Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2014102	06/10/2025
Name of Provider or Supplier	**Street Address, City, State**	
Contemporary Womens Care Of Breaux Bridge	1546 Gary Drive, Breaux Bridge, 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	An Initial certification survey was performed at Contemporary Women's Care of Breaux Bridge, CLIA # 19D2014102, on June 10, 2025. Contemporary Womens Care of Breaux Bridge was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1403 CONDITION: Laboratories performing moderate complexity testing; Laboratory Director 42 CFR 493.1421 CONDITION: Laboratories performing moderate complexity testing; Testing Personnel
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 observation, review of manufacturers' instructions and the laboratory's temperature records, and interview with personnel, the laboratory failed to define acceptable room temperature limits within the manufacturers' required ranges for supplies stored in the laboratory. Findings: 1. Observation by surveyor during the laboratory tour on June 10, 2025 at 9:42 a.m. revealed the following laboratory supplies stored at room temperature in the laboratory: a) BD CTGCTV2 - Manufacturer's storage requirements: 2 - 25 degrees Celsius b) BD Max Vaginal Panel - Manufacturer's storage requirements: 2 - 25 degrees Celsius c) Microbiologics Vaginal Control Panel - Manufacturer's storage requirements: 2 - 25 degrees Celsius d) Microbiologics CT/GC/TV Control Panel - Manufacturer's storage requirements: 2

	- 25 degrees Celsius 2. Review of the laboratory's room temperature records from May 2025 and June 2025 revealed the laboratory defined the acceptable room temperature limits as 18 - 30 degrees Celsius which exceeded the manufacturers' upper temperature limits. 3. In interview on June 10, 2025 at 9:54 a.m., Personnel 3 confirmed the laboratory's acceptable room temperature limits exceeded the manufacturers' limits as identified above.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(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: Based on review of the laboratory's performance specification studies and interview with personnel, the laboratory failed to verify complete performance specification studies to include complete precision studies for microbiology testing on the BD MAX analyzer. Findings: 1. Review of the laboratory's performance specification studies for microbiology testing on the BD MAX analyzer the laboratory did not perform precision studies to include run-to-run and within-run variation for the following test panels: a) BD MAX Vaginal Panel (Bacterial vaginosis, Candida spp, Candida glabrata, Candida krusei, and Trichomonas vaginalis) b) BD MAX CT/GC /TV2 Panel (Chlamydia trachomatis, Neisseria gonorrhoeae, and Trichomonas vaginalis) 2. In interview on June 10, 2025 at 12:26 p.m., the Technical Consultant confirmed the laboratory did not perform precision studies as identified above.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) 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. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: Based on observation, review of the laboratory's Individualized Quality Control Plan (IQCP) records, and interview with personnel, the laboratory failed to have a complete Quality Control Plan to include the frequency of quality control (QC) performance for Microbiology testing. Findings: 1. Observation by surveyor during the laboratory tour on June 10, 2025 at 9:42 a.m. revealed the laboratory utilized the BD MAX Vaginal Panel on the BD MAX analyzer for testing of the following: Bacterial vaginosis (BV),

	Candida spp, Candida glabrata, Candida krusei, and Trichomonas vaginalis. 2. In interview on June 10, 2025 at 10 a.m., Personnel 3 stated the laboratory performed QC with each new lot and/or shipment and monthly. 3. Review of the laboratory's IQCP records revealed an IQCP for the BD MAX Vaginal Panel, but the laboratory's Quality Control Plan (QCP) did not include performance of QC once per month. 4. In interview on June 10, 2025 at 2 p.m., the Technical Consultant confirmed the Quality Control Plan did not include the laboratory's requirement of performing QC materials monthly.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) (d)(3)(ii) Each qualitative procedure, include a negative and positive control material; This STANDARD is not met as evidenced by: Based on observation; review of the laboratory's policies, manufacturer's package insert, quality control records, and patient test records; as well as interview with personnel, the laboratory failed to perform external quality control (QC) each day of patient testing for the BD MAX Vaginal Panel for three (3) of seven (7) patients reviewed. Findings: 1. Observation by surveyor during the laboratory tour at 9:42 a.m. revealed the laboratory utilized the BD MAX Vaginal Panel on the BD MAX analyzer for Bacterial vaginosis (BV), Candida spp, Candida glabrata, Candida krusei, and Trichomonas vaginalis testing. 2. Review of the laboratory's policy "BD MAX Vaginal Panel" revealed "One External Positive Control and one External Negative Control should be run at least daily until adequate process validation is achieved on the BD Max System in each laboratory setting." 3. Review of the manufacturer's package insert "BD Max Vaginal Panel" revealed "One External Positive Control and one External Negative Control should be run at least daily until adequate process validation is achieved on the BD Max System in each laboratory setting." 4. In interview on June 10, 2025 at 1:45 p.m., the Technical Consultant stated the laboratory implemented an Individualized Quality Control Plan (IQCP) in the middle of May of 2025. She further stated the laboratory was performing QC each day of use for the BD MAX Vaginal panel prior to the implementation of the IQCP. 5. Review of the laboratory's patient test records and QC records from March 2025 through May 12, 2025 revealed the laboratory did not perform external QC each day of patient testing for the following dates and patients: a) 04/17/2025: Accession 13688570 b) 04 /24/2025: Accession 13782130 c) 05/08/2025: Accession 13744335 6. In interview on June 10, 2025 at 1:55 p.m., the Technical Consultant confirmed the laboratory did not have documentation of performance of external quality controls for the identified dates.
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. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to establish complete procedures to identify issues within the analytic system.

	Findings: 1. Review of the laboratory policy and procedures revealed the laboratory had a quality assessment process in place; however, the following deficient practices were not identified: a) The laboratory failed to define acceptable room temperature limits within the manufacturers' required ranges for supplies stored in the laboratory. Refer to D5413. b) The laboratory failed to verify complete performance specification studies to include complete precision studies for microbiology testing on the BD Max analyzer. Refer to D5421. c) The laboratory failed to have a complete Quality Control Plan to include the frequency of quality control (QC) performance for Microbiology testing. Refer to D5445. d) The laboratory failed to perform external quality control (QC) each day of patient testing for the BD MAX Vaginal Panel for three (3) of seven (7) patients reviewed. Refer to D5449.
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. Refer to D6029.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on record review, and interview with personnel, the Laboratory Director failed to ensure that complete verification procedures were performed. Refer to D5421.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) (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 performed test methods as required. Refer to D5413.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

	This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that quality programs were in place to assure quality laboratory testing. Findings: 1. The laboratory failed to have a complete Quality Control Plan to include the frequency of quality control (QC) performance for Microbiology testing. Refer to D5445. 2. The laboratory failed to perform external quality control (QC) each day of patient testing for the BD MAX Vaginal Panel for three (3) of seven (7) patients reviewed. Refer to D5449. 3. The laboratory failed to establish complete procedures to identify issues within the analytic system. Refer to D5791.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) (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 review of laboratory policy, personnel records and interview with personnel, the Laboratory Director failed to ensure the laboratory employed testing personnel that met the licensure and educational requirements. Findings: 1. The laboratory failed to ensure testing personnel met the state of Louisiana licensure requirement for two (2) of three (3) testing personnel reviewed. Refer to D6064. 2. The laboratory failed to provide documentation that testing personnel met the educational qualifications for performing moderate complexity testing for one (1) of three (3) testing personnel. Refer to D6065.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. The technical consultant is not required to be onsite at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide consultation, as specified in paragraph (a) of this section. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to define acceptable room temperature limits within the manufacturers' required ranges for supplies stored in the laboratory. Refer to D5413.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) (b)(2) Verification of the test procedures performed and the establishment of the laboratorys test performance characteristics, including the precision and accuracy of each test and test system;

	This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultant failed to ensure performance specification verification studies were complete. Refer to D5421.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (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 observation, record review and interview with personnel, the Technical Consultant failed to ensure the quality control program was established to assure the quality of laboratory testing. Findings: 1. The laboratory failed to have a complete Quality Control Plan to include the frequency of quality control (QC) performance for Microbiology testing. Refer to D5445. 2. The laboratory failed to perform external quality control (QC) each day of patient testing for the BD MAX Vaginal Panel for three (3) of seven (7) patients reviewed. Refer to D5449.
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 review of personnel records and interview with personnel, the laboratory failed to provide documentation to ensure all testing personnel met licensure and education requirements. Findings: 1. The laboratory failed to ensure testing personnel met the state of Louisiana licensure requirement for two (2) of three (3) testing personnel reviewed. Refer to D6064. 2. The laboratory failed to provide documentation that testing personnel met the educational qualifications for performing moderate complexity testing for one (1) of three (3) testing personnel. Refer to D6065.
D6064	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(a) Each individual performing moderate complexity testing must-- (a) possess a current license issued by the State in which the laboratory is located, if such licensing is required; and This STANDARD is not met as evidenced by:

	Based on review of the CMS-209 (Laboratory Personnel Report), personnel records, and interview with personnel, the laboratory failed to ensure testing personnel met the state of Louisiana licensure requirement for two (2) of three (3) testing personnel reviewed. Findings: 1. Review of the laboratory's CMS-209 revealed that the following testing personnel performed moderate complexity testing for the specialty of Bacteriology: * Personnel 3 * Personnel 4 * Personnel 5 2. Review of personnel records revealed the laboratory did not include a state license covering moderate complexity testing issued by Louisiana State Board of Medical Examiners (LSBME) for the following personnel: * Personnel 4 * Personnel 5 3. In interview on June 10, 2025 at 11:00 am, Personnel 3 confirmed the above identified testing personnel did not have a Louisiana State laboratory license to perform moderate complexity testing.
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 (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of personnel records and interview with personnel, the laboratory failed to provide documentation that testing personnel met the educational qualifications for performing moderate complexity testing for one (1) of three (3) testing personnel. Findings: 1. Review of the laboratory's personnel records revealed the laboratory did not maintain documentation of at least a High School Diploma or equivalent for the following testing personnel: * Personnel 5 2. In interview on June 10, 2025 at 11:00 a.m., Personnel 3 confirmed the laboratory did not have documentation of education for Personnel 5.