

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 48D0885251	(X3) Date Survey Completed 05/15/2019
Name of Provider or Supplier Red Hook Family Practice	Street Address, City, State 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
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on interview with the laboratory director and technical consultant, and review of records, the laboratory failed to follow manufacturer's instruction to perform external quality control procedures prior to use of Icon 25 hCG urine pregnancy test kit and Urispec 10SG urine chemistry testing. The findings included: a. The laboratory started testing pregnancy test using urine sample, upon discontinuance of serum sample in 2018. No quality control records were seen. b. No quality control records presented for Urispec 10SG chem strip test system for lot #76239, expiration date 4/18/2020.</p>
D2121	<p>HEMATOLOGY CFR(s): 493.851(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on interview with the laboratory director, technical consultant and testing personnel, the laboratory failed to evaluate the unsatisfactory score (47%) for white blood cell (WBC) differential in the first event FY 2019. The findings included: a.</p>

Although a review was affixed, there was no documentation of evaluation of the failure and subsequent corrective actions to prevent future failure. d. The attestation statement was not signed by the laboratory director and testing personnel.