Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0889544	04/27/2022
Name of Provider or Supplier	**Street Address, City, State**	
Physicians For Womens Health	345 North Main St, Ste 201, West Hartford, CT	

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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to provide an up to date step by step procedure for the BD Affirm test in the specialty of Microbiology. Findings include: 1. Record review on 04/27/2022 of the laboratory's CLIA Compliance Manual and Testing Reference Manual revealed the following three procedures for the BD Affirm for detection of Trichomonas, Gardnerella and Candida. a. Tab 5: Analytical policies and procedures. b. Tab 9: Standard operating procedure for Affirm VPIII Microbial Identification Test. c. BD Affirm VPIII Microbial Identification Test CLSI Laboratory Procedure. The above three procedures were

	distinctly different from each other, and all had been reviewed and approved by the laboratory director on February 21, 2022. 2. Record review on 04/27/2022 of the BD Affirm VPIII Microbial Identification Test CLSI Laboratory Procedure revealed an asterisk at the bottom of page 1 stating "Sample Procedure is not indicated as a substitute for your facility procedure manual, instrument manual, or reagent labeling /package insert. This "Sample Procedure" is intended as a model for use by your facility to be customized to meet the needs of your laboratory". 3. Staff interview on 4 /27/2022 at 10:55 AM with the laboratory supervisor (LS) confirmed the above three procedures were different for the BD Affirm test. The LS was unaware which procedure was accurate. 4. The laboratory performs 3,600 tests annually for the detection of Trichomonas, Gardnerella and Candida in the specialty of Microbiology.
D5455	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(v)(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 molecular amplification procedure, include two control materials and, if reaction inhibition is a significant source of false negative results, a control material capable of detecting the inhibition. (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 perform daily external quality control (QC) on both MicroProbe processors to detect errors in the extraction phase when performing the Affirm VPIII test assay in the specialty of microbiology. Findings include: 1. Surveyor observation on 04/27/2022 at 12:50 PM of the laboratory work bench revealed two MicroProbe processors labeled number 1 and 2 accordingly. 2. Record review on 04/27/2022 of the BD Affirm patient test logs revealed the following: a. One set of external positve and negative QC per test date. b. Lack of evidence of which instrument (number 1 or 2) external QC was performed on. 3. Staff interview on 4/27/2022 at 10:05 AM with the laboratory supervisor (LS) confirmed the above. LS was unaware of the daily QC requirement when having muiltiple instruments. 4. The laboratory performs 3,600 tests annually for the detection of Trichomonas, Gardnerella and Candida in the specialty of Microbiology.
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 humidity and temperatures were below established acceptable ranges in the specialty of Microbiology for the period of January 2021 through April 27, 2022. Findings include: 1. Record review on 04/27/2022 of the manufacturer's instrument user manual for 'BD MicroProbe Processor' revealed the following envirenmental conditions: a. Ambient temperature of 22 to 28 degrees Celsius. b. Ambient humidity 10-85%. 2. Record review on 04/27/2022 of the laboratory's 'Affirm Temperature/Humidity Chart' for the period of January 2021 through April 27, 2022, revealed lack of documentation of corrective action for the following: a. Acceptable refrigerator temperature range was 2 to 8 degrees Celsius (35 to 46 Fahrenheit). i. Temperatures were out of range for 72 of 333 working days. b. Acceptable room temperature range was 22 to 28 degrees Celsius (71.6 to 82.4 Fahrenheit). i. Temperatures were out of range for 155 of 333 working days. c. Acceptable humidity range was 10 to 85 percent. i. Humidity was marked 'LOW' for 137 of 333 working days. 3. Staff interview on 4/27/2022 at 10:05 AM with the laboratory supervisor (LS) confirmed the above findings. LS was unaware of the meaning of 'LOW'. 4. The laboratory performs 3,600 tests annually for the detection of Trichomonas, Gardnerella and Candida in the specialty of Microbiology.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to follow its written quality system policy to monitor, assess and when necessary correct issues surrounding equipment checks in the specialty of Microbiology for the period of January 2021 through April 27, 2022. Findings include: 1. Record review on 04/27/2022 of the laboratory's 'Quality System Policy' revealed "Process Improvement: Corrective Actions & Preventative Actions are taken and documented when problems are identified, to prevent recurrence of identified problems". 2. Record review on 04/27/2022 of the laboratory's 'Affirm Temperature/Humidity Chart' for the period of January 2021 through April 27, 2022, revealed lack of documentation of corrective action for the following: a. Refrigerator temperature was out of range for 72 of 333 working days. b. Room temperature was out of range for 155 of 333 working days. c. Humidity was marked 'LOW' for 137 of 333 working days. 3. Staff interview on 4/27/2022 at 11:55 AM with the laboratory supervisor confirmed the above findings. 4. The laboratory performs 3,600 tests annually for the detection of Trichomonas, Gardnerella and Candida in the specialty of Microbiology.