Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0314857	12/14/2023
Name of Provider or Supplier	**Street Address, City, State**	
Women's Care Center Of Memphis Mpllc	1727 Kirby Parkway Suite 200, Memphis, TN	

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 review of the laboratory procedure manual and interview with the laboratory liaison, the laboratory procedure manual for use of the Cepheid GeneXpert did not include the system for entering patient test results into the patient record. The findings include: 1. Review of the laboratory procedure for the Cepheid GeneXpert revealed the procedure for entering/reporting patient results for Neisseria gonorrhea and Chlamydia trachomatis into the patient record was not included in the procedure. 2. Interview with the laboratory liaison on 12/14/23 at 1:45 pm confirmed the laboratory procedure manual did not include the laboratory's process for entering patient test

	results for the Neisseria gonorrhea and Chlamydia trachomatis performed on the Cepheid GeneXpert into the patient record.
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 observation of the laboratory, review of the laboratory procedure manual, and interview with the laboratory liaison, the laboratory failed to ensure the procedure for use of the Cepheid GeneXpert had been approved by the lab director prior to patient testing. The findings include: 1. Observation of the laboratory on 12/14/23 at 10 am revealed the Cepheid GeneXpert on the counter in use for patient testing for Neisseria gonorrhea and Chlamydia trachomatis. 2. Review of the document titled Xpert CT/NG SOP Template revealed the procedure had not been approved by the lab director. 3. Interview with the laboratory liaison on 12/14/23 at 1:45 pm confirmed the laboratory director had not approved the procedure for use of the Cepheid GeneXpert with patient testing being performed.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the manufacturer operator's manual, the maintenance log used by the laboratory, and interview with the laboratory liaison, the maintenance log used by the laboratory for the Cepheid GeneXpert failed to include the tasks specified on the manufacturer log and in the manufacturer operator's manual. The findings include: 1. Observation of the laboratory on 12/14/23 at 10 am revealed a Cepheid GeneXpert (serial # 110019567) on the counter in use for performing patient testing for Neisseria gonorrhea and Chlamydia trachomatis. 2. Review of the GeneXpert Dx System Operator Manual revealed the following under the section for service and maintenance: Daily-clean work area, close all module doors, discard used cartridges; Weekly-power down computer and instrument, clean fan prefilters; Monthly-Archive tests, purge tests, replace fan filters; Quarterly-clean plunger rod and cartridge bays, clean instrument services; Yearly-Check annual instrument maintenance; As needed: print system log report, back up database, Clean I-CORE using I-CORE cleaning brush. 3. Review of the maintenance form in use by the laboratory on the day of the survey revealed the individual maintenance tasks were not specified/documented on the form. 4. Interview with the laboratory liaison on 12 /14/23 at 1:45 pm confirmed the laboratory did not document the individual maintenance tasks according to the manufacturer requiremens.
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 review of the laboratory's Individualized Quality Control Plan (IQCP) for the Neisseria gonorrhea and Chlamydia trachomatis testing performed on the Cepheid GeneXpert and interview with the laboratory liaison, the laboratory's IQCP failed to include the process for quality assessment and monitoring of the quality control procedures. The findings include: 1. Review of the laboratory's IQCP for the Neisseria gonorrhea and Chlamydia trachomatis testing performed on the Cepheid GeneXpert revealed the plan failed to include the procedures for monitoring and assessing the quality control procedures. 2. Interview with the laboratory liaison on 12/14/23 at 1:45 pm confirmed the IQCP developed for use of the Cepheid GeneXpert did not include the laboratory process for quality assessment.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of a final patient test report, review of patient accessioning logs, and interview with the laboratory liaison, the final patient test report for Neisseria gonorrhea and Chlamydia trachomatis failed to include the address of the laboratory and the specimen source, with approximately ten patients reported since testing began on 10/27/23. The findings include: 1. Observation of the laboratory on 12/14/23 at 10 am revealed a Cepheid GeneXpert (serial # 110019567) on the counter in use for performing patient testing for Neisseria gonorrhea and Chlamydia trachomatis on both urine samples and vaginal swabs. 2. Review of a final patient test report for patient #920102, performed on 10/27/23, revealed the address of the laboratory and the specimen source was not on the report. 3. Review of the patient accessioning log revealed patient reporting began on 10/27/23 with approximately ten patients reported since testing began. 4. Interview with the laboratory liaison on 12/14 /23 at 1:45 pm confirmed the final patient report did not include the laboratory address or the source of the specimen.
D6011	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(2) 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)(2) and provide a safe environment in which employees are protected from physical, chemical, and biological hazards. This STANDARD is not met as evidenced by: Based on observation of the laboratory testing areas and interview with the laboratory liaison, the laboratory director failed to ensure employees were protected from potential exposure to biohazards when the laboratory testing was performed in areas of the facility with no posted biohazard signage. The findings include: 1. Observation of laboratory testing areas on 12/14/23 at 10 am revealed the following: a. A microscope on a counter used for performing vaginal wet prep examination in the staff bathroom. A sharps container was noted on the counter half-filled with glass slides. No biohazard signage was present on the door. b. A Cepheid GeneXpert instrument on the counter in use for performing patient testing for Neisseria gonorrhea and Chlamydia trachomatis. No biohazard signage was posted on the door or in the testing area. 2. Interview with the laboratory liaison on 12/14/23 at 1:45 pm confirmed the laboratory director failed to ensure the safety of employees when laboratory testing was occurring in areas with potential for employee exposure to biohazards with no signage posted.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) 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. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the Cepheid GeneXpert validation documents, the laboratory accessioning log, and interview with the laboratory liaison, the technical consultant failed to review or approve the validations performed for use of the Cepheid GeneXpert prior to patient testing which began on 10/27/23. The findings include: 1. Observation of the laboratory on 12/14/23 at 10 am revealed a Cepheid GeneXpert (serial # 110019567) on the counter in use for performing patient testing for Neisseria gonorrhea and Chlamydia trachomatis on both urine samples and vaginal swabs. 2. Review of the validations performed for the Cepheid GeneXpert in May 2023 revealed the validations had not been reviewed or approved by the technical consultant. 3. Review of the patient accessioning log revealed patient reporting began on 10/27/23 with patient #920102, with approximately ten patients reported since testing began. 4. Interview with the laboratory liaison on 12/14/23 at 1: 45 pm confirmed the technical consultant failed to review or approve the validation studies that were performed in May 2023.