Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0934180	01/11/2018
Name of Provider or Supplier	**Street Address, City, State**	
Greater North Texas Pediatrics	12200 Park Central Dr Suite 255, Dallas, TX	

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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of the laboratory's procedure manual, approved by the laboratory director in May 1998, manufacturer assay records of new quality control (QC) reagent received during the period 1/1/l7 to 1/11/18 and staff interview, the laboratory failed to follow their own instructions on verifying each new lot of QC reagent. Findings were: A. On page 47 of 50 of the laboratory's procedure manual it stated, "New lot numbers of reagents, test kits and media are verified for quality before use." B. Upon request, the laboratory was unable to provide evidence that new lot numbers of QBC quality control reagent were verified for quality before being placed into service. C. During interview with testing person #2, who was also the clinic manager, she stated that she was unaware of this requirement. The finding was confirmed with the clinic manager on 1/11/18 at 1615 hours in an administrative office. Also see D6021
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 a review of the laboratory's policy/procedure manual, established patient reference ranges as defined in the QBC hematology test system and staff interview, the laboratory director failed to define in writing the approved and verified patient normal ranges for this laboratory's patient population for CBC (complete blood count) testing. Findings were: A. Under subparagraph number 10. of this regulation, the laboratory must define and state in the procedure manual the reference intervals (normal values) as approved by the laboratory director. A review of the approved laboratory procedure manual revealed that the lab director failed to define those reference intervals. B. The reference intervals for CBC testing was to be confirmed during the initial installation of the QBC test system and before initial patient testing; and be representative of the laboratory's patient population.(See 493.1253(b)(1)(ii)) Upon request, the performance verification of the test system was not found and could not be provided. C. The test system showed eleven (11) different reference ranges, dependent of age and sex. The laboratory's procedure manual, nor separate policy statement was provided to the surveyor to confirm or support these 11 reference ranges. D. During interview with the laboratory director on 1/11/18 at 1615 hours in an administrative office, she turned to an undisclosed reference document containing reference intervals for CBC testing. It was unclear whether the 11 reference ranges programmed into the QBC test system were from this reference. She stated to the clinic manger, "we can just use these." E. The above findings were confirmed by interview with testing person #2, who was also the clinic manager, on 1/11/18 at 1615 hours in an administrative office.
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 a review of the manufacturer's operation manual, the lab's Instrument Maintenance plan, request for maintenance records for the period 6/01/16 to 1/11/18 and staff interview, the laboratory failed to perform required maintenance/function checks for the QBC Autoread hematology analyzer system. The QBC system performs CBC (complete blood count) testing. Findings were: A. The manufacturer' operations manual stated that the QBC centrifuge rotor speed, a part of the test system, must be checked "At least every 6 months or after any adjustments or repairs.

	The rotor of the QBC Centrifuge is designed to spin at 12,000 +/- 80 rpm." (rpm = revolutions per minute) The electronic timer of the centrifuge must be checked "for accuracy against a reliable stopwatch or quartz timer at least every three months." B. The lab's Instrument Maintenance policy stated "Check the centrifuge speed twice a year, using a tachometer (e.g. Adams photoelectric tachometer. Results should be within 11,920 and 12,080 rpm. Record results on the QBC System Maintenance Log." C. Upon request for maintenance and function check documentation records from 6/1 /16 to 1/11/18, the laboratory was unable to present data for this period. The lab did present a "QBC System Maintenance Log" for: cleaning the the QBC's system Housing, clean/inspection of the rotor and a timer check. On this record, rotor speed was not checked. The date was not provided. The year was provided; 2010. There was no evidence of its review. Two other records were presented upon request. Both were service records performed by "PSS Service Center Repair." One record consisted of work identified as "Calibrated centrifuge" on 4/23/99. The service record did not specify what "Calibrated Centrifuge" actually meant or what adjustments, if any, were necessary or even performed. The second service record was also from PSS Service Center Repair. It stated the action taken as, "Tax-test QBC centrifuge." The date of service was 4/29/98. Again, the service record did not specify what Tax-test QBC centrifuge actually meant or what adjustments, if any, were necessary or even performed. D. The above findings were confirmed by interview with testing person #2, as identified on Form CMS-209. This testing person was also introduced as the clinic manager upon arrival to the laboratory. This interview occurred on 1/11/18 at 1605 hours in an administrative office. NOTE: THIS WAS A REPEAT DEFICIENCY (from last survey conducted 6/1/16)
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based upon a review of quality control records for QBC hematology testing from 1/1 /17 to 1/11/18 and staff interview, the laboratory's technical consultant/laboratory director failed to document that quality control accuracy and precision were monitored over time. Findings were: A. A review of the laboratory's quality control records from the stated period revealed the lab failed to have documentation to confirm that quality control results were monitored over time for shifts and trends (accuracy and precision) of quality control results for the QBC hematology system. The test system was used to report CBC (complete blood count) results for clinic patients. B. Upon request for this documentation, as well as, a defined mechanism for this process none was provided. C. The above finding was confirmed by interview

	with testing person #2, who was also the clinic manager, on 1/11/18 at 1610 hours in an administrative office. NOTE: THIS WAS A REPEAT DEFICIENCY (from last survey conducted 6/1/16)
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 upon a review of the laboratory's quality assessment program policy and records during the period 6/1/16 to 1/11/18 for pre-analytic, analytic, post-analytic phases of testing, and staff interview, the laboratory director failed to ensure that their quality assessment/assurance plan was followed. Findings were: A. Review of the laboratory's Quality Assurance (QA) policy, approved and signed by the laboratory director on 5/8/1998 revealed the laboratory's quality assurance included the following components: 1. Personnel Training and Qualifications 2. Proficiency Testing 3. Procedure Manual 4. Specimen Collection and Handling Specifications 5. Patient Test Management/Record Keeping 6. Quality Control Program 7. Instrument Maintenance Program 8. Laboratory Safety The source of this QA plan was the CLIA Compliance Assistance Manual. The above components included all three phases of testing. B. The QA plan also stated, "A sample Monthly Quality Assurance Checklist is also provided so that your laboratory can evaluate the effectiveness of your policies and procedures, i.e., your Quality Assurance Program." Upon request for records to support the laboratory's participation in this approved plan, the laboratory was unable to provide records to substantiate the effectiveness of their quality plan during the period 6/1/16 to 1/11/18. Also see: D5401 D5429 D5441 C. The above finding was confirmed by interview with testing person #2, who was also the clinic manager, on 1 /11/18 at 1525 hours in an administrative office.
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 a review of the laboratory's policy/procedure manual in effect during the

	time of the survey and staff interview, the laboratory director failed to identify the duties and responsibilities of consultants and persons involved in the three phases of testing. Findings were: A. A review of the policy/procedure manual, derived from the "CLIA Compliance Assistance Manual, revision A-August 1996, revealed that the duties and responsibilities of the laboratory director, technical consultant and testing persons were not defined. B. The lab director failed to document the list of procedures each testing person was authorized to perform, whether supervision was required for specimen processing, testing, and result reporting. C. The laboratory director failed to specify whether laboratory/technical consultant review was required prior to the reporting results by testing persons.
D6054	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 annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of the laboratory's Quality Assurance Program, personnel records from the period 6/1/16 to 1/11/18 and staff interview, the technical consultant failed to ensure that competency was assessed for new testing persons prior to analyzing specimens. Findings were: A. Under the laboratory's policy on quality assurance under the heading of Personnel Training and Qualifications it stated, "Personnel are evaluated semiannually during the first year of employment or when new methodologies are incorporated. Thereafter, evaluations are performed yearly." B. A review of personnel records for the survey period revealed that testing persons number (#) 1 and #4 as listed on Form CMS-209 were not evaluated for competency during calendar year 2017. (Competency assessments were performed during calendar year 2016.) C. The above findings were confirmed by interview with testing person #2, as identified on Form CMS-209. This testing person was also introduced as the clinic manager upon arrival to the laboratory. This interview occurred on 1/11/18 at 1340 hours in an administrative office.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on a review of the laboratory's Quality Assurance Program, personnel records from the period 6/1/16 to 1/11/18 and staff interview, the lab failed to ensure that training was completed for new testing persons prior to analyzing specimens. Findings were: A. Under the laboratory's policy on quality assurance under the heading of Personnel Training and Qualifications it stated, "All laboratory personnel have been trained to perform the tests that they are authorized to perform. Training can be provided by the physician or under the physician's supervision, by a manufacturer's representative, a technical consultant or a professional group." B. A review of personnel records for the survey period revealed no evidence that training was completed for testing persons number (#) 2 and #3 as listed on Form CMS-209. Upon

	request for training documentation, none was provided. C. The above findings were confirmed by interview with testing person #2, as identified on Form CMS-209. This testing person was also introduced as the clinic manager upon arrival to the laboratory. This interview occurred on 1/11/18 at 1340 hours in an administrative office.