

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0719719	(X3) Date Survey Completed 02/15/2024
Name of Provider or Supplier St Petersburg Womans Health Center	Street Address, City, State 3401 66 St N, Saint Petersburg, FL	
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 on-site announced CLIA recertification survey was conducted at St Petersburg Woman's Health Center on 02/15/2024. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D5400 - 493.1250 Condition: Analytic systems D6033 - 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview with the Laboratory Director, the laboratory failed to verify the performance specifications of the i-STAT1 instrument prior to reporting patient test results (See D5421) and failed to run two levels of external quality controls each day of patient testing for 6 out of 6 months (05/19/23 - 11/29/23) for Beta (B) Human Chorionic Gonadotropin (HCG) (See D5447).</p>
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>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)</p>

(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 record review and interview with Testing Personnel #B (laboratory owner) and the Laboratory Director, the laboratory failed to verify the performance specifications of the i-STAT1 instrument prior to reporting 29 of 29 patient test results from 05/19/2023 to 11/29/2023 for Beta (B) Human Chorionic Gonadotropin (HCG). Findings included: Record review confirmed that the laboratory failed to verify the performance specifications of the i-STAT1 instrument prior to reporting patient test results on 05/19/2023. Record review of the "i-STAT1 System Manual" revised 10/18/2021 revealed "It is important to validate the performance of the i-STAT System and the recommended quality control regimen..." On 02/15/2023 at 1:05 PM, Testing Personnel #B confirmed the laboratory had not verified the performance specifications of the i-STAT1 instrument. On 02/15/2023 at 4:00 PM, the Laboratory Director stated he was unaware the laboratory had not verified performance specifications for the i-STAT1 Instrument.

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 lack of record review and interview with Testing Personnel #B (laboratory owner) and the Laboratory Director, the laboratory failed to run two levels of external quality controls each day of testing for 6 out of 6 months (05/19/23 - 11/29/23) reviewed for Beta (B) Human Chorionic Gonadotropin (HCG) tested on the i-STAT1 instrument. Findings included: Record review revealed no Quality Control (QC) records for two levels of external quality controls were available for review. Record review of the "STAT Beta Cartridge" log revealed 29 patients had been tested from 05/19/23 - 11/29/23. On 02/15/2023 at 2:00 PM, Testing Personnel #B confirmed two levels of external QC had not been run on the instrument before patient testing. On 02/15/2023 at 4:05 PM, the Laboratory Director stated he did not know two levels of external quality controls had not been run before testing patients.

D6033

TECHNICAL CONSULTANT-MODERATE COMPEXITY
CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:
Based on record review and interview, the Technical Consultant (who is also the

	<p>Laboratory Director) failed to verify the Total Beta (B) Human Chorionic Gonadotropin procedure and establish of the laboratory's test performance characteristics before patient testing (See D6040) and establish a quality control program including the parameters for acceptable levels of analytic performance for the Total B HCG procedure (See D6042).</p>
<p>D6040</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2)</p> <p>The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Technical Consultant, the Technical Consultant failed to verify the Total Beta (B) Human Chorionic Gonadotropin (HCG) procedure that was performed on the i-STAT1 instrument before testing 29 patients from 05/19/23 - 11/29/23. Findings included: Record review of the CMS 209, Laboratory Personnel Report signed by the Laboratory Director and dated 02/13/2024, revealed the Laboratory Director was also the Technical Consultant. Record review of the "STAT Beta Cartridge" logs revealed the laboratory performed Total B HCG testing for 29 patients on the i-STAT1 instrument from 05/19/2023 through 11/29/2023. Record review revealed no performance verification records were present for the i-STAT1. On 02/15/2023 at 4:00 PM, the Technical Consultant stated he did not know performance of verification had not been completed for Total B HCG test procedure on the i-STAT1 prior to testing and reporting patient results.</p>
<p>D6042</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4)</p> <p>(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the Technical Consultant failed to ensure acceptable levels of analytic performance were established and maintained from 05/19/2023 - 11/29/2023 for the Total Beta (B) Human Gonadotropin (HCG) test that was performed on the i-STAT1 . Finding included: Record review of the CMS 209, Laboratory Personnel Report signed by the Laboratory Director and dated 02/13/2024, revealed the Laboratory Director was also the Technical Consultant. Record review revealed the laboratory did not have two levels of external quality control records for the Total B HCG from 05/19/2023 - 11/29/2023. On 02/15/2023 at 04:05 PM, the Technical Consultant stated he did not know two levels of external quality control records for Total B HCG were not being tested before reporting patients.</p>