Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	48D0702841	07/27/2021
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
D0000	An unannounced CLIA off-site proficiency testing (PT) review of Doctors Clinical Laboratory was conducted on July 27, 2021 by a federal surveyor from the Centers for Medicare and Medicaid Service CLIA New York Operation Branch. The laboratory was inspected under 42 CFR Part 493 CLIA regulations. Specific deficiencies cited are as follows:
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 proficiency testing (PT) desk review, the laboratory failed to achieve

	satisfactory performance of at least 80% for three consecutive events for the Hematology analyte for the first and second testing event in 2021. (Cross Reference D2121)
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on an off-site review of the federal proficiency testing Casper Reports 0096D CLIA Application and Survey Summary Report and 0153D Unsuccessful proficiency testing (PT) report, the laboratory failed to achieve satisfactory performance of at least 80% for two out of three consecutive events for the Hematology, Hematocrit (HCT) for the first and second testing events in 2021. Findings include: 1. Review of the CASPER 153D Unsuccessful PT report and 0096D CLIA Application and Survey Summary report Hematology PT scores for the first and second testing events in 2021 revealed the following scores: a. Analyte: 0760 Hematology i. American Association of Bioanalyst 2021 1st event 53% ii.American Association of Bioanalyst 2021 2nd event 73% b. Analyte: 0785 Hematocrit (HCT) (Non-Waived) i. American Association of Bioanalyst 2021 1st event 60% ii .American Association of Bioanalyst 2021 2nd event 40%
D2123	HEMATOLOGY CFR(s): 493.851(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on an off-site review of the federal proficiency testing Casper Reports 0096D CLIA Application and Survey Summary Report and 0153D Unsuccessful proficiency testing (PT) report, the laboratory failed to participate in both first and second testing events in 2020 and 2021 resulting in a score of 0 for the testing event . Findings include: 1) Review of the CASPER 153D Unsuccessful PT report and 0096D CLIA Application and Survey Summary report cores for the first and second testing events 2020 and 2021revealed the following scores: a)Analytes: 0765 Cell I.D. or WBC Diff i) American Association of Bioanalyst 2020 Event 1 Score 0% ii) American Association of Bioanalyst 2020 Event 2 Score 0% iii) American Association of Bioanalyst 2021 Event 1 Score 0% iv) American Association of Bioanalyst 2021 Event 2 Score 0%
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 an off-site review of the federal proficiency testing Casper Reports 0096D CLIA Application and Survey Summary Report and 0153D Unsuccessful proficiency testing (PT) report, the laboratory director failed to ensure the laboratory successfully participated in the American Associate of Bioanalyst (AAB) PT program for Hematology, Hematocrit (HCT) Non- waived and Cell I.D. or WBC Diff testing in which the laboratory is certified under CLIA. (Cross reference D2121, D2123)