

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2032872	(X3) Date Survey Completed 09/27/2021
Name of Provider or Supplier Women's Health Care Center	Street Address, City, State 4009 W Fullerton Ave, Chicago, IL	
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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on direct observation, record review, lack of documentation, and interview, the laboratory failed to enroll in an HHS approved proficiency testing (PT) program for tests performed in the specialty of Microbiology during the year of 2020 and 2021. Findings include: 1. The Affirm VPIII Lab testing log from 06/10/2020 to 09/25/2021 was reviewed. 2. On 09/27/2021 at 9:50 AM during a tour of the laboratory, the surveyor observed that the laboratory used BD Affirm VPIII Microbial Identification Test system to detect and identify Candida species (Yeast), Gardnerella vaginalis (GV) and Trichomonas vaginalis (Trich). 3. The VPIII test log showed the following: * The laboratory began testing on 06/10/2020 * 167 patients have been tested using the BD Affirm VPIII 4. Review of laboratory records found the laboratory lacked any documentation for proficiency testing enrollment for Gardnerella vaginalis testing using the VPIII Affirm test system. 5. On an Initial survey conducted on 09/27/2021 at 11:15 AM, the laboratory director confirmed the above findings.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p>

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:

Based on record review, lack of documentation, and interview, the laboratory failed to establish and follow written policies and procedures to assess employees performing the Affirm VPIII Microbial Identification test for three out of three testing personnel (TP). Findings include: 1. The Affirm VPIII Lab testing log from 06/10/2020 to 09/25/2021 and the Laboratory Personnel Report (CMS 209) were reviewed. 2. The laboratory used the BD Affirm VPIII Microbial Identification Test to detect and identify *Candida* species (Yeast), *Gardnerella vaginalis* (GV) and *Trichomonas vaginalis* (Trich). 3. CMS 209 listed three TP (TP1, TP2, and TP3) performing the BD Affirm VPIII test. 4. The laboratory failed to establish a step-by-step procedure that includes the following criteria to assess TP competency: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing, as applicable; b) Monitoring the recording and reporting of test results (for example, recording patients and their results in the labs' test log and EMR system); c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; d) Direct observation of performance of instrument maintenance and function checks; e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; f) Assessment of problem solving skills; and g) Evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. Thereafter, evaluations must be performed at least annually. 5. 167 patients were tested during the time period reviewed by TP1, TP2, and TP3. 6. On an Initial survey conducted on 09/27/2021 at 11:15 AM, the laboratory director confirmed the above findings.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

Based on direct observation, record review, lack of documentation, and interview, the laboratory failed to verify the accuracy of the *Candida* species (Yeast) and *Trichomonas vaginalis* (Trich) testing performed during the years of 2020 and 2021. Findings include: 1. The Affirm VPIII Lab testing log from 06/10/2020 to 09/25/2021 was reviewed. 2. On 09/27/2021 at 9:50 AM during a tour of the laboratory, the surveyor observed that the laboratory used BD Affirm VPIII Microbial Identification Test system to detect and identify *Candida* species (Yeast), *Gardnerella vaginalis* (GV) and *Trichomonas vaginalis* (Trich). 3. Review of laboratory records found the laboratory lacked any documentation and failed to establish a method to verify the accuracy of its Yeast and Trich test system at least twice annually. 4. The VPIII test log showed the Yeast and Trich tests were reported for 167 patients during the time reviewed. 5. On an Initial survey conducted on 09/27/2021 at 11:15 AM, the laboratory director confirmed the above findings.

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 record review, manufacturer's instructions, lack of documentation, and interview, the laboratory failed to have written procedures (D5401); failed to monitor and document manufacturer required environmental and testing conditions to ensure accurate and reliable testing (D5411, D5413), and failed to establish and follow control procedures for 71 out of 91 days of BD Affirm Microbial Identification testing (D5441), affecting 117 patients.

D5401

PROCEDURE MANUAL

CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Based on direct observation, record review, lack of documentation, and interview, the laboratory failed to establish and follow a written procedure for the BD Affirm VPIII Microbial Identification Test Microbiology test performed affecting 167 patients. Findings include: 1. The Affirm VPIII Lab testing log from 06/10/2020 to 09/25/2021 was reviewed. 2. On 09/27/2021 at 9:50 AM during a tour of the laboratory, the surveyor observed that the laboratory used BD Affirm VPIII Microbial Identification Test system to detect and identify Candida species (Yeast), Gardnerella vaginalis (GV) and Trichomonas vaginalis (Trich). 3. The laboratory failed to have a written procedure manual that includes the following, as applicable: (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. (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) Verification procedures; manufacturer's instructions. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures and manufacturer's requirements. (8) Corrective action to take when 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. 4.

Review of laboratory records found the laboratory lacked any written procedure documentation and failed to obtain the all the product inserts and instructions from the manufacturer of the VPIII Affirm test system. 5. 167 patients were tested during the time period reviewed 6. On an Initial survey conducted on 09/27/2021 at 11:15 AM, the laboratory director confirmed the above findings.

D5411

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(a)

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:
Based on direct observation, record review, lack of documentation, and interview, the laboratory failed to follow the manufacturer's instructions and verify required temperatures to provide test results within the laboratory's stated performance specifications for the BD Affirm Microbial Identification test affecting 167 patients' tests. Findings include: 1. The Affirm VPIII Lab testing log from 06/10/2020 to 09/25 /2021 and manufacturer's instructions were reviewed. 2. On 09/27/2021 at 9:50 AM during a tour of the laboratory, the surveyor observed the following: *The BD Affirm test was performed at room temperature. *The Lysis block thermometer temperatures were not documented during testing. *The room thermometer was visible but the temperatures were not monitored or documented. 3. The manufacturer instructions stated the following in the "Procedure" section: *Verify that the BD MicroProbe Lysis Block is at 85 5 C, and that reagents are at 22-28 C; *All reagents and Probe Analysis Cards (PACs) must be at 22 to 28 C prior to use. *The total time between placing the swab into the sample collection tube and proceeding with the sample preparation should be no longer than 1 hour if the sample is stored at room temperature, or 4 hours if the sample is stored at 2 to 8 degrees Celsius. 4. The VPIII test log showed the laboratory failed to document both the time each patient sample was collected, the time the patient's sample was tested and whether stored at room temperature or refrigerated prior to testing. 5. The laboratory failed to document and monitor room and refrigerator temperatures, Lysis Block temperatures prior to testing, and failed to record specimen collection and testing times to ensure the manufacturer's required conditions were met for accurate and reliable testing. 6. 167 patients were tested during the time period reviewed. 7. On an Initial survey conducted on 09/27/2021 at 11:15 AM, the laboratory director confirmed the above findings.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
Based on direct observation, record review, lack of documentation, and interview, the laboratory failed to monitor and document conditions essential for proper storage of the BD Affirm kits, patient specimens, and test conditions to ensure accurate and reliable test system operations, affecting 167 patients' tests. Findings include: 1. The Affirm VPIII Lab testing log from 06/10/2020 to 09/25/2021 and manufacturer's instructions were reviewed. 2. On 09/27/2021 at 9:50 AM during a tour of the laboratory, the surveyor observed the following: *The BD Affirm test was performed at room temperature. *The room had a thermometer but the temperatures were not monitored or recorded. *The reagents, patient specimens, and test kits were stored in a refrigerator. *The refrigerator did not have an internal thermometer. 3. The manufacturer instructions stated the following in the "Procedure" and "Storage of Reagents" sections: *Before testing: "Verify ...that reagents are at 22-28 C"; "BD Affirm VPIII test kit is stable until the expiration date indicated on the kit box when stored at 2 to 8 C"; "All reagents and Probe Analysis Cards (PACs) must be at 22 to 28 C prior to use". 4. The laboratory failed document and monitor the room temperature and refrigerator temperature to ensure the manufacturer's required storage and testing conditions were met for accurate and reliable testing. 5. 167 patients were tested during the reviewed time period. 6. On an Initial survey conducted on 09/27 /2021 at 11:15 AM, the laboratory director confirmed the above findings.

D5441

CONTROL PROCEDURES
CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on record review, lack of documentation, and interview, the laboratory failed to establish and follow control procedures that monitor the accuracy and precision of the complete analytic process for each day BD Affirm tests were performed for 71 out of 91 days. Findings: 1. The Affirm VPIII Lab testing log from 06/10/2020 to 09/25 /2021, Affirm VPIII quality control (QC) log, and manufacturer's instructions were reviewed. 2. The laboratory used the BD Affirm VPIII Microbial Identification Test to detect and identify *Candida* species (Yeast), *Gardnerella vaginalis* (GV) and *Trichomonas vaginalis* (Trich). 3. The manufacturer required the laboratory to perform QC procedures with each new kit lot or shipment and in accordance to local, state and federal regulations. 4. The VPIII patients test and QC logs revealed the laboratory failed to perform QC procedures on 71 out of 91 days of patient testing. 5. The laboratory tested and reported 117 patients results without performing QC procedures during the time period reviewed. 6. The laboratory failed to perform QC procedures with each new kit or shipment as required by the manufacturer. 7. Further

	<p>reviewed showed the last documented QC procedure kit check was performed on 08/20/2020. 8. On an Initial survey conducted on 09/27/2021 at 11:15 AM, the laboratory director confirmed the above findings.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on record review, manufacturer's instructions, the Laboratory Personnel Report (CMS-209), lack of documentation, and interview, the laboratory director (LD) failed to ensure proficiency testing enrollment (D6015) for the BD Affirm Microbial Identification test system; failed to ensure quality control (QC) procedures were established and performed for 71 out of 91 days of patient testing (D6020); failed to ensure quality assurance (QA) procedures were established to assess all aspects of the testing process (D6021); and failed to ensure employees meet the education and training requirements to perform the moderately complex Microbiology Identification test (D6029) affecting 167 patients tests.</p>
<p>D6015</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.</p> <p>This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview, the laboratory director (LD) failed to enroll the laboratory in an approved proficiency testing (PT) program for the tests performed in the specialty of Microbiology. Findings: 1. The Affirm VPIII Lab testing log from 06/10/2020 to 09/25/2021 was reviewed. 2. The laboratory used the BD Affirm VPIII Microbial Identification Test to detect and identify Candida species (Yeast), Gardnerella vaginalis (GV) and Trichomonas vaginalis (Trich). 3. The LD failed to establish policies and procedures to ensure PT enrollment and participation for the Microbiology test procedures it performs. See D2000 and D5217. 4. On an Initial survey conducted on 09/27/2021 at 11:15 AM, the laboratory director confirmed the above findings.</p>
<p>D6020</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory</p>

director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on record review, lack of documentation, and interview, the laboratory director (LD) failed to ensure that quality control (QC) procedures were established and maintained to assure the quality of laboratory services for 167 patients. Findings: 1. The LD failed to establish written procedures for the BD Affirm Microbial Identification test system. See D5401. 2. The LD failed to ensure manufacturer's instructions and federal requirements were followed and documented. See D5411, D5413, and D5441.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on record review, lack of documentation, and interview, the laboratory director (LD) failed to ensure that quality assessment (QA) programs were established and maintained to assure the quality of laboratory services provided. Findings: 1. The LD failed to establish written procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the following systems: *General Laboratory systems - Assessing practices/issues related to patient confidentiality; specimen identification and integrity; complaint investigations; communications; personnel competency; and proficiency testing performance.. *Pre-analytic - assessing patients' (electronic) records (transcription errors, etc.), specimen submission, handling, and referral. *Analytic - assessing test procedures; accurate and reliable test systems, equipment, instruments, reagents, materials, and supplies; specimen and reagent storage condition; equipment/instrument/test/system maintenance and function checks; verification of method performance specifications; control procedures; corrective actions; and test records. *Post-analytic systems -assessing practices/issues related to test reports. 2. On an Initial survey conducted on 09/27 /2021 at 11:15 AM, the LD confirmed the above findings.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(11)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
Based on record review, lack of documentation, the Laboratory Personnel Report (CMS-209), and interview, the laboratory director (LD) failed to ensure all personnel had the appropriate education and training prior to testing patients' specimens for three out of three testing personnel (TP) affecting 167 patients. Findings: 1. The Affirm VPIII Lab testing log from 06/10/2020 to 09/25/2021, employee BD Affirm training records, and CMS-209 were reviewed. 2. The CMS 209 listed three TP (TP1, TP2, and TP3) who performed BD Affirm Microbial Identification test in the laboratory. 3. The LD failed to ensure three out of three TP met the education criteria to perform the BD Affirm test, prior to testing patients. See D6063 and D6065. 4. The LD failed to ensure one out of three TP received training to perform the BD Affirm test, prior to testing patients.

D6063

LABORATORY TESTING PERSONNEL
CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:
Based on record review, lack of documentation, and interview, the laboratory failed to ensure three out of three individuals meet the education and training requirements to perform Bacteriology testing, affecting 167 patients (D6065).

D6065

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:
Based on record review, lack of documentation, the Laboratory Personnel Report (CMS-209), and interview, the laboratory failed to ensure laboratory employees meet the education qualification requirements for performing moderately complex testing in the specialty of Microbiology for three out of three testing personnel (TP) affecting 167 patient tests. Findings: 1. The Affirm VPIII Lab testing log from 06/10/2020 to 09/25/2021 and the Laboratory Personnel Report (CMS 209) were reviewed. 2. The laboratory used the BD Affirm VPIII Microbial Identification Test to detect and identify Candida species (Yeast), Gardnerella vaginalis (GV) and Trichomonas

vaginalis (Trich). 3. CMS 209 listed three TP (TP1, TP2, and TP3) performing the BD Affirm VPIII. 4. The laboratory director (LD) failed provide proof of education for three out of three TP. 5. 167 patients were tested during the time period reviewed by TP1, TP2, and TP3. 6. On an Initial survey conducted on 09/27/2021 at 11:15 AM, the LD confirmed the above findings.