Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D1076804	(X3) Date Survey Completed 01/25/2018
Name of Provider or Supplier Children's Specialized Hospital	**Street Address, City, State** 200 Somerset Street, New Brunswick, NJ	

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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) 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. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) records and interview with the Laboratory Director (LD), the laboratory failed to maintain copies of PT sample printouts for Blood Gas tests performed with the College of American Pathologists (CAP) in 2017. The finding includes: 1. A review of PT records revealed that the laboratory didn't maintain printouts for events 2 and 3 in 2017. 2. The LD confirmed on 1/25/18 at 11:05 am that all PT records were not maintained.
D3027	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(1) Test requisitions and authorizations. Retain records of test requisitions and test authorizations, including the patient's chart or medical record if used as the test requisition or authorization, for at least 2 years.

	This STANDARD is not met as evidenced by: Based on lack of the Test Requisitions (TR) and interview with the Laboratory Director (LD), the laboratory failed to retain TR for Blood Gas tests from 8/11/15 to the date of survey. The LD confirmed on 1/25/18 at 11:00 am that the TR were not retained.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on lack of Patient, Quality Control (QC) and Calibration printouts and interview with the Laboratory Director (LD), the laboratory failed to retain iStat analyzer printouts for Routine Chemistry tests from 8/11/15 to the date of survey. The LD confirmed on 1/25/18 at 10:30 am that analyzer printouts were not retained.
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 surveyor review of the Competency Assessment (CA) records and interview with the Laboartory Director (LD), the laboratory failed to perform CA correctly on 11 out of 11 TP in 2016 and 2017. The findings include: 1. The laboratory did not document when testing personnel were observed, what records were reviewed and how assessment was done. 2. The LD confirmed on 1/25/18 at 11:00 am that CA was not performed correctly.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on lack of the Accession Log (AL) and interview with the Laboratory Director (LD), the laboratory failed to maintain an Accession Log (AL) for Routine Chemistry tests from 8/11/15 to the date of survey. The LD confirmed on 1/25/18 at 11:10 am that the laboratory did not maintain an AL for laboratory tests.

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 surveyor review of Final Reports (FR) and interview with the Laboratory Director (LD), the laboratory failed to ensure that Test Report Date (TRD) was indicated on the FR from 8/11/15 to the date of survey. The LD confirmed on 1/25/18 at 11:30 am that TRD was not on the FR.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(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 surveyor review of the Procedure Manual and interview with the Laboratory Director (LD), the Laboratory Director failed to establish a Competency Assessment (CA) procedure with the required elements from 8/11/15 to the date of the survey. The LD confirmed on 1/25/18 at 11:00 am that a CA procedure was not established for TP.
D6034	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section. This STANDARD is not met as evidenced by: Based on surveyor review of the Personnel Files and interview with the Laboratory

	Director (LD) via phone, the laboratory failed to employ a qualified Technical Consultant (TC) by education from 8/11/15 to the date of survey. The findings include: 1. The TC was not qualified by education. 2. The TC was not qualified to perform competency assessment on testing personnel. 3. The LD confirmed on 1/25 /18 at 11:00 AM that the laboratory did not have a qualified TC.