Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0464516	02/07/2019
Name of Provider or Supplier	**Street Address, City, State**	
Louisiana Center For Women's Health, Llc	401 Mcmillan Road, West Monroe, LA	

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	A Certification survey was performed at La Center for Women's Health - CLIA # 19D0464516 on February 7, 2019. La Center for Women's Health was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1250 CONDITION: Analytic Systems 42 CFR 493.1403 CONDITION: Laboratories performing moderate complexity testing, Laboratory Director
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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 and interview with personnel, the laboratory failed to establish complete written policies and procedures to assess competency for testing personnel. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not include the following six (6) procedures as a minimal requirement for assessing the competency of all personnel performing laboratory testing: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting or test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative 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. 2. In interview on February 7, 2019 at 10:13 am, Personnel 2 confirmed the laboratory's current competency procedure did not include the identified six (6) procedures.

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 observation, record review, and interview with personnel, the laboratory failed to ensure the quality of testing within the analytic systems. Findings: 1. The laboratory failed to have a complete policy and procedure manual. Refer to D5401. 2. The laboratory failed to have complete performance specification studies for the Cepheid GeneXpert analyzer. Refer to D5421 I. 3. The laboratory failed to have complete performance verification studies for the BD Affirm VPIII analyzer. Refer to D5421 II. 4. The laboratory failed to perform Quality Control every thirty days as required by the Individualized Quality Control Plan (IQCP) for Chlamydia and Gonorrhoeae testing. Refer to D5445 I. 5. The laboratory failed to perform Quality Control every seven (7) days as required by the Individualized Quality Control Plan (IQCP) for Trichomonas, Gardnerella, and Candida testing. Refer to D5445 II. 6. The laboratory failed to have a system in place for twice a year comparison testing for testing performed on the BD Affirm VPIII analyzer. Refer to D5775. 7. The laboratory's Quality Assurance monitors failed to identify and correct quality issues in Analytic Systems. Refer to D5791.
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 record review and interview with personnel, the laboratory failed to have a complete policy and procedure manual. Findings: 1. Review of the laboratory's policy and procedure manuals revealed the laboratory did not have detailed policies for the following: Performance specifications: detailed policy of how the laboratory will verify accuracy, complete precision, reportable range and refernce range of new instrumentation prior to use and acceptable criteria of each. Test Comparison: detailed policy of how the laboratory will monitor all tesing it performs at a minimum of twice per year 2. In interview on February 7, 2019 at 11:00 am, Personnel 2 stated she was unaware of the policies required. Personnel 2 confirmed the above areas were not included in the current policies.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system

	must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: I. Based on observation, record review, and interview with personnel, the laboratory failed to have complete performance specification studies for the Cepheid GeneXpert analyzer. Findings: 1. Observation by surveyor during the laboratory tour on February 7, 2019 revealed the laboratory utilizes the Cepheid GeneXpert analyzer for the following testing: a) Neisseria gonorrhoeae b) Chlamydia 2. In interview on February 7, 2019 at 10:31 am, Personnel 2 stated the laboratory started patient testing on September 6, 2018. 3. Review of the laboratory's policy manual revealed the laboratory did not have a written, detailed policy for Performance Specification which includes studies for accuracy, complete precision (day-to-day, run-to-run, within run, and operator variance), reportable range, and reference range. 4. Review of the Cepheid GeneXpert installation records revealed the laboratory did not have any documentation that performance specification studies were performed. 4. In interview on February 7, 2019 at 10:31 am, Personnel 2 stated she was unaware the Cepheid GeneXpert analyzer performed moderate complexity testing and that performance specification studies were required. Personnel 2 confirmed the laboratory did not perform any studies prior to patient testing. 5. Review of the laboratory's Task 1 & 3 form provided by laboratory revealed the following annual volumes: Neisseria gonorrhoeae - 851 Chlamydia - 851 II. Based on observation, record review, and interview with personnel, the laboratory failed to have complete performance specification studies for the BD Affirm VPIII analyzer. Findings: 1. Observation by surveyor during the laboratory tour on February 7, 2019 revealed the laboratory utilizes two (2) BD Affirm VPIII analyzers for Trichomonas, Gardnerella, and Candida testing. 2. In interview on February 7, 2019 at 10:47 am, Personnel 2 stated the laboratory was performing a large amount of tests on the BD Affirm VPIII so another analyzer was purchased to help with the workload. 3. Review of the laboratory's records revealed the laboratory did not perform verification studies on the new BD Affirm VPIII analyzer. 4. In interview on February 7, 2019 at 10:47 am, Personnel 2 confirmed that verification studies were not performed. 5. Review of the laboratory's Task 1 & 3 forms provided to surveyors revealed the following annual volumes performed: Trichomonas - 2445 Gardnerella - 2445 Candida - 2445
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: I. Based on observation, record review, and interview with personnel, the laboratory failed to perform Quality Control every thirty days as required by the Individualized Quality Control Plan (IQCP) for Chlamydia and Gonorrhoeae testing. Findings: 1. Observation by surveyor during laboratory tour on February 7, 2019 revealed the laboratory utlizes the Cepheid GeneXpert analyzer for Chlamydia and Neisseria Gonorrhoeae testing. 2. Review of the laboratory's IQCP policy and records revealed the laboratory is to perform external quality control (QC) every thirty (30) days. 3. Review of the laboratory's quality control records from October 1, 2018 through January 31, 2019 revealed the laboratory did not perform QC as required for the following: a) QC performed on December 12, 2018 then again on January 18, 2019 (QC due on January 11, 2019 per IQCP) 4. Review of the laboratory's patient records from January 12, 2019 through January 17, 2019 revealed the following fifty one (51) patients without QC performed as required: a) January 14, 2019 - Patients 1 - 18 (three (3) days over IQCP requirement of every thirty (30) days) b) January 15, 2019 - Patients 19 - 32 (four (4) days over IQCP requirement of every thirty (30) days) c) January 16, 2019 - Patients 33 - 46 (five (5) days over IQCP requirement of every thirty (30) days) d) January 17, 2019 - Patients 47 - 51 (six (6) days over IQCP requirement of every thirty (30) days) 5. In interview on February 7, 2019 at 11:52 am, Personnel 2 stated she thought QC could be performed once during the month and did not understand that it was to be performed every thirty (30) days. Personnel 2 confirmed the QC was not performed per IQCP policy. 6. Review of the Task 1 & 3 provided to surveyor revealed the following annual volumes: Chlamydia - 851 Gonorrhoeae - 851 II. Based on observation, record review and interview with personnel, the laboratory failed to perform Quality Control every seven (7) days as required by the Individualized Quality Control Plan (IQCP) for Trichomonas, Gardnerella, and Candida testing. Findings: 1. Observation by surveyor during laboratory tour on February 7, 2019 revealed the laboratory utilizes the BD Affirm VP III analyzer for Trichomonas, Gardnerella, and Candida testing. 2. Review of the laboratory's IQCP policy revealed the laboratory performs external quality control (QC) every seven (7) days (weekly). 3. Review of the laboratory's QC records from January 1, 2018 through February 6, 2019 revealed the laboratory did not perform QC as required for the following: a) QC performed on December 10, 2018 then again on December 26, 2018 (QC due on December 17, 2018 per IQCP) 4. Review of the laboratory's patient records from December 18, 2018 through December 26, 2018 revealed the following sixty two (62) patients without QC performed as required: a) December 17, 2018 - Patients 52 - 64 (QC due December 17, 2018) b) December 18, 2018 - Patients 65 - 76 (QC due December 17, 2018) c) December 19, 2018 - Patients 77 - 94 (QC due December 17, 2018) d) December 20, 2018 - Patients 95 - 108 (QC due December 17, 2018) e) December 21, 2018 - Patients 109 - 113 (QC due December 17, 2018) 5. In interview on February 7, 2019 at 11:41 am, Personnel 2 stated she must have forgot to document the weekly QC. Personnel 2 confirmed the QC was not performed as required by the IQCP. 6. Review of the Task 1 & 3 form provided to surveyor revealed the following annual volumes: Trichomonas - 2445 Gardnerella - 2445 Candida - 2445
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The

	laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to have a system in place for twice a year comparison testing for testing performed on the BD Affirm VPIII analyzer. Findings: 1. Observation by surveyor during laboratory tour on February 7, 2019 revealed the laboratory utlizes the following analyzers for patient testing: a) two (2) BD Affirm VPIII: testing for Trichomonas, Gardnerella, and Candida 2. Review of the laboratory's policy manual revealed the laboratory did not have a procedure for twice a year comparison testing performed on analyzers utilized. 3. In interview on February 7, 2019 at 10:47 am, Personnel 2 stated she was unaware the laboratory was required to perform comparison testing. Personnel 2 confirmed there is no policy for twice a year comparison testing.
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 observation, record review, and interview with personnel, the laboratory's Quality Assurance monitors failed to identify and correct quality issues in Analytic Systems. Findings: 1. A review of patient test records and quality control records indicated problems found in the analytic systems as follows: a) The laboratory failed to have a complete policy and procedure manual. Refer to D5401. b) The laboratory failed to have complete performance specification studies for the Cepheid GeneXpert analyzer. Refer to D5421 I. c) The laboratory failed to have complete performance verification studies for the BD Affirm VPIII analyzer. Refer to D5421 II. d) The laboratory failed to perform Quality Control every thirty days as required by the Individualized Quality Control Plan (IQCP) for Chlamydia and Gonorrhoeae testing. Refer to D5445 I. e) The laboratory failed to perform Quality Control every seven (7) days as required by the Individualized Quality Control Plan (IQCP) for Trichomonas, Gardnerella, and Candida testing. Refer to D5445 II. f) The laboratory failed to have a system in place for twice a year comparison testing for testing performed on the BD Affirm VPIII analyzer. Refer to D5775. 2. The laboratory had a Quality Assurance Policy that identified specific monitors that were routinely performed by the laboratory; however, the monitors failed to identify the deficiencies identified. 3. Interview with Personnel 2 on February 7, 2018 confirmed the laboratory failed to identify the deficiencies cited above.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 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.

	This CONDITION is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure that complete verification procedures were performed. Refer to D6013. 2. The Laboratory Director failed to ensure the laboratory personnel were performing test methods as required for accurate and reliable results. Refer to D6014. 3. The Laboratory Director failed to ensure that a quality control program was established and maintained to assure quality laboratory services were provided. Refer to D6020. 4. The Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided. Refer to D6021. 5. The Laboratory Director failed to ensure policies and procedures were established for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Refer to D6030. 6. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Refer to D6031.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on observation, record review, and interview with laboratory personnel, the Laboratory Director failed to ensure that complete verification procedures were performed. Findings: 1. The laboratory failed to have complete performance specification studies for the Cepheid GeneXpert analyzer. Refer to D5421 I. 2. The laboratory failed to have complete performance verification studies for the BD Affirm VPIII analyzer. Refer to D5421 II.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) 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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel were performing test methods as required for accurate and reliable results. Refer to D5775.

D6020	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 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 observation, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality control program was established and maintained to assure quality laboratory services were provided. Findings: 1. The laboratory failed to perform Quality Control every thirty days as required by the Individualized Quality Control Plan (IQCP) for Chlamydia and Gonorrhoeae testing. Refer to D5445 I. 2. The laboratory failed to perform Quality Control every seven (7) days as required by the Individualized Quality Control Plan (IQCP) for Trichomonas, Gardnerella, and Candida testing. Refer to D5445 II.
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 observation, record review and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided. Refer to D5791.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by:

	Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures were established for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Refer to D5209.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Refer to D5401.