QTR3, 2017 by laboratories in USVI and Puerto Rico due to natural disasters. 3. Based on review of PT records and interview with the laboratory director, the laboratory failed to participate in QTR1 2018 event for the specialty of Hematology. The laboratory director stated that CBC Quality Control samples for Act Diff2 Coulter instrument did not come on time from the supplier for the PT samples to be tested.