Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0239261	02/23/2021
Name of Provider or Supplier	**Street Address, City, State**	
Central Carolina Ob-Gyn	3200 Northline Ave Suite 130, Greensboro, NC	

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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(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 2019 and 2020 CAP (College of American Pathologists) proficiency testing records, review of patient logs, and interview with TP (testing personnel) #1 on 2/23/21, the laboratory failed to ensure that proficiency testing samples for 1 of 1 event in 2019 and 1 of 1 event in 2020 were tested with the laboratory's routine patient workload by personnel who normally perform patient testing. Findings: 1. Review of proficiency testing records for the 2019 CAP HC7-C test event and the 2020 CAP HC7-C test event revealed that 5 of 5 samples for both events were tested by TP #1. The laboratory has 9 TP who perform patient GeneXpert testing for Chlamydia trachomatis and Neisseria gonorrhea. During interview 2/23/21 at approximately 1:20 p.m., TP #1 confirmed that she tested 5 of 5 proficiency samples for both events (2019 CAP HC7-C, 2020 CAP HC7-C). 2. Review of 2019 and 2020 patient logs revealed that proficiency samples were not recorded on the GeneXpert patient logs in the same manner as patients are recorded.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.

	This STANDARD is not met as evidenced by: Based on review of 2019 and 2020 CAP (College of American Pathologists) proficiency testing records and interview with TP (testing personnel) #1 on 2/23/21, the laboratory director and TP failed to sign the attestation statement to attest to integration of proficiency samples into the laboratory's routine patient workload for 1 of 1 event in 2019 and 1 of 1 event in 2020. Findings: 1. Review of records for the 2019 CAP HC7-C test event revealed the attestation statement was not signed by the laboratory director to attest to integration of the proficiency samples into the laboratory's routine patient workload. 2. Review of records for the 2020 CAP HC7-C test event revealed the attestation statement was not signed by the laboratory director or the TP to attest to integration of the proficiency samples into the laboratory's routine patient workload. During interview 2/23/21 at approximately 1:20 p.m., TP #1 confirmed that the attestation statements had not been signed.
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 and procedures, review of the CMS (Centers for Medicare and Medicaid Services) 209 personnel form, the absence of records, the deficiency cited at D6004, and interview with TP (testing personnel) #1 2 /23/21, the laboratory failed to ensure their competency evaluation policy was followed. Findings: Review of the laboratory's "QUALITY ASSESSMENT" policy revealed "... 5. Personnel Competency ... At least annually, the laboratory director and /or technical consultant will review the performance of each employee working in the laboratory to assure employee competency. ..." 1. Review of the CMS-209 personnel form completed for the survey revealed the laboratory has 7 providers who perform vaginal wet preps and fern tests. There was no documentation of competency evaluation available for 7 of 7 providers. During interview 2/23/21 at approximately 2: 00 p.m., TP #1 stated they were not aware the providers were required to have competency evaluations performed by the laboratory director. 2. Review of personnel records revealed the laboratory director evaluated the competency of TP #1 and TP #1 evaluated the competency of the other 8 TP (TP #2, #3, #4, #5, #6, #7, #8, #9). See the deficiency cited at D6004.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of 2019, 2020, and 2021 CAP (College of American Pathologists) proficiency testing records, the absence of verification records, and interview with TP (testing personnel) #1 2/23/21, the laboratory failed to enroll in proficiency testing or establish a system to verify the accuracy of the wet/KOH (potassium hydroxide) preps and fern tests at least twice a

	year. Review of the laboratory's "QUALITY ASSESSMENT" procedure revealed "... 6. Proficiency Testing This laboratory will enroll in formal proficiency testing appropriate to the test menu ..." Review of 2019, 2020, and 2021 CAP proficiency testing records revealed the laboratory was not enrolled in proficiency testing for wet /KOH preps and fern tests in 2019, 2020, or 2021. There were also no records available to indicate that the laboratory performed any activity to verify the accuracy of the wet/KOH preps and fern tests in 2019, 2020, or 2021. During interview 2/23/21 at approximately 10:30 a.m., TP #1 confirmed that the laboratory was not enrolled in proficiency testing and had not performed any activity to verify the accuracy of the wet/KOH preps and fern tests in 2019, 2020, or 2021. She stated they were unaware it was required.
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's policies and procedures and interview with TP (testing personnel) #1 2/23/21, the laboratory's procedure manual was not complete and current for the testing performed. Findings: 1. The laboratory's procedure manual did not include a written, step-by-step procedure for the performance of the fern test. 2. The laboratory's "WEP Prep" procedure did not include: a. labeling instructions for the slide; b. instructions for performing the "whiff test" and reporting the results; c. instructions for reporting each element (epithelial cells, white blood cells, red blood cells, clue cells, bacteria, yeast, trichomonas). During interview at approximately 12: 20 p.m., TP #1 stated she wrote the wet prep procedure when she realized they didn't have one.
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 review of the Cepheid GeneXpert Operator's Manual and review of 2019, 2020, and 2021 Cepheid GeneXpert maintenance logs 2/23/21, the laboratory failed to follow manufacturer's instructions for monthly maintenance performed on the Cepheid GeneXpert instrument for 8 of 12 months in 2020. Findings: Review of the Cepheid GeneXpert Operator's Manual revealed the following monthly maintenance is specified for the Cepheid GeneXpert: Archive tests Purge tests Replace fan filters Review of 2020 GeneXpert maintenance logs revealed: a. The laboratory failed to perform any of the required monthly maintenance tasks 2 of 12 months (January, August); b. The laboratory failed to perform purge tests 3 of 12 months (February, March, April); c. The laboratory failed to replace fan filters 5 of 12 months (March, April, May, July, October).
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: Based on review of IQCP (Individualized Quality Control Plan) records, review of the laboratory's policies and procedures, and interview with TP (testing personnel) #1 2/23/21, the laboratory's IQCP for the Cepheid GeneXpert test system did not include all required elements. Findings: Review of the laboratory's IQCP records revealed a coversheet which stated "Internal Quality Control will be performed daily for 10 days after Verification Panel has been completed. Quality Control will be performed with each new reagent lot change. All results will be documented in the Quality Control section of the procedure manual and verified. Any failed Quality Control prevents running live patient samples until the issue has been identified and properly corrected with supportive documentation." The coversheet stated that the IQCP start date was 10/10/18 and the IQCP completion date was 10/23/18. TP #1 signed the "Resulted by" area of the coversheet. Review of the laboratory's IQCP records revealed the laboratory tested positive and negative control samples each day from 10/10/18-10/23/18, but there was no documentation available to indicate whether the results were acceptable. The coversheet was signed by the laboratory director 10/23/18. 1. The IQCP did not include a Risk Assessment. 2. The IQCP's Quality Control Plan was incomplete and did not include the number and type of quality control material used. 3. The IQCP did not include a Quality Assessment Plan for monitoring the testing performed on the GeneXpert. The laboratory's "QUALITY ASSESSMENT" plan states "... 11. Quality Control For each test system used, we follow the manufacturer's instructions, including the CLIA regulations (or other regulatory agency regulations, whichever are stricter), to ensure accuracy and precision for our test results. Our quality control system is designed to help us detect errors due to the test system, environmental conditions or operator error. ..." During interview at approximately 2:10 p.m., TP #1 stated they did not have any other IQCP records.

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 review of a random patient test report (#1989200) and interview with TP (testing personnel) #1 on 2/23/21, the laboratory failed to ensure that patient Chlamydia trachomatis/Neisseria gonorrhea test reports included the address of the laboratory. Review of a random patient test report (#1989200) from the Cepheid GeneXpert revealed the test report included the laboratory's name, but did not include the laboratory's address. During interview 2/23/21 at approximately 1:35 p.m., TP #1 confirmed that the laboratory's address was not included on the test report.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of personnel records, and interview with TP (testing personnel) #1 on 2/23/21, the laboratory director failed to ensure 8 of 9 testing personnel competency evaluations were performed by personnel who met the qualifications to serve as technical consultant. Findings: Review of the laboratory's "QUALITY ASSESSMENT" policy revealed "... 5. Personnel Competency ... At least annually, the laboratory director and/or technical consultant will review the performance of each employee working in the laboratory to assure employee competency. ..." Review of personnel records revealed the laboratory director evaluated the competency of TP #1 and TP #1 evaluated the competency of the other 8 TP (TP #2, #3, #4, #5, #6, #7, #8, #9). Review of personnel records revealed TP #1 has an Associate in Applied Science degree in Medical Assisting and does not meet the qualification requirements to serve as technical consultant in a moderate complexity laboratory. During interview 2/23/21 at approximately 11:20 a. m., TP #1 confirmed that the laboratory director evaluated her competency and she performed the competency evaluations for the other testing personnel.

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 review of the laboratory's policies and procedures and review of method verification records 2/23/21, the laboratory director failed to ensure verification procedures performed were adequate to determine the accuracy and precision of the GeneXpert system. Findings: Review of the laboratory's "QUALITY ASSESSMENT" policy revealed "... 10. Test Systems ... For new test systems, we will verify performance specifications, such as accuracy, precision, sensitivity, specificity, and reference intervals. ..." Review of the laboratory's procedure manual revealed the "METHOD VERIFICATION" section in the manual included: a. test reports for 4 CT (Chlamydia trachomatis) positive samples tested by 4 different TP 10/8/18; b. test reports for 6 NG (Neisseria gonorrhea) positive samples, 5 CT positive samples, and 2 negative samples tested by 2 different TP 10/9/18. There was no summary of the validation process, including whether the results were acceptable. There was also no documentation that the results were reviewed and approved by the laboratory director prior to patient testing.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of 2019 and 2020 CAP (College of American Pathologists) proficiency testing enrollment order confirmations, and interview with TP (testing personnel) #1 2/23/21, the laboratory director failed to ensure the laboratory enrolled in proficiency testing as required. Findings: Review of the laboratory's "QUALITY ASSESSMENT" policy revealed "... 6. Proficiency Testing This laboratory will enroll in formal proficiency testing appropriate to the test menu ..." Review of 2019 and 2020 CAP enrollment order confirmations revealed: 1. The laboratory failed to enroll in time to receive the first two proficiency testing events of 2019. The transaction date on the invoice was 8/21 /19, and the laboratory received only the third test event (Event C). 2. The laboratory failed to enroll in time to receive the first two proficiency testing events of 2020. The transaction date on the invoice was 10/6/20, and the laboratory received only the third test event (Event C). During interview 2/23/21 at approximately 10:15 a.m., TP #1

	stated she thought they would send proficiency samples automatically twice a year. She stated she did not realize they had to enroll each year.
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 2/23/21 and the deficiency cited at D6065, the laboratory failed to verify that 6 of 9 testing personnel (TP #3, #4, #5, #6, #8, #9) met the minimum education requirements for performing 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 have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(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 testing personnel (TP) #1 on 2/23/21, the laboratory failed to verify that 6 of 9 testing personnel (TP #3, #4, #5, #6, #8, #9) met the minimum education requirements for performing moderate complexity testing. Findings: 1. Review of personnel records for TP #3 revealed an Associate of Applied Science degree in Medical Assisting and certification as a CMA (Certified Medical Assistant). There were no other education credentials available for review. 2. Review of personnel records for TP #4 revealed an Associate of Applied Science degree in Medical Assisting and certification as a CMA. There were no other education credentials available for review. 3. Review of personnel records for TP #5 revealed an Associate in Science degree in General Studies. There were no other education credentials available for review. 4. Review of personnel records for TP #6 revealed certification by the National Association for Health Professionals. There were no other credentials available for review. 5. Review of personnel records for TP #8 revealed there were no education credentials available for review. 6. Review of personnel records for TP #9 revealed there were no education credentials available for review. During the exit interview 2/23/21 at approximately 2:15 p.m., TP #1 confirmed that there were no other records available for review.