Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	48D0702841	09/23/2021
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 announced routine CLIA recertification survey was conducted at Doctor Clinical Laboratory on September 23, 2021 by the Centers for Medicare and Medicaid Services (CMS) New York branch federal surveyor. The laboratory was surveyed under 42 CFR part 493 CLIA requirements: Specific deficiencies cited are as follows:
D1002	REPORTING OF SARS-CoV-2 TEST RESULTS During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on lack of COVID reporting documentation and interview with the testing person (TP) the laboratory failed to ensure both negative and positive results we reported to the local department of health. Findings include: On 09/23/2021 at approximately 10:40 AM the surveyor requested documentation of COVID results to the local department. TP stated "We only phone in positive results to the health department by Hotline #340-776-1519 and do not have a have log " During the exit interview at 5:00 PM the laboratory director confirmed the laboratory did not report positive and negative results.
D3001	FACILITIES CFR(s): 493.1101(a)(1) The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process.

	This STANDARD is not met as evidenced by: Based on observation and interview with the laboratory director (LD) the laboratory failed to have appropriate space necessary for conducting all phases of testing. Findings include: On 09/23/2021 at approximately 11:05 AM during a tour of the laboratory the surveyor observed the chemistry analyzer not in use in the back section of the testing area with numerous binders, files, and papers on top of the instrument. The surveyor asked if the chemistry analyzer in use for testing. The LD confirmed is was not is use, she stated, "The chemistry analyzer has not been in use since the 2016 hurricane" During the exit interview at 5:00 PM the LD confirmed the above findings.
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 observation, lack of documentation, and interview the laboratory failed to provide an established policy and procedure (P&P) that ensures proper identification from specimen collection through reporting of results. Findings include: On 09/23 /2021 at approximately 10:50 AM during a tour of the laboratory the surveyor noted a specimen logbook. The surveyor requested the policy of Specimen Processing of how the laboratory labels specimens and ensures the correct test is performed and resulted with the correct specimen. The testing person (TP) verbally explained the process however no written policy was provided. During the exit interview at 5:00PM the laboratory director confirmed the laboratory does not have written procedures for specimen identification and integrity.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on lack of documentation of corrective action, record review and interview the laboratory failed to establish and follow written policies and procedures (P&P) to monitor, access, and correct problems for proficiency testing (PT) performance. Findings include: On 09/23/2021 at approximately 12:00 PM during a review of American Association of Bioanalyst (AAB) PT records Testing event 1 and 2 for the year 2021 for the following analytes: Hematology, HCT, Cell I.D., revealed the laboratory received unsatisfactory scores. AAB Testing Event 2021 Event 1: Hematology 53 HCT:60 Cell I.D.: 0 Event 2: Hematology 73 HCT: 40 Cell ID :0 The surveyor requested the documentation of evaluation, review, and correction of the unsatisfactory PT results. The laboratory director (LD) stated, "we don't have anything

	like that" During the exit interview at 5:00 PM the LD confirmed the laboratory does not have a written policy and procedure for general laboratory system quality assessment in regards to proficiency testing performance.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of protocol and procedure (P&P), lack of documentation , and interview, the laboratory failed to develop a procedure manual for the following sections of the laboratory: i. Hematology - Coulter Ac Tdiff 2 - Critical values ii. COVID-19 - COVID reporting Findings include: On 09/23/2021 at approximately 12: 30 PM during a review of (P&P) the surveyor requested a procedure manual for the Hematology and COVID Sections of the laboratory. The laboratory testing person provided an operation manual for Coulter Ac Tdiff2 and procedure manual last signed 2008 approved for a hematology instrument no longer in use. The laboratory failed to provide a COVID section procedure manual. During the exit interview at 5:00 PM the laboratory director confirmed the laboratory did not have a procedure manual for COVID-19 reporting, and Hematology Section: Coulter Ac Tdiff2 and Critical values.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the laboratory director (LD) the laboratory failed to document corrective action for the following: equipment malfunction, calibrations and controls out of acceptable parameters, test systems do not meet verification specifications and reproducibility studies. Findings include : On 09/23/2021 at 2:50 PM the surveyor requested corrective action reports or logs. The LD stated " We call the ex- Beckman Coulter tech to troubleshoot problems" The LD failed to provide documented reports of corrective action performed for the following: equipment malfunction, calibration and controls parameters out of range and test system not meeting verification specifications/ reproducibility studies. During the exit interview at 5:00 PM the LD confirmed the above finding.
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: Refer to 6019; D6021; D6024
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 proficiency testing (PT) records, lack of documentation and interview the laboratory director (LD) failed to ensure an approved corrective action plan was followed when any PT results had unsatisfactory scores. Findings Include: AAB Testing Event 2021 Event 1: Hematology 53 HCT:60 Cell I.D.: 0 Event 2: Hematology 73 HCT: 40 Cell ID :0 The surveyor requested corrective action PT documents. The LD provided email correspondence between the laboratory and testing service that did not state how the laboratory corrected the failed PT scores. During the exit interview at 5:00 PM the LD confirmed there is no corrective action policy followed for unsuccessful PT results.
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 lack of policy documents for actions including monitoring, accessing, correcting quality for general laboratory system, analytical (testing), and post-analytical system the laboratory director failed to establish a quality assessment program to assure the standard of laboratory services provided. Findings include: On 09/23/2021 a review of the laboratory policy and procedures revealed no written policy for the following: General Laboratory System: Specimen Identification, Specimen Integrity, Proficiency Testing Performance Analytical System: Verification

	of Performance Specification, Maintenance and Function Checks, Control Procedures Post- Analytical System : Notification of Test Results (Critical Values) During the exit interview at 5:00 PM the LD confirmed the above findings.
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 maintenance and calibration records, lack of documentation and interview the laboratory director failed to ensure remedial action was taken and documented when performance specifications was out of range on the Hematology Coulter Ac TDiff 2 Analyzer. Findings include Coulter Ac TDiff 2 Analyzer Calibration report from 09/14/2021 -09/15/2021 09-14-2021 Carryover results :WBC Failed ;PLT: Failed Reproducibility: HGB: Failed Calibration: HGB: Needed; PLT: Failed; MPV: Failed 09-15-2021 Carryover Results: WBC : Passed; PLT :Failed Calibration: RBC: Needed; HGB: Needed; MCV: Needed; PLT: Needed; MPV: Failed The surveyor requested procedure to correct the failed performance specification, the laboratory provided the operation manual that showed how to perform remedial action when performance specification is out of range. The LD stated " we don't troubleshoot ourselves we just call the service contractor when there are issues." During the exit interview at 5:00 PM the LD confirmed the above findings.