Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D1070727	01/09/2025
Name of Provider or Supplier	**Street Address, City, State**	
Raleigh Children & Adolescents Medicine	10208 Cerny Street, Raleigh, 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**
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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 laboratory procedure manual, review of quality control (QC) reagent package insert, review of operators manuals, review of Individual Quality Control Plan (IQCP), and interview with technical consultant (TC) #1, 01/09/25, the laboratory procedure manual failed to include QC procedures for the Neonatal Bilirubin (NBil) testing performed on the Reichert Unistat Bilirubinometer and the Chlamydia (CT) and Neisseria Gonorrhea (NG) testing performed on the Cepheid GeneXpert that included the type and levels of QC, the frequency of QC, the criteria

used to determine if QC is acceptable and what corrective actions to take if QC is unacceptable. 1. The laboratory procedure manual failed to include a QC procedure for the NBil testing performed on the Reichert Unistat Bilirubinometer that included the type and levels of QC, the frequency of QC, the criteria used to determine if QC is acceptable and what corrective actions to take if QC is unacceptable. Findings: Review of laboratory procedure manual revealed a policy "Quality Control and Calibrations Procedure...General Laboratory Policy" which states "...All quality control materials utilized are recommended by the instrument, system and method manufacturer's and/or have established assay values for the methods being performed. Patient results are acceptable if their results have been established during a run when manufacture controls of known values have been acceptable...Performance and Frequency...All control procedures are to be performed according to manufacturer's instructions for the instruments, methods and controls. Each separate procedure details exactly when controls need to be run...For moderate complexity testing, controls will be run each day that patient testing is performed...after most performed maintenance and always after any major maintenance...after any calibration...as dictated by CLIA guidelines...". The procedure fails to state the type and levels of QC used, fails to define the correct frequency as established by the laboratories IQCP, fails to define the criteria of QC acceptability and fails to include the corrective actions to take if QC is determined unacceptable. Review of package insert for "BIO-RAD Liquichek Pediatric Control Levels 1 and 2 revealed the package insert fails to state the frequency of QC, fails to define the criteria of QC acceptability and fails to include the corrective actions to take if QC is determined unacceptable. Review of operator's manual for the Unistat revealed "7.0 Quality Control...7.1...Analysis of at least a normal and abnormal level of commercial serum control, assayed for total bilirubin, is recommended for checking performance of the Reichert Unistat Bilirubinometer...7.2 Quality control procedures should be performed before and after each sample run in response to questionable patient results and/or as mandated by local regulations.". The operator's manual fails to include the type of QC used by the laboratory, fails to define the correct frequency as established by the laboratory's IQCP, fails to define the criteria of QC acceptability and fails to include the correction actions to take if QC is determined unacceptable. Interview with TC #1 at approximately 1:00 p.m. confirmed the laboratory failed to have a QC procedure for the NBil testing performed on the Reichert Unistat Bilirubinometer that included the type and levels of QC, the frequency of QC, the criteria used to determine if QC is acceptable and what corrective actions to take if QC is unacceptable. 2. The the laboratory procedure manual failed to include a QC procedure for the CT and NG testing performed on the Cepheid GeneXpert that included the type and levels of QC, the frequency of QC, the criteria used to determine if QC is acceptable and what corrective actions to take if QC is unacceptable. Findings: Review of laboratory procedure manual reveal a policy "Quality Control and Calibrations Procedure...General Laboratory Policy" which states "...All quality control materials utilized are recommended by the instrument, system and method manufacturer's and/or have established assay values for the methods being performed. Patient results are acceptable if their results have been established during a run when manufacture controls of known values have been acceptable...Performance and Frequency...All control procedures are to be performed according to manufacturer's instructions for the instruments, methods and controls. Each separate procedure details exactly when controls need to be run...For moderate complexity testing, controls will be run each day that patient testing is performed... after most performed maintenance and always after any major maintenance...after any calibration...as dictated by CLIA guidelines...". The procedure fails to state the type and levels of QC used, fails to define the correct frequency as established by the laboratories Individual Quality Control Plan (IQCP), fails to define the criteria of QC

	acceptability and fails to include the corrective actions to take if QC is determined unacceptable. Review of operator's manual for the Cepheid GeneXpert revealed "6.3 External Quality Controls...External controls may be used in accordance with local, state, or federal accrediting organizations, as applicable.". The operator's manual fails to include the type of QC used by the laboratory, fails to define the correct frequency as established by the laboratory's IQCP, fails to define the criteria of QC acceptability and fails to include the correction actions to take if QC is determined unacceptable. Review of IQCP for the for the CT and NG testing performed on the Cepheid GeneXpert revealed the title of the "IQCP Risk assessment/QC Plan/QA Review" as System...Cepheid GeneXpert...Test...CT/NG...IQCP Policy...2 Levels of Controls are to be run when: *Each time a new lot of Xpert Xpress SARS-CoV 2 is received. *Each time a new shipment of Xpert Xpress SARS-CoV2 is received even if it is the same lot previously received...". The IQCP plan fails to state the type and levels of QC used, fails to define the correct test system (CT/NG) for the IQCP, fails to define the criteria of QC acceptability and fails to include the corrective actions to take if QC is determined unacceptable. Interview with TC #1 at approximately 1:00 p.m. confirmed the procedure manual failed to include a QC procedure for the CT and NG testing performed on the Cepheid GeneXpert that included the type and levels of QC, the frequency of QC, the criteria used to determine if QC is acceptable and what corrective actions to take if QC is unacceptable. The TC also confirmed the IQCP policy present at time of survey did not have the correct test system. They stated the policy is the same and it was just a typo in regards to the test system used.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (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, review of 2024 quality control (QC) records and testing personnel (TP) #1 interview 01/09/25, the laboratory failed to ensure expired reagents were not available for use. Findings: During laboratory tour at approximately 2:00 p.m. surveyor observed on the top shelf of laboratory refrigerator one box of quality control (QC) reagent, Zepto Matrix, NATtrol CT/NG Panel Lot # 332207, with an expiration date of "2024-11-20". Review of 2024 QC records for the Chlamydia (CT) and Neisseria Gonorrhea (NG) testing revealed no documentation the expired reagent had been used past the expiration date of 2024-11-20. Interview with TP #1 at approximately 2:15 p.m. confirmed the QC reagent was expired. They stated it must have been overlooked but was sure it had not been used past the expiration date. The TP disposed of the expired reagent at time of interview.