Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	48D0885251	09/09/2021
Name of Provider or Supplier	**Street Address, City, State**	
Red Hook Family Practice	6500 Red Hook Plaza Suite 205, 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
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of patient test records, manufacturers package insert, and laboratory director interview, the laboratory failed to meet the analytic system requirements in 42 CFR 493.1251 through 42 CFR 493.1283. Findings include: 1) Failure to perform performance specifications. See D5421. 2) Failure to perform two different concentrations of control material. See D5447.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by:

	Based on review of the manufacturers package insert, patient test results and interview, the laboratory failed to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for IgG/IgM qSARS-CoV-2 antibody testing. One of one patient test result and one of one manufacturers package insert was reviewed. Findings include: 1) Patient test results obtained on July 13, 2021 shows the following test results: a) Cellex q Sars Cov-2 IgM Antibody test- Negative b) Cellex q Sars Cov-2 IgG Antibody test- Positive 2) Review of the manufacturer's package insert for Cellex qSARS-CoV-2 IgG/IgM Rapid Test contains the following verbiage: a) Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, to perform moderate and high complexity tests. 3) The surveyor requested data demonstrating that the laboratory could obtain performance specifications comparable to those established by manufacturer for Cellex qSARS-CoV-2 IgG/IgM Rapid Test. No performance specification data was provided. 4) The laboratory director confirmed in an e-mail communication dated September 9, 2021 at 11:29 AM, the following: a) "Did not perform verification of performance specifications"
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of patient test results and laboratory director interview, the laboratory director failed to perform two control materials of different concetrations at least once a day patients are assayed for Cellex q Sars Cov-2 IgM/IgG Antibody test. One of one patient test result was reviewed. Findings include: 1) Patient test results obtained on July 13, 2021 shows the following test results: a) Cellex q Sars Cov-2 IgM Antibody test- Negative b) Cellex q Sars Cov-2 IgG Antibody test- Positive 2) Review of the manufacturer's package insert for Cellex qSARS-CoV-2 IgG/IgM Rapid Test contains the following verbiage: a) Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, to perform moderate and high complexity tests. 3) The surveyor requested two control materials of different concentrations that were assayed for the patient test results obtained on July 13, 2021 for Cellex q Sars Cov-2 IgM/IgG antibody testing. No quality control (QC) or control material data was provided. 4) The laboratory director confirmed in an e-mail communication dated September 9, 2021 at 1:59 PM, the following: a) No QC testing was performed for batch or shipments on the test cards. Per manufacturer-comes with internal control. Internal control present on each test card. No QC was performed for patient test report on 07 /13/21.