

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0239261	(X3) Date Survey Completed 06/20/2024
Name of Provider or Supplier Central Carolina Ob-Gyn	Street Address, City, State 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
D0000	<p>A routine recertification survey was conducted 06/20/24. Based on the survey findings, Immediate Jeopardy was identified and the laboratory was notified 06/20/24 at approximately 2:30 p.m. The following condition level deficiencies were identified during the survey. D2000 - 493.801 Enrollment and testing of samples D5400 - 493.1250 Analytic Systems D6000 - 493.1403 Laboratories performing moderate complexity testing; laboratory director On 06/20/24, the laboratory ceased testing on the GeneXpert Dx analyzer; therefore, Immediate Jeopardy was removed.</p>
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation, manufacturers' instructions and interview with testing personnel (TP) #1, 06/20/24, the laboratory failed to ensure the OSOM BV (bacterial vaginosis) Blue Test test vessels and the OSOM Trichomonas Rapid Test sample buffer had not exceeded their expiration dates. Findings: At approximately 10:30 a.m. surveyor observed on the laboratory counter the following testing vessels and reagents that had expired and were available for use: 1. OSOM BV Blue Test - Lot #23CC02 - 27 test vessels - expiration 02/29/24. 2. OSOM Trichomonas Rapid Test - 2 bottles of trichomonas sample buffer - Lot # 221453 - expiration 05/31/24 and 1 bottle of trichomonas sample buffer - Lot #221311 - expiration 02/29/24. Review of package insert for OSOM BV Blue Test revealed "WARNINGS AND PRECAUTIONS....Do not use after the expiration date printed on the kit.". Review of package insert for OSOM Trichomonas Rapid Test revealed "WARNINGS AND PRECAUTIONS....Do not use after the expiration date printed on the kit.". Interview with TP #1 at approximately 10:30 a.m. confirmed the test vessels and bottles of buffer had</p>

exceeded their expiration dates. She stated they just use the testing as a back up, and they have not been used recently. The test kits, vessels and bottles of buffer were disposed of at time of survey.

D2000

ENROLLMENT AND TESTING OF SAMPLES
CFR(s): 493.801

Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.

This CONDITION is not met as evidenced by:
Based on review of laboratory policy, absence of 2023 and 2024 proficiency testing (PT) records, review of CMS (Centers for Medicare & Medicaid Services) Form 116, and interview with practice manager 06/20/24, the laboratory failed to enroll in PT for the subspecialty of bacteriology for the Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (NG) testing since 2022, a period of approximately 18 months. Approximately 1,944 tests are performed each year. Findings: Review of laboratory policy "Quality Assessment" revealed "6. Proficiency Testing...This laboratory will enroll in formal proficiency testing appropriate to the test menu...". Review of laboratory records revealed no documentation of enrollment or participation in PT for 2023 and 2024 for the CT and NG bacteriology testing performed. Review of CMS Form 116 revealed the laboratory performs approximately 1,944 CT and NG bacteriology tests per year. Interview with practice manager at approximately 11:00 a. m. confirmed the laboratory had not enrolled in a PT program for the CT and NG testing for 2023 and 2024. They stated they were not aware of the requirement to enroll in PT.

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 laboratory policy, review of 2022 College of American Pathologists (CAP) PT records and lack of documentation 06/20/24, the laboratory failed to verify the accuracy of the Amniotic Fluid Crystallization Test (FERN) and Potassium Hydroxide (KOH)/Wet Prep testing twice annually since October of 2022, a period of approximately 20 months. Review of laboratory policy "Quality Assessment" revealed "6. Proficiency Testing...This laboratory will enroll in formal proficiency testing appropriate to the test menu...". Review of CAP PT records revealed no documentation of enrollment in PT for the FERN and KOH/Wet Prep testing in 2023 or 2024. There were also no records available to indicate that the

laboratory performed any activity to verify the accuracy of the FERN and KOH/Wet Prep testing since the last CAP PT event in October of 2022. This deficiency was previously cited 02/23/21.

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 review of Form CMS-116, review of laboratory policy, review of laboratory procedure manual, review of form CMS-116 processed 05/24/23, review of manufacturer's storage temperatures and specifications, review of 2022, 2023 and 2024 temperature and humidity charts, surveyor observation, interview with TP #1, review of GeneXpert Dx operator's manual, review of 2023 and 2024 maintenance logs, review of 2023 and 2024 quality control (QC) records, and review of Individualized Quality Control Plan (IQCP) 6/20/24, the laboratory failed to monitor and evaluate the overall quality of the analytic system, identify problems and implement corrections. Findings: 1. The laboratory procedure manual failed to include a procedure for FERN testing and a procedure or system used for entering test results in the patient record (see D5403). 2. The current laboratory director failed to sign and date their approval of the laboratory procedure manual (see D5407). 3. The laboratory failed to document refrigerator temperature, room temperature and humidity each day of patient testing (see D5413). 4. The laboratory failed to ensure control reagents that exceeded their expiration date were not available for use (see D5417). 5. The laboratory failed to perform and document all monthly and quarterly maintenance as required on the GeneXpert Dx analyzer (see D5429). 6. The laboratory failed to perform QC each day of patient testing on the GeneXpert Dx analyzer (see D5449).

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 CMS-116, review of laboratory policy and review of laboratory procedure manual 06/20/24, the procedure manual failed to include a procedure for the Amniotic Fluid Crystallization Test (FERN) and also failed to include a procedure for entering test results in the patient record. 1. The laboratory procedure manual failed to include a procedure for FERN testing. Findings: Review of CMS-116, submitted at time of survey revealed the laboratory performs FERN testing. Review of laboratory policy "Quality Assessment" revealed "9. Procedure Manual...The laboratory maintains a procedure manual that includes all tests performed.". Review of laboratory procedure manual revealed no procedure for FERN testing. This deficiency was previously cited 02/23/21. 2. The laboratory procedure manual failed to include a procedure or system used for entering test results in the patient record. Findings: Review of laboratory policy "Quality Assessment" revealed "9. Procedure Manual...The Procedure Manual addresses site-specific information not included in the manufacturer's instructions, such as...how test results are reported...". Review of laboratory procedure manual revealed no procedure for entering test results in the patient record.

D5407

PROCEDURE MANUAL
CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:

Based on review of form CMS-116 processed 05/24/23, review of laboratory policy and review of laboratory procedure manual 06/20/24, the current laboratory director failed to sign and date their approval of the laboratory procedure manual. Findings: Review of CMS-116 submitted for change in laboratory director revealed the current laboratory director signed the CMS-116 on 05/04/23. The application was processed and the change made on 05/24/23. Review of laboratory policy "Quality Assessment" revealed "9. Procedure Manual...The current laboratory director will review and approve the manual and any subsequent additions or revisions.". Review of procedure manual revealed no documentation of the current laboratory directors' review and approval of the laboratory procedure manual.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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 review of laboratory policy, review of manufacturer's storage temperatures and specifications and review of 2022, 2023 and 2024 temperature and humidity charts 06/20/24, the laboratory failed to document refrigerator temperature, room temperature and humidity each day of patient testing, approximately 272 days of 641 days reviewed. Findings: Review of laboratory policy, "Quality Assessment" revealed "10. Test Systems...We will ensure that our testing environment (temperature, humidity, water quality) meets the manufacturer's specifications...". Review of manufacturer's instructions for storage temperatures and operating specifications revealed the following: ZeptoMetrix External controls for CT/NG testing require storage at 2-8 degrees Celsius. Expert CT/NG cassettes require storage at 2-28 degrees Celsius. GeneExpert Dx analyzer requires an operating temperature of 15-30 degrees Celsius and a humidity range of 10-95 percent. Review of 2022, 2023 and 2024 temperature and humidity charts revealed the following number of days in which refrigerator temperatures, room temperatures and humidity were not documented. 1. 2022 - January - 6 of 20 days, February - 9 of 20 days, March - 12 of 24 days, April - 7 of 21 days, May - 14 of 22 days, June - 16 of 20 days, July - 14 of 20 days, August - 10 of 23 days, September - 12 of 22 days, October - 13 of 21 days, November - 9 of 21 days, and December - 9 of 22 days. 2. 2023 - January - 12 of 22 days, February - 8 of 20 days, March - 14 of 23 days, April - 4 of 20 days, May - 2 of 23 days, June - 3 of 22 days, July - 6 of 22 days, August - 6 of 24 days, September - 10 of 21 days, October - 13 of 22 days, November - 14 of 22 days, and December - 5 of 20 days. 3. 2024 - January - 13 of 23 days, February - 4 of 21 days, March - 10 of 22 days, April - 11 of 22 days, May - 6 of 23 days and June - 0 of 19 days.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
 CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:
 Based on surveyor observation and interview with TP #1 06/20/24, the laboratory failed to ensure control reagents that exceeded their expiration date were not available for use. Findings: At approximately 10:40 a.m. the surveyor observed in the laboratory refrigerator the following vials of control reagent available for use: 1. 5 vials of ZeptoMetrix NATtrol Chlamydia trachomatis (CT) Positive Control, Lot # 331327, expiration date 06/05/24. 2. 2 vials of ZeptoMetrix NATtrol Neisseria gonorrhoeae (NG) Positive Control, Lot # 330831, expiration date 02/16/24. 3. 1 vial of ZeptoMetrix NATtrol CT/NG Negative Control, Lot # 331331, expiration date 06/05/24. Interview with TP #1 at approximately 10:40 a.m. confirmed the control reagents had exceeded their expiration date. She stated they had just received new controls recently. Surveyor also observed that the new lot of controls received recently had not been opened and put into use as of date of survey, 06/20/24. The expired reagents were disposed of at time of survey.

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 operator's manual and review of 2023 and 2024 maintenance logs 06/20/24, the laboratory failed to perform and document all monthly and quarterly maintenance as required on the GeneXpert Dx analyzer since testing began in August of 2023, a period of approximately 10 months. Findings: The laboratory began testing on the GeneXpert Dx analyzer August 16, 2023. Review of operators manual for the GeneXpert Dx analyzer section 9.1 "Maintenance Tasks...Table 9-1. Maintenance Tasks and Frequency" revealed the following maintenance tasks and their frequency; a. Clean work area - Daily b. Close all module doors - Daily c. Discard used cartridges - Daily d. Power down the GeneXpert instrument - Weekly e. Power down the GeneXpert computer - Weekly f. Clean Fan PreFilters - Weekly g. Archive tests - Monthly h. Purge tests - Monthly i. Clean plunger rod and cartridge bay - Quarterly j. Clean instrument surfaces - Quarterly k. Replace fan filters - Quarterly l. Perform annual instrument maintenance - Annually Review of 2023 and 2024 maintenance logs revealed the monthly task "Archive tests" was completed 2 of 10 months since installation, November of 2023 and January of 2024. There was no documentation of the monthly task "Purge tests" since testing began in August of 2023. Review of 2023 and 2024 maintenance logs revealed the quarterly tasks of "Clean plunger rod and cartridge bays" and "Clean instrument surfaces" was completed in November of 2023. There was no documentation of additional quarterly tasks since testing began in August of 2023. This deficiency was previously cited 02/23/21.

D5449

CONTROL PROCEDURES

CFR(s): 493.1256(d)(3)(ii)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of laboratory policy, review of 2023 and 2024 quality control (QC) records, review of Individualized Quality Control Plan (IQCP) and review of laboratory records 06/20/24, the laboratory failed to perform QC each day of patient testing on the GeneXpert Dx analyzer since testing began August 16, 2023, a period of approximately 10 months. Findings: Review of laboratory policy "Quality Assessment" revealed "11. Quality Control...for qualitative tests we run controls based on test kit lot change.". Review of 2023 and 2024 QC records for the GeneXpert Dx analyzer revealed the laboratory performed QC with each new lot number. Review of IQCP, signed in 2018 by previous laboratory director, revealed the IQCP was developed for the previous analyzer. Review of laboratory records revealed the laboratory had not developed an IQCP for the current analyzer.

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 review of laboratory policies and records, review of 2022 CAP PT records, lack of documentation, review of CMS 116, interviews with practice manager, review of laboratory quality assessment policy, review of quality assessment records, absence of quality assessment records, review of CMS-209, review of 2021 TP competency records, and lack of competency records 06/20/24, the laboratory director failed to provide overall management and direction of the laboratory. Findings: 1. The laboratory director failed to ensure a twice annual verification of accuracy of the FERN and KOH/Wet Prep testing was performed (see D6013). 2. The laboratory director failed to ensure the laboratory was enrolled in PT for the CT and NG testing performed (see D6015). 3. The laboratory director failed to ensure the establishment and maintenance of an effective quality assessment program to identify and correct problems and prevent their recurrence (see D6021). 4. The laboratory director failed to ensure 3 of 3 testing personnel had received training for the new GeneXpert Dx analyzer (see D6029). 5. The laboratory director failed to specify in writing what testing each individual is authorized to perform (see D6032). 6. The laboratory director failed to perform competency assessments on 9 of 9 testing personnel (see D6046).

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 laboratory policy, review of 2022 CAP PT records and lack of documentation 06/20/24, the laboratory director failed to ensure a twice annual verification of accuracy of the FERN and KOH/Wet Prep testing was performed. Findings: See D5217.

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 laboratory policy, absence of 2023 and 2024 PT , review of CMS

116, and interview with practice manager 06/20/24, the laboratory director failed to ensure the laboratory was enrolled in PT for the CT and NG testing performed. Findings: See D2000.

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 review of laboratory quality assessment policy, quality assessment records, and absence of quality assessment records 06/20/24 and deficiencies cited at D6013, D6015, D6029, D6032 and D6046, the laboratory director failed to ensure the establishment and maintenance of an effective quality assessment program to identify and correct problems and prevent their recurrence. Findings: Review of laboratory quality assessment policy "Quality Assessment" revealed "This laboratory of "name of facility" has established quality systems for all general laboratory systems and for all phases of the total testing process, including pre-analytic, analytic, and post analytic phases. We will ensure continuous improvement of our performance through ongoing monitoring of each system....". The policy fails to state what specific pre-analytic, analytic and post analytic assessments (monitoring) will be performed and at what frequency to identify potential problems, correct them and prevent their recurrence. Review of laboratory quality assessments records revealed the last quality assessment "SEMI-ANNUAL QA CHECKLIST" was performed March 30, 2022. There was no documentation of any quality assessments performed since March 30, 2022, a period of approximately 27 months in which pre-analytic, analytic and post analytic processes were not monitored and assessed.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(11)

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)(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 records, review of laboratory policy and lack of documentation 06/20/24, the laboratory director (LD) failed to ensure 3 of 3 testing personnel (TP) had received training for the new GeneXpert Dx analyzer. Findings: Review of laboratory records revealed the laboratory installed a new GeneXpert Dx analyzer and began testing August 16, 2023. Review of laboratory policy "Quality

Assessment" revealed "5. Personnel Competency...This laboratory will ensure that all testing personnel are properly trained and are competent prior to testing patient specimens." . Review of testing personnel training records for the GeneXpert Dx analyzer revealed no documentation of training for 3 of 3 TP; TP #1, TP #2, and TP #3.

D6032

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(14)

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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:
Based on review of laboratory records and interview with practice manager 06/20/24, the laboratory director (LD) failed to specify in writing what testing each individual is authorized to perform. Findings: Review of laboratory records revealed no documentation the LD had specified in writing what testing each individual is authorized to perform. Interview with practice manager at approximately 1:30 p.m. confirmed there were no records in which the LD specified what testing each individual is authorized to perform. They stated all they could find were the records that were brought into this room and if there were additional records they did not know where they would be.

D6046

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

(b) The technical consultant is responsible for-- (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.

This STANDARD is not met as evidenced by:
Based on review of CMS-209, review of 2021 TP competency records, lack of competency records and interview with practice manager 06/20/24, the technical consultant (laboratory director) failed to perform competency assessments on 9 of 9 TP since December of 2021, a period of approximately 30 months in which competency of testing personnel was not accessed. Findings: Review of CMS-209 submitted at time of survey revealed the laboratory director also serves as the technical consultant. Review of TP competency records revealed the last competency assessments were completed in December of 2021. There was no documentation of competency assessments performed for 9 of 9 TP in 2022, 2023 or 2024. Interview with practice manager at approximately 1:30 p.m. confirmed there was no documentation of TP competency assessments since December of 2021.