Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0989149	03/26/2025
Name of Provider or Supplier	**Street Address, City, State**	
Womens Health & Wellness,Llc/Scott P Striplin,Md	77 Starbrush Circle, Covington, 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 Validation survey was performed at Women's Health and Wellness, LLC, CLIA ID 19D0989149, on March 26, 2025. Women's Health and Wellness, LLC 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 42 CFR 493.1409 CONDITION: Laboratories performing moderate complexity testing; Technical Consultant
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS 209 form, personnel records, proficiency testing (PT) records, policies, and interview with personnel, the laboratory failed to ensure that proficiency tests for Bacteriology and Parasitology were performed by personnel who routinely perform laboratory testing for four (4) of six (6) events reviewed. Findings: 1. Review of the laboratory's CMS 209 (Laboratory Personnel) form and personnel records revealed the Laboratory Director was listed as the laboratory's sole Testing Personnel. 2. Review of the laboratory's American Proficiency Testing (API) records for 2023 and 2024 revealed the Nurse, who was not listed as testing personnel, signed the attestation statements as personnel performing the test for the following events: 2023 Microbiology 2nd Event 2023 Microbiology 3rd Event 2024 Microbiology 2nd Event 2024 Microbiology 3rd Event 3. In interview on March 26, 2025 at 12:06 pm, the Nurse stated she was told to sign the attestation forms. The Nurse further stated that she does not test PT or patient samples.

D2014	TESTING OF PROFICIENCY TESTING SAMPLES (b)(6) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records and interview with personnel, the laboratory failed to maintain the attestation statements for two (2) of six (6) testing events reviewed. Findings: 1. Review of the laboratory's American Proficiency Institute (API) proficiency records for 2023 and 2024 revealed the laboratory did not have the attestation statement forms for the 2023 Microbiology 1st Event and 2024 Microbiology 1st Event. 2. In interview on March 26, 2025 at 1:30 pm, the Compliance Personnel confirmed the laboratory did not have the attestation forms for the Microbiology 1st events for 2023 and 2024.
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 review of the laboratory's policies, competency assessment records, and interview with personnel, the laboratory failed to follow their established competency assessment procedures for one (1) of one (1) testing personnel reviewed for 2023 and 2024. Findings: 1. Review of the laboratory's "Proficiency Testing and Employee Competency" policy under the "Employee Competency" section revealed "Employee competency assessment will measure the following points to determine and measure the employee competency to perform the testing performed by the laboratory: The direct observation of perform each test performed by the employee {sic}, monitoring the employee's ability to report testing results, review of all QC, QA, proficiency testing, maintenance logs in ensure all proper documentation {sic}, direct observation of instrument maintenance, assessment of employee's test performance utilizing proficiency test results, and assessment of employee's problem solving skills." 2. Review of the laboratory's "Competency Assessment-Single Instrument-Testing Person" form for 2023 and 2024 revealed the following activities were included: "Direct observation of instrument maintenance: daily, monthly, six months" "Assessment of problem solving skills: Review of instrument problem log, review of QC issues, quiz or scenario" 3. Further review of the 2023 and 2024 competency assessment forms for the Laboratory Director, who served as Testing Personnel, revealed the direct observation of maintenance for daily and monthly, and the assessment of problem solving skills were not performed. 4. In interview on March 26, 2025 at 10:24 am, the Consulting Personnel confirmed the laboratory did not have documentation of performance of the identified tasks.

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 by surveyor, record review, and interview with personnel, the laboratory failed to ensure quality of testing within the analytic systems. Findings: 1. The laboratory failed to follow the manufacturer's instructions for unacceptable patient results for Bacteriology and Parasitology testing for three (3) of three (3) patients reviewed. Refer to D5411. 2. The laboratory failed to monitor the room temperature of one (1) of one (1) storage closets where laboratory supplies were stored. Refer to D5413. 3. The laboratory failed to test external controls every thirty days as defined in their laboratory policy for four (4) of nine (9) months reviewed. Refer to D5441. 4. The laboratory failed to perform corrective actions when the QC value was unacceptable for Parasitology testing for one (1) of nine (9) months reviewed. Refer to D5783. 5. The laboratory's quality assessment monitors failed to identify and correct quality issues in the analytic systems. Refer to D5793.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (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 review of the laboratory's policies, manufacturer's instructions, instrument printout, and interview with personnel, the laboratory failed to follow the manufacturer's instructions for unacceptable patient results for Bacteriology and Parasitology testing for three (3) of three (3) patients reviewed. Findings: 1. Review of the laboratory's policies revealed the laboratory did not have a written policy related to interpretation and actions for unacceptable/flagged patient results. 2. Review of the "BD Max CT/GC/ TV" instructions revealed " Unresolved (UNR) results may be obtained in the event that specimen-associated inhibition or reagent failure prevents proper target of Sample Processing Control amplification. The BD Max System reports results for each target individually and a UNR results may be obtained for one or more BD max CT/GC/TV targets. In the case of a complete UNR, where all targets have a UNR result, it is necessary to repeat the test. In the case of a partial UNR, when one or more targets have a POS result and all other targets have a UNR result, it is recommended that the test be repeated as described below." 3. Review of random selection of patient test logs revealed the laboratory had the following patients with unacceptable patient results without further action performed: a) October 9, 2024: Patient 5 had UNR results for Chlamydia trachomatis, Neisseria gonorrhea, and Trichomonas vaginalis Patient 7: had IND results for Chlamydia

	trachomatis, Neisseria gonorrhea, and Trichomonas vaginalis with message "Error in Full Fill Check" b) February 11, 2025: Patient 7 had UNR results for Chlamydia trachomatis, Neisserra gonorrhea, and Trichomonas vaginalis 4. Review of the laboratory's " Monthly Quality Assurance forms" revealed the Technical Consultant signed the monthly QA forms; however, no actions or issues were documented for the identified months. 5. In interview on March 26, 2025 at 11:38 am, the Nurse stated the laboratory does not repeat samples with Unresolved results. The Nurse stated the patient may be notified and told to come back for recollection, but may not return. The Nurse further stated the follow-up is the doctor's call. The Nurse stated for patients with unresolved results, no actions are documented in the patient's chart.
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 by surveyor, review of manufacturers' storage requirements, and interview with personnel, the laboratory failed to monitor the room temperature of one (1) of one (1) storage closets where laboratory supplies were stored. Findings: 1. Observation by surveyor during the laboratory tour on March 26, 2025 at 9:46 am revealed the following items were stored in a storage closet located inside the laboratory: a) Cobas PCR Media Dual Swab Sample Kit b) e-Swab Aerobic, Anaerobic, and Fastidious Bacteria c) Thin Prep 2. Review of the manufacturers' storage requirements revealed the following: a) Cobas PCR Media Dual Swab Sample Kit storage requirements requirement 15-30 degrees Celsius b) e-Swab Aerobic, Anaerobic, and Fastidious Bacteria storage requirement 5-25 degrees Celsius c) Thin Prep storage requirement 15-30 degrees Celsius 3. In interview on March 26, 2025 at 9:55 am, the reference laboratory employee stated the room temperature of storage closet where the identified supplies were stored was not monitored.
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.

	This STANDARD is not met as evidenced by: Based on observation by surveyor, review of the laboratory's policies, quality control records, patient test logs, and interview with personnel, the laboratory failed to test external controls every thirty days as defined in their laboratory policy for four (4) of nine (9) months reviewed. Findings: 1. Observation by surveyor during the laboratory tour on March 26, 2025 at 9:46 am revealed the laboratory utilizes the BD Max instrument for Bacteriology (Chlaymydia trachomatis and Neisseria gonorrhea) and Parasitology (Trichomonas vaginalis) testing. 2. Review of the laboratory's "Molecular Quality Control" policy under the "External Quality Controls" section revealed "An IQCP study will be performed using 30 days of External Positive and Negative controls. After an acceptable IQCP study is performed Qc frequency will be as follows: Every 30 days, Every new Lot # of Reagent Kits, and Every new shipment, regardless of Lot #." 3. In interview on March 26, 2025 at 11:00 am, the Nurse stated the laboratory did not currently have any external controls for the BD Max. 4. Review of the laboratory's QC records from July 2024 through March 2025 and patient test logs revealed the laboratory did not perform external controls every thirty days for the following months: July 2024: no controls performed (total of 192 patients tested in July 2024) November 2024: laboratory performed on November 19, 2024, previously performed on October 3, 2024 February 2025: laboratory performed on February 11, 2025, previously performed on January 6, 2025 March 2025: laboratory did not perform as of March 26, 2025 (total of forty eight patients tested since March 18, 2025) 5. In interview on March 26, 2025 at 11:50 am, the Compliance Personnel confirmed that the laboratory did not have documentation of performance of QC for July 2024. 6. In further interview on March 26, 2025 at 1:30 pm, the Nurse initially stated the external controls for March 2025 were ran. The Nurse later stated the laboratory did not run the external controls for March 2025 and continued patient testing.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on observation of surveyor, review of policies, patient test logs, quality control (QC) records, and quality assurance (QA) records, the laboratory failed to perform corrective actions when the QC value was unacceptable for Parasitology testing for one (1) of nine (9) months reviewed. Findings. 1. Observation by surveyor during the laboratory tour on March 26, 2025 at 9:46 am revealed the laboratory utilizes the BD Max instrument for Bacteriology (Chlaymydia trachomatis and Neisseria gonorrhea) and Parasitology (Trichomonas vaginalis) testing. 2. Review of the laboratory's "Molecular Quality Control" policy revealed "The laboratory technician will review the QC and evaluate and correct and QC result that are not within acceptable range {sic}. The technician is to document all corrective action taken in the log book. QC results are acceptable if: Qc Positive is Positive, Qc Negative is Negative and No UNR, IND or INC error flags." 3. Review of the QC and QA records for September 2024 revealed the following unacceptable QC result without documentation of

	corrective actions: September 4, 2024 Positive Control: Trichomonas vaginalis (TV) documented as Negative. 4. Review of the patient test log revealed nine (9) patients were tested after the unacceptable control without documentation of corrective actions.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of the laboratory's policies, records, and interview with personnel, the laboratory's quality assessment monitors failed to identify and correct quality issues in the analytic systems. Findings: 1. Review of the laboratory's "Quality Assurance" policy rvealed the facility "Controls and regulates multiple aspects, including pre-analytical, analytical and post-analytical, of the laboratory to assure that the quality of the test results are accurate and meets federal and state guidelines. A monthly review of particular quality assurance measures will be performed and documented by the laboratory supervisor. Documentation of the steps, findings and corrective action that occured from the monthly quality assurance plan will be stated and documentd in the quality assurance log." 2. Review of the laboratory's "Molecular Testing Monthly QC Review Signature" sheets for July 2024 through February 2025 revealed the Technical Consultant signed and dated her review each month; however, the following quality issues were not identified: a) The laboratory failed to follow the manufacturer's instructions for unacceptable patient results for Bacteriology and Parasitology testing for three (3) of three (3) patients reviewed. Refer to D5411. b) The laboratory failed to monitor the room temperature of one (1) of one (1) storage closets where laboratory supplies were stored. Refer to D5413. c) The laboratory failed to test external controls every thirty days as defined in their laboratory policy for four (4) of nine (9) months reviewed. Refer to D5441. d) The laboratory failed to perform corrective actions when the QC value was unacceptable for Parasitology testing for one (1) of nine (9) months reviewed. Refer to D5783.
D5805	TEST REPORT CFR(s): 493.1291(c) (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 review of patient final test reports, test menu, and interview with personnel, the laboratory failed to ensure the patient final test reports for Bacteriology and Parasitology testing included the name and address of the laboratory where testing was performed for one (1) of one (1) patient reviewed. Findings: 1. Review of a patient final test report for Patient HF73700809 from July 31, 2024 revealed the name and address of the laboratory where testing was performed was not included. 2. In interview on March 26, 2025 at 11:38 am, the Nurse stated if a patient requested a final report the instrument printout with the patient's result would be provided. The Nurse confirmed the laboratory's name and address are not included on the patient final reports. 3. Review of the laboratory's test menu revealed the laboratory performs 3,628 Bacteriology and 1,814 Parasitology tests annually.
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 observation by surveyor, 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 the laboratory personnel performed test methods as required. Refer to D6014. 2. The Laboratory Director failed to ensure proficiency testing samples are tested as required. Refer to D6016. 3. The Laboratory Director failed to ensure the quality control and assessment programs were maintained to assure the quality of laboratory testing. Refer to D6020. 4. The Laboratory Director failed to ensure patient final reports included required pertinent information. Refer to D6026. 5. The Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D6030.
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 record review and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to follow the manufacturer's instructions for unacceptable patient results for Bacteriology and Parasitology testing for three (3) of three (3) patients reviewed. Refer to D5411. 2. The laboratory failed to monitor the room temperature of one (1) of one (1) storage closets where laboratory supplies were stored. Refer to D5413.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this

	part; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure proficiency testing samples are tested as required. Findings: 1. The laboratory failed to ensure that proficiency tests for Bacteriology and Parasitology were performed by personnel who routinely perform laboratory testing for four (4) of six (6) events reviewed. Refer to D2007. 2. The laboratory failed to maintain the attestation statements for two (2) of six (6) testing events reviewed. Refer to D2014.
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 observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure the quality control and assessment programs were maintained to assure the quality of laboratory testing. Findings: 1. The laboratory failed to test external controls every thirty days as defined in their laboratory policy for four (4) of nine (9) months reviewed. Refer to D5441.
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) (e)(8) Ensure that reports of test results include pertinent information required for interpretation; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure patient final reports included required pertinent information. Refer to D5805.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) (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 for assessing personnel competency were maintained. Refer to D5209.

D6033	TECHNICAL CONSULTANT-MODERATE COMPLEXITY 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 observation by surveyor, record review, and interview with personnel, the Technical Consultant failed to provide technical oversight of the laboratory for moderate complexity testing. Findings: 1. The Technical Consultant failed to provide technical and scientific oversight to the laboratory. Refer to D6036. 2. The Technical Consultant failed to ensure the quality control program was maintained to assure the quality of laboratory testing. Refer to D6042. 3. The Technical Consultants failed to ensure corrective actions were documented when deviations from the laboratory's policies occurred. Refer to D6043. 4. The Technical Consultant failed to perform complete competency assessment procedures for one (1) of one (1) testing personnel reviewed for 2023 and 2024. Refer to D6046.
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 by surveyor, 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 follow the manufacturer's instructions for unacceptable patient results for Bacteriology and Parasitology testing for three (3) of three (3) patients reviewed. Refer to D5411. 2. The laboratory failed to monitor the room temperature of one (1) of one (1) storage closets where laboratory supplies were stored. Refer to D5413.
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 by surveyor, record review, and interview with personnel, the Technical Consultant failed to ensure the quality control program was maintained to assure the quality of laboratory testing. D5441.

D6043	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(5) (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratorys established performance specifications; This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Technical Consultant failed to ensure corrective actions were documented when deviations from the laboratory's policies occurred. Refer to D5783.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to-- This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, competency assessment records, and interview with personnel, the Technical Consultant failed to perform complete competency assessment procedures for one (1) of one (1) testing personnel reviewed for 2023 and 2024. Refer to D5209.