Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0684710	01/08/2019
Name of Provider or Supplier	**Street Address, City, State**	
Knoxville Pediatric Associates	2201 Clinch Avenue, Knoxville, TN	

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 2018 Hematology Proficiency Testing (PT) attestation sheets and upon interview with the Nurse Manager, determined the PT samples were not tested by 15 of 16 testing personnel as listed on the Laboratory Personnel Report Form 209. The findings include: 1. Review of the Hematology PT records for 2018 revealed only one of sixteen testing personnel's signature on the attestation sheets. 2. Interview with the Nurse Manager January 8th, 2019 at approximately 1:30 p.m. confirmed the attestation sheets for 2018 Hematology PT were signed by only one of sixteen testing personnel. ==========
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 review of three patient CBC (Complete Blood Count) reports manually entered in Electronic Medical Records (EMR) for 2018, lack of CBC instrument printouts and upon interview with

	the Nurse Manager, the laboratory failed to retain CBC instrument printouts for the last 2 years. The findings include: 1. Review of three patient CBC reports for January 26, 2018, February 28, 2018 and November 21, 2018 revealed manually entered results in the Electronic Medical Records. 2. CBC instrument printouts for manually entered CBC's into EMR for dates in January, February and November of 2018 were not retained. 3. Interview with Nurse Manager January 8th, 2019 at approximately 1: 30 p.m. confirmed the laboratory was not able to retrieve CBC instrument printouts for the dates of review in 2018 and also had not been retained for 2017. ==========
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 Laboratory Procedure Manual, lack of procedures for CBC (Complete Blood Count) testing and reporting and upon interview with the Nurse Manager, determined the laboratory failed to have procedures to include pre-analytic, analytic and post-analytic requirements for performing Complete Blood Counts for 2017 and 2018. The findings include: 1. Review of Laboratory Procedure Manual revealed lack of procedures for testing and reporting Complete Blood Counts (CBC's). 2. Lack of pre-analytic, analytic and post-analytic procedures for Complete Blood Counts to include: a. Specimen collection and rejection. b. Specimen labeling. c. Operation and maintenance of CBC analyzer. d. Quality Control requirements and rules for acceptability. e. Calibration Verification. d. Result reporting. 3. Interview with the Nurse Manager January 9th, 2019 at approximately 1:30 p.m. confirmed there were no procedures available for review for CBC testing and reporting for the period reviewed between 2017 and 2018. ==========
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed

	following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: ========== Based on review of four patient urine culture reports for dates in 2018, review of randome urine cultures for 2017, review of media package inserts and interview with the Nurse Manager, determined the laboratory failed to follow manufacturer's directions of reading and reporting urine cultures between 18-24 hours for 2017 and 2018. The findings include: 1. Review of four patient urine culture reports for August 1, 2, 3, and 9 of 2018 and review of random urine cultures for dates in August and November of 2017 revealed cultures were reported at 48 hours 2. Review of Trypticase Soy Agar and MacConkey Media package inserts revealed incubation time to be 18-24 hours. 3. Interview with Nurse Manager January 8th, 2019 at approximately 1:30 p.m. confirmed the laboratory had been incubating urine culture plates for final report at 48 hours for 2017 and 2018. ==========
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: ========== Based on a review of the laboratory's employee competency evaluations and upon interview with the Nurse Manager, determined the Technical Consultant failed to perform and document semi-annual competency evaluations for two new testing personnel with hire dates in 2017. The findings include: 1. A review of the laboratory's semi-annual competency evaluation results were not available for testing persons #1 and #5 of 16 who were hired to perform Complete Blood Counts (CBC's), throat and urine culture testing in 2017. 2. An interview with the Nurse Manager January 8th, 2019 at approximately 1: 30 p.m. confirmed there were no semi-annual competency evaluations for review for testing persons #1 and #5 hired in 2017 for CBC and Microbiology testing. ==========