

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D0988676	(X3) Date Survey Completed 07/25/2019
Name of Provider or Supplier Women's Health Center	Street Address, City, State 1318 Harrison Ave, McComb, MS	
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 review of the Centers for Medicare and Medicaid Services (CMS) data system for proficiency testing, the laboratory's proficiency testing (PT) records since the last survey on 7-5-17, and interview on 7-25-19 at 1:30 p.m. with Testing Personnel #1, listed on the CMS 209 personnel form, the laboratory failed to enroll in an HHS approved proficiency testing program for the subspecialty of bacteriology since patient testing for Neisseria gonorrhoeae and Chlamydia trachomatis began on 2-12-19. Findings include: Review of the CMS data system for proficiency testing and the laboratory's PT records since the last survey on 7-5-17 revealed no documentation of the performance of proficiency testing for Neisseria gonorrhoeae and Chlamydia trachomatis in the subspecialty of bacteriology. In an interview on 7-25-19 at 1:30 p. m., Testing Personnel #1 confirmed the laboratory was not enrolled in PT for bacteriology.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test</p>

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 Cepheid GeneXpert Procedure and Policy manual and the laboratory's general policy and procedure manual, the laboratory failed to establish written quality control procedures for testing performed on the Cepheid GeneXpert system, to include type of control, frequency of testing controls, and criteria to determine acceptable control results. Findings include: Review of the Cepheid GeneXpert Procedure and Policy manual and the laboratory's general policy and procedure manual revealed the laboratory failed to establish written quality control procedures for *Neisseria gonorrhoeae*, *Chlamydia trachomatis*, and *Trichomonas vaginalis* testing performed on the Cepheid GeneXpert system since the system was put in use for patient testing on 2-12-19.

D5449

CONTROL PROCEDURES

CFR(s): 493.1256(d)(3)(ii)(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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of quality control records and patient test logs for *Neisseria gonorrhoeae*, *Chlamydia trachomatis*, and *Trichomonas vaginalis* testing with the Cepheid GeneXpert test system from 2-12-19 through 5-31-19, lack of documentation of establishment of an Individualized Quality Control Plan (IQCP), and confirmation by Testing Personnel #1, the laboratory failed to include a positive and negative control each day of testing from 2-12-19 through 5-31-19, when results were reported on a total of 169 patients. Findings include: 1. Review of quality control records and patient test logs for *Neisseria gonorrhoeae*, *Chlamydia trachomatis*, and *Trichomonas vaginalis* testing with the Cepheid GeneXpert test system from 2-12-19 through 5-31-19 revealed no documentation of performance of a positive and negative control for all three tests on the following days, when results for these three tests were reported on a total of 169 patients: 2-13-19 - 4 patients reported. 2-14-19 - 5 patients reported.

2-18-19 - 5 patients reported 2-21-19 - 2 patients reported. 2-25-19 - 18 patients reported. 2-26-19 - 7 patients reported. 3-1-19 - 6 patients reported. 3-5-19 - 3 patients reported. 3-8-19 - 13 patients reported. 3-12-19 - 2 patients reported. 3-14-19 - 9 patients reported. 3-15-19 - 4 patients reported. 3-19-19 - 2 patients reported. 3-21-19 - 3 patients reported. 3-26-19 - 11 patients reported. 3-27-19 - 6 patients reported. 3-29-19 - 3 patients reported. 4-3-19 - 2 patients reported. 4-10-19 - 4 patients reported. 4-11-19 - 2 patients reported. 4-15-19 - 3 patients reported. 4-22-19 - 6 patients reported. 4-23-19 - 2 patients reported. 4-25-19 - 5 patients reported. 4-26-19 - 2 patients reported. 4-29-19 - 1 patient reported. 5-2-19 - 4 patients reported. 5-6-19 - 1 patient reported. 5-8-19 - 3 patients reported. 5-10-19 - 9 patients reported. 5-13-19 - 1 patient reported. 5-15-19 - 8 patients reported. 5-17-19 - 3 patients reported. 5-21-19 - 3 patients reported. 5-24-19 - 1 patient reported. 5-31-19 - 6 patients reported. 2. Review of quality control records and patient test logs for Neisseria gonorrhoeae and Chlamydia trachomatis testing with the Cepheid GeneXpert test system from 2-12-19 through 5-31-19 revealed no documentation of performance of a positive and negative control for these two tests on the following days, when results for these two tests were reported on a total of 19 patients: 4-12-19 - 1 patient reported. 4-24-19 - 5 patients reported. 4-30-19 - 8 patients. 5-7-29 - 5 patients. 3. Review of quality control records and patient test logs for Trichomonas vaginalis testing with the Cepheid GeneXpert test system from 2-12-19 through 5-31-19 revealed no documentation of performance of a positive and negative control for this test on the following days, when results for this test were reported on a total of ten patients: 2-15-19 - 5 patients reported. 4-16-19 - 3 patients reported. 5-1-19 - 2 patients reported. Testing Personnel #1 confirmed that an IQCP had not been established for Neisseria gonorrhoeae, Chlamydia trachomatis, and Trichomonas vaginalis testing with the Cepheid GeneXpert test system and that a positive and negative control were not performed each day of patient testing.

D5787

TEST RECORDS
CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:
Based on review of patient test reports, the patient test log, and interview with Testing Personnel #1, listed on the CMS 209 personnel form, on 7-25-19 at 2:00 p.m., the laboratory's record system does not include the identity of the personnel who performed Neisseria gonorrhoeae, Chlamydia trachomatis, and Trichomonas vaginalis testing on the Cepheid GeneXpert test system since it was put in use on 2-12-19. Findings include: Review of patient test reports from the Cepheid GeneXpert test system scanned into patients' electronic medical records and the patient test log revealed no documentation of the identity of the personnel who performed Neisseria gonorrhoeae, Chlamydia trachomatis, and Trichomonas vaginalis testing on the Cepheid GeneXpert test system. Testing Personnel #1 confirmed the laboratory's record system does not include the identity of testing personnel for the Cepheid GeneXpert test system, since it was put in use on 2-12-19.

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 the deficiencies for technical consultant responsibilities, the technical consultant (as listed on the CMS 209 personnel form) failed to provide technical oversight in accordance with 493.1413 of this subpart. Refer to D6041 (Failure to enroll in a proficiency testing program for bacteriology). Refer to D6042 (Failure to establish a quality control program). Refer to D6049 (Failure to review quality control records). Refer to D6054 (Failure to evaluate competency of testing personnel at least annually). Refer to D6055 (Failure to evaluate competency of testing personnel on new instrumentation).

D6041

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(3)

(b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered;

This STANDARD is not met as evidenced by:

Based on review of proficiency testing (PT) records since the last survey on 7-5-17 and interview with Testing Personnel #1 on 7-25-19 at 1:30 p.m., the technical consultant failed to enroll in an HHS approved proficiency testing program for the subspecialty of bacteriology since patient testing for *Neisseria gonorrhoeae* and *Chlamydia trachomatis* began on 2-12-19. Findings include: Review of proficiency testing records since the last survey on 7-5-17 revealed no documentation of enrollment in an HHS approved proficiency testing program for the subspecialty of bacteriology. In an interview on 7-25-19 at 1:30 p.m., Testing Personnel #1 confirmed the laboratory was not enrolled in proficiency testing for bacteriology.

D6042

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(4)

(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;

This STANDARD is not met as evidenced by:

Based on review of the Cepheid GeneXpert Procedure and Policy manual and the laboratory's general policy and procedure manual, quality control records and patient test logs for *Neisseria gonorrhoeae*, *Chlamydia trachomatis*, and *Trichomonas vaginalis* testing with the Cepheid GeneXpert test system from 2-12-19 through 5-31-19, lack of documentation of establishment of an Individualized Quality Control Plan (IQCP), and lack of documentation of performance of controls each day of patient

testing, the technical consultant failed to establish a quality control program appropriate for the testing performed on the Cepheid GeneXpert test system. Findings include: Review of the Cepheid GeneXpert Procedure and Policy manual and the laboratory's general policy and procedure manual, quality control records, and patient test logs for Neisseria gonorrhoeae, Chlamydia trachomatis, and Trichomonas vaginalis testing with the Cepheid GeneXpert test system from 2-12-19 through 5-31-19 revealed the technical consultant failed to establish a quality control program requiring performance of a positive and negative control each day of patient testing or to establish an IQCP for testing performed on the Cepheid GeneXpert test system. Refer to D5403 (Failure to establish written quality control procedures). Refer to D5449 (Failure to include a positive and negative control each day of testing).

D6049

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)(iii)

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:
Based on review of quality control (QC) records and patient test logs for Neisseria gonorrhoeae, Chlamydia trachomatis, and Trichomonas vaginalis testing with the Cepheid GeneXpert test system since 2-12-19 and lack of documentation of review of the QC records, the technical consultant failed to include, in the evaluation of the competency of testing personnel, the review of QC records for the Cepheid GeneXpert test system since the system was put in use for patient testing on 2-12-19. Findings include: Review of patient test logs for Neisseria gonorrhoeae, Chlamydia trachomatis, and Trichomonas vaginalis testing with the Cepheid GeneXpert test system revealed patient testing began on 2-12-19. Review of QC records for the Cepheid GeneXpert test system since 2-12-19 revealed the technical consultant failed to document review of the QC records since testing began on 2-12-19. Refer to D5449 (Failure to include a positive and negative control each day of patient testing).

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:
Based on review of the CMS 209 personnel form and personnel records since the last survey on 7-5-17, the technical consultant failed to evaluate and document the performance of Testing Personnel #1, responsible for moderate complexity testing, at least annually since this individual's initial training for performing microscopic urinalysis on 10-13-17. Findings include: Review of the CMS 209 personnel form and personnel records since 7-5-17 revealed no annual evaluation by the technical consultant documenting the performance of Testing Personnel #1 for performing microscopic urinalysis since this individual's initial training for performing microscopic urinalysis on 10-13-17. The semiannual evaluation for Testing Personnel #1 was performed by the technical consultant on 3-30-18.

D6055

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of the CMS 209 personnel form, personnel records, and patient test logs for *Neisseria gonorrhoeae*, *Chlamydia trachomatis*, and *Trichomonas vaginalis* testing with the Cepheid GeneXpert test system, the technical consultant failed to evaluate and document the performance of Testing Personnel #1, responsible for moderate complexity testing, prior to reporting patient test results for tests performed on the Cepheid GeneXpert, put in use for patient testing on 2-12-19. Findings include: Review of the CMS 209 personnel form, personnel records since the last survey on 7-5-17, and patient test logs for *Neisseria gonorrhoeae*, *Chlamydia trachomatis*, and *Trichomonas vaginalis* testing with the Cepheid GeneXpert test system from 2-12-19 through 5-31-19 revealed the technical consultant failed to evaluate and document the performance of Testing Personnel #1, responsible for moderate complexity testing, prior to reporting patient test results for tests performed on the Cepheid GeneXpert, which was put in use for patient testing on 2-12-19.