Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0242389	03/12/2026
Name of Provider or Supplier	**Street Address, City, State**	
Eastern Carolina Pediatrics	1702 Medical Park Drive, Wilson, 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	A validation survey was conducted March 12, 2026. The facility was found to be NOT in compliance with the following CLIA condition: 42 CFR 493.1250 Analytic Systems
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 direct observations, review of manufacturer's instructions, laboratory policies /procedures, laboratory quality control records, patient test records, and confirmed in interview, the laboratory failed to monitor and evaluate the overall quality of its analytic systems. Findings: 1. The laboratory failed to follow their own Indiviualized Quality Control Plan for the Cepheid GeneXpert Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (NG) testing for 11 of 12 months in 2025. Refer to D5445. 2. The laboratory failed to have documentation of acceptable quality control testing prior to reporting Cepheid GeneXpert CT/NG patient results for 11 of 12 months. Refer to D5481.
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, laboratory environmental records for 2025, and confirmed in interview with the Technical Consultants (TC), the laboratory failed to ensure manufacturer's room temperature and relative humidity specifications for 12 of 12 months. Findings: 1. During a tour of the laboratory on March 12, 2026, at 9:30 am the following was observed: a. One Cepheid GeneXpert (Serial Number 120000823) for Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (NG) testing. b. One Medonic Hematology analyzer (Serial Number 28829) for complete blood count testing. c. Two boxes Cepheid GeneXpert CT/NG test cartridges (Lot number 1001488610; Expiration date 06/13/2027). 2. The manufacturers' instructions stated: a. Cepheid GeneXpert: " ...A.3 Operational Environmental Parameters ...Operating Temperature: 15-30C ...Relative Humidity: 20%-80%, non-condensing ..." b. Medonic Hematology analyer: " ...Short List of Specifications ...Temperature 64-90F (18-32C) Humidity (noncondensing) Up to 80%..." c. Cepheid GeneXpert CT/NG test cartridges: " ...7 Storage and Handling Store the Xpert CT/NG cartridges and reagents at 2C - 28C until the expiration date provided on the label ..." 3. Review of the laboratory's 2025 environmental records titled "Temperatures" revealed the laboratory testing area's acceptable room temperature range of 20-32C. This upper limit of 32 C exceeded the manufacturer's specified upper limit for the GeneXpert (30C) and the GeneXpert CT/NG cartridges (28C). Further review of the laboratory's environmental records revealed an acceptable relative humidity range of 18-85%. This lower limit of 18% exceeded the manufacturer's specified lower limit for the GeneXpert (20%). This upper limit of 85% exceeded the manufacturer's specified upper limit for the GeneXpert (80%) and the Medonic analyzer (80%). 4. In an interview on March 12, 2026, at 12:06 pm, the laboratory's Technical Consultants confirmed the findings.
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 laboratory policy, laboratory's Individualized Quality Control Plan (IQCP), 2025 quality control (QC) records, patient records, and confirmed in interview with the Technical Consultant (TC), the laboratory failed to

	follow their own IQCP for the Cepheid GeneXpert Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (NG) testing for 11 of 12 months in 2025. Findings: 1. During a tour of the laboratory on March 12, 2026, at 9:30 am, one Cepheid GeneXpert (Serial Number 120000823) was observed in use for CT/NG testing. 2. The laboratory policy titled "Quality Control and Calibrations Procedure General Laboratory Policy" stated, "Policy: Quality control and calibrations are performed on a regular and routine basis in accordance with CLIA regulations. Purpose: Quality control is performed in this laboratory to provide an ongoing system for assessing the reliability and accuracy of instruments, systems and methods ..." 3. The laboratory's IQCP titled "Cepheid GeneXpert CT/NG" (Approved by the laboratory director 03/01/2024) stated " ...IQCP Policy 2 Levels of Controls are to be run ...Monthly on boxes that have been open more than 30 days ..." 4. Review of the laboratory's monthly quality control records for the Cepheid GeneXpert CT/NG testing revealed the laboratory failed to perform monthly QC for January 2025 through November 2025. 5. Review of patient records revealed the laboratory performed 81 CT/NG tests from 01/01/2025 through 11/30/2025. The following is a random sampling for patients tested 01/01 /2025 through 11/30/2025: Patient Identification: 602884; Date of testing: 09/08/2025 Patient Identification: 83978; Date of testing: 09/16/2025 Patient Identification: 20947; Date of testing: 09/16/2025 Patient Identification: 44031; Date of testing: 09/25 /2025 Patient Identification: 72023; Date of testing: 10/02/2025 Patient Identification: 602884; Date of testing: 10/14/2025 Patient Identification: 75665; Date of testing: 10 /14/2025 Patient Identification: 87905; Date of testing: 10/24/2025 Patient Identification: 19763; Date of testing: 10/28/2025 6. In an interview on March 12, 2026 at 10:59 am, TC-2 was asked to provide documentation of monthly testing for the Cepheid GeneXpert CT/NG testing per the laboratory's IQCP. No documentation was provided. This confirmed the findings.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, laboratory policy, laboratory's Individualized Quality Control Plan (IQCP), 2025 quality control (QC) records, patient records and confirmed in an interview with the TC, the laboratory failed to have documentation of acceptable quality control testing prior to reporting Cepheid GeneXpert CT/NG patient results for 11 of 12 months. Findings: 1. The manufacturer's instructions for the Cepheid GeneXpert CT/NG testing (301-0234, Revision L, June 2023) stated " ...13.2 External Controls External Controls ...are available but not provided and may be used in accordance with local, state, and federal accrediting organizations, as applicable ..." 2. The laboratory policy titled "Quality Control and Calibrations Procedure General Laboratory Policy" stated, "Policy: Quality control and calibrations are performed on a regular and routine basis in accordance with CLIA regulations. Purpose: Quality control is performed in this laboratory to provide an ongoing system for assessing the reliability and accuracy of instruments, systems and methods ..." 3. The laboratory's IQCP titled "Cepheid GeneXpert CT/NG" (Approved by the laboratory director 03/01/2024) stated " ... IQCP Policy 2 Levels of Controls are to be run ...Monthly on boxes that have been open more than 30 days ..." 4. Review of patient records revealed the laboratory

	performed and resulted 81 CT/NG tests from 01/01/2025 through 11/30/2025 without acceptable quality control testing. Refer to D5445 for a random sampling of patients resulted without quality control. 5. In an interview on March 12, 2026 at 10:59 am, TC-2 confirmed the findings.