Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0719719	10/03/2019
Name of Provider or Supplier	**Street Address, City, State**	
St Petersburg Womans Health Center	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 announced CLIA recertification survey was conducted at St. Petersburg Womans Health Center on 10/03/2019. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the policy and procedure manual and phone interview with Testing Personnel #C, the Laboratory Director failed to sign the Policy and Procedure manual. Findings Included: Record review of the procedure manual revised 11/23 /2005 revealed "The Laboratory Director should: 1. Review the entire procedure manual annually and initial and date each procedure." Continued review of the procedure manual revealed that there was a form titled "Test Procedures Form." The form was blank. No Laboratory Director signature was present to indicate procedures had been reviewed. Telephone interview on 10/03/19 at 12:45 PM with Testing Personnel #C revealed the signature page was in front of the policy and procedure manual and if not someone had removed the signature page. No signature page could be located.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to ensure the Rh (D antigen) positive quality control was documented from 02/16/18 to 10/02/19. Findings included: Record review of the package insert, "Blood Grouping Reagent Anti - D (Monoclonal Blend) Gamma-Clone By Slide, Tube, or Microwell Test" from Immunocor, revealed that "the reactivity of blood grouping reagents should be confirmed on each day of use by testing with red blood cells known to be negative and positive for the relevant antigen." Record review of the "Daily Laboratory Log Sheet" showed that the laboratory had not documented the Rh (D antigen) positive control from 02/16/18, when a revised "Daily Laboratory Log Sheet" had been implemented, to 10/02/19. Phone interview on 10/03/19 at 10:30 AM with the Office Manager revealed she did not know the "Daily Laboratory Log Sheet" had been revised and did not include documentation of the Rh (D antigen) positive control. She stated that every day of testing, staff performed positive and negative controls, and they did document the negative control on the "Daily Laboratory Log Sheet."
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 record review and staff interview, the laboratory failed to document corrective action when the room temperature was out of range from January 17, 2018 to August 21, 2019. Findings included: Record review of the policy and procedure manual revealed a procedure titled "Laboratory Design," which stated the temperature of the testing area should be maintained between 65 degrees and 75 degrees F. Record review of the "Daily Laboratory Log Sheet" from 1/10/2018 to 10/2/2019 showed the room temperature was out of range for the following days with no documented corrective action performed: 01/17/2018 - 76 degrees F 02/02/2018 - 58 degrees F 03/12/2018 - 77 degrees F 04/11/2018 - 76 degrees F 04/27/2018 - 76 degrees F 05/09/2018 - 76 degrees F 07/11/2018 - 77 degrees F 08/31/2018 - 76 degrees F 09/07/2018 - 76 degrees F 09/12.2018 - 76 degrees F 09/14/2018 - 76 degrees F 09/21/2018 - 76 degrees F 09/26/2018 - 76 degrees F 10/19/2018 - 76 degrees F 10/24/2018 - 76 degrees F 10/31/2018 - 76 degrees F 11/02/2018 - 76 degrees F 11/07/2018 - 76 degrees F 01/02/2019 - 76 degrees F 01/18/2019 - 63 degrees F 01/30/2019 - 64 degrees F 02/22/2019 - 76 degrees F 04/10/2019 - 76 degrees F 05/01/2019 - 76 degrees F 05/24/2019 - 76 degrees F 05/29/2019 - 77 degrees F 06/19/2019 - 77 degrees F 07/05/2019 - 78 degrees F 07/10/2019 - 76 degrees F 07/31/2019 - 76 degrees F 08/02/2019 - 76 degrees F 08/14/2019 - 76 degrees F 08/21/2019 - 76 degrees F Interview on 10/03/2019 at 12:00 PM with the Office Manager revealed she was unaware staff had documented temperatures that were out of range.