Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0934180	12/15/2020
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
D0000	An entrance conference was held with the laboratory representative. The survey process was discussed, and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The laboratory representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be NOT in compliance with the CLIA conditions for specialties /subspecialties surveyed for 42 CFR 493.1409 Technical Consultant 493.1421 Testing Personnel (moderate complexity) Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of laboratory records, American Proficiency Institute (API) Proficiency Testing (PT) records (2019 1st, 2nd, and 3rd Events and 2020 1st and 2nd Events) and staff interview, the laboratory director failed to attest to the routine integration of proficiency samples into the patient workload for 1 of 5 hematology events in 2019 and 2020. Findings included: 1. Review of laboratory records revealed the laboratory tested hematology samples for the following analytes on the QBC

	AutoRead Plus hematology analyzer: White Cell Count, Red Cell Count, Hemoglobin, Hematocrit, Platelet Count, Granulocytes, and Lymphocytes 2. Review of API test records revealed the following statement: "Attestation Statement SIGNATURES REQUIRED- Testing personnel and the laboratory director must physically sign an attestation statement for all PT results and retain the signed statement (or a copy) for a minimum of 2 years. Either the attestation statement below or a printed copy of the form provided online can be used for this purpose." 3. Review of API PT records from 2019 and 2020 revealed the laboratory director failed to sign the attestation forms for the following event: 2019 Hematology 3rd Event 4. During an interview on 12/15/2020 at 11:30 am in a facility office, Testing Person #5 confirmed the above findings.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of laboratory records, American Proficiency Institute (API) Proficiency Testing (PT) records (2019 1st, 2nd, and 3rd Events and 2020 1st and 2nd Events) and in interview with staff, the laboratory failed to have documentation of verifying the accuracy of analytes that were not graded by the proficiency testing program. Findings included: 1. Review of laboratory records revealed the laboratory tested hematology samples for the following analytes on the QBC AutoRead Plus hematology analyzer: White Cell Count, Red Cell Count, Hemoglobin, Hematocrit, Platelet Count, Granulocytes, and Lymphocytes 2. Review of API PT records from 2019 and 2020 revealed the following events with ungraded performance: a. 2019 API Hematology 2nd Event: White Cell Count QBC-06 Reported Result: 2.8 Expected Result: 3.2 - 4.5 The reported result was not within the expected result range Further review of the "Performance Review and Corrective Action" revealed under the following statement for corrective action taken: "All results reviewed and noted and the not graded results noted. Reviewed and no action needed." b. 2019 API Hematology 3rd Event: White Cell Count QBC-13 Reported Result: 12.2 Expected Result: 8.2 - 11.3 The reported result was not within the expected result range White Cell Count QBC-14 Reported Result: 18.4 Expected Result: 13.9 - 18.9 White Cell Count QBC-15 Reported Result: 5.3 Expected Result: 4.3 - 6.0 Further review of the "Performance Review and Corrective Action" revealed under the following statement for corrective action taken: "All results reviewed and noted and the not graded results noted. Reviewed and no action needed." c. 2020 API Hematology 1st Event Platelet QBC-01 Reported Result: 206 Expected Result: 113 - 190 The reported result was not within the expected result range. Platelet QBC-02 Reported Result: 193 Expected Result: 99 - 165 The reported result was not within the expected result range. Platelet QBC-04 Reported Result: 145 Expected Result: 95 - 160 White Cell Count QBC-01 Reported Result: 22.7 Expected Result: 18.4 - 25.1 White Cell Count QBC-02 Reported Result: 21.7 Expected Result: 17.0 - 23.2 White Cell Count QBC-03 Reported Result: 12.8 Expected Result: 9.8 - 13.4 White Cell Count QBC-04 Reported Result: 19.1 Expected Result: 16.7 - 22.7 White Cell Count QBC-05 Reported Result: 3.0 Expected Result: 2.7 - 3.7 Further review of the "Performance Review and Corrective Action" revealed under the following statement for corrective action taken: "All results reviewed and noted and the not graded results noted.

	Reviewed and no action needed." d. 2020 API Hematology 2nd Event Platelet QBC-06 Reported Result: 710 Expected Result: 551 - 919 Platelet QBC-07 Reported Result: 405 Expected Result: 327 - 546 Platelet QBC-08 Reported Result: 173 Expected Result: 158 - 265 Platelet QBC-09 Reported Result: 182 Expected Result: 127 - 213 Platelet QBC-10 Reported Result: 417 Expected Result: 315 - 526 White Cell Count QBC-06 Reported Result: 7.1 Expected Result: 6.2 - 8.5 White Cell Count QBC-07 Reported Result: 35.6 Expected Result: 5.6 - 7.7 The reported result was not within the expected result range. White Cell Count QBC-08 Reported Result: 12.4 Expected Result: 11.6 - 15.8 White Cell Count QBC-09 Reported Result: 20.0 Expected Result: 17.7 - 24.1 White Cell Count QBC-10 Reported Result: 5.3 Expected Result: 5.3 - 7.3 Further review of the "Performance Review and Corrective Action" revealed under the following statement for corrective action taken: "None needed, reviewed all results within range, and those not graded noted." The laboratory failed to have documentation of verifying the accuracy of analytes that were not graded by the proficiency testing program. 4. During an interview on 12/15/2020 at 11: 30 am in a facility office, after a review of the proficiency testing records, Testing Person #5 confirmed the above findings.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of laboratory policy and confirmed in staff interview, it was revealed that the Laboratory-Practice Guidelines policy was not approved, signed, or dated by the laboratory director before use. Findings included: 1. The laboratory policy titled "Laboratory-Practice Guidelines" stated the following: "Scope/Purpose: To provide an overview of guidelines and safe practices related to specimen collection/processing and care of laboratory equipment/environment ....Original Date: April 4, 2016 ...Date Reviewed ...Date Revised ...Responsible Party." The laboratory policy failed to include a date reviewed, date revised, or signature of the responsible party. The laboratory policy was not approved, signed and dated by the laboratory director. 2. During an interview on 12/15/2020 at 12:30 pm in a facility office, Testing Person #5 confirmed the above findings.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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 direct observation, review of QBC AutoRead Plus operator's manual, random review of laboratory environmental records (03/2019, 04/2019, 05/2019, 09

	/2020, 10/2020, and 11/2020) and staff interview, the laboratory failed to ensure room temperature and humidity readings were within manufacturer's specifications for the QBC AutoRead Plus hematology analyzer for 6 of 6 months. Findings included: 1. A tour of the laboratory area on 12/15/2020 at 12:10 pm revealed the laboratory used a QBC AutoRead Plus hematology analyzer (Serial Number 505220010). 2. The QBC AutoRead Plus operator's manual, in the Section titled "Specifications" stated the following: "Climate requirements for QBC tests: Temperature 20C to 32C (68F to 90F) ....Relative Humidity 10% to 95%" 3. A random review of the laboratory environmental records (03/2019, 04/2019, 05/2019, 09/2020, 10/2020, and 11/2020) revealed entries for the following: Day; Time AM/PM; Indoor Room Temp AM/PM; Out Door Temp AM/PM; Humidity AM/PM The form failed to provide an acceptable room temperature range or an acceptable humidity range. The laboratory failed to ensure that room temperature and humidity readings were within the manufacturer's specifications. 4. During an interview on 12/15/2020 at 11:30 am in a facility office, Testing Person #5 confirmed the above findings.
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 direct observation, review of QBC AutoRead Plus manufacturer's instructions, laboratory maintenance records (09/2018 through 08/2020) and staff interview, the laboratory failed to have documentation of timer check and centrifuge check readings for 5 of 5 maintenance cycles. Findings included: 1. A tour of the laboratory area on 12/15/2020 at 12:10 pm revealed the laboratory used a QBC AutoRead Plus hematology analyzer (Serial Number 505220010). 2. The QBC AutoRead Plus instructions (Rev B 07/2007), in the section titled " Centrifuge" stated, "Check the centrifuge timer twice a year ... ...The timer check should be 5 minutes +/- 15 seconds ...record results on the QBC System Maintenance Log ...Check the centrifuge speed twice a year, using a tachometer ...Results should be within 11,920 and 12,080 revolutions per minute ...Record results on the QBC System Maintenance Log." 3. Review of the QBC System Maintenance Log from 09/27/2018 through 08/26 /2020 revealed the following entries for Check Rotor Speed; Date/Tech and Check Timer; Date/Tech: a. Check Rotor Speed; Date/Tech: 09/27/2018 Check Timer; Date /Tech: 09/27/2018 b. Check Rotor Speed; Date/Tech: 03/13/2019 Check Timer; Date /Tech: 03/13/2019 c. Check Rotor Speed; Date/Tech: 09/23/2019 Check Timer; Date /Tech: 09/23/2019 d. Check Rotor Speed; Date/Tech: 02/24/2020 Check Timer; Date /Tech: 02/24/2020 e. Check Rotor Speed; Date/Tech: 08/26/2020 Check Timer; Date /Tech: 08/26/2020 The laboratory failed record the rotor speed and the timer check values in order to access acceptability and failed to document who performed that rotor speed and timer checks. 4. During an interview on 12/15/2020 at 12:30pm in a facility office, Testing Person #5 confirmed the above findings.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures

	necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory records and staff interview, the laboratory failed to ensure an effective QA (quality assessment) system was in place to monitor, assess, and correct problems in the laboratory, as evidenced by: 1. The laboratory director failed to attest to the routine integration of proficiency samples into the patient workload for 1 of 5 hematology events in 2019 and 2020. Refer to D2009 2. The laboratory failed to have documentation of verifying the accuracy of analytes that were not graded by the proficiency testing program. Refer to D5213 3. The laboratory failed to ensure room temperature and humidity readings were within manufacturer's specifications for the QBC AutoRead Plus hematology analyzer for 6 of 6 months. Refer to D5413 4. The laboratory failed to have documentation of timer check and centrifuge check readings for 5 of 5 maintenance cycles. Refer to D5429 5. The technical consultant failed to evaluate and document annual competency in 2018 for 4 of 4 Testing Persons (TP-1, TP-2, TP-3, and TP-5) who perform moderate complexity testing. Refer to D6046. 6. The technical consultant failed to perform testing personnel competency assessments at least twice the first year of patient testing for 1 of 6 testing persons listed on Form CMS-209. Refer to D6053 7. The Technical Consultant (TC) failed to evaluate competency annually in 2019 for 4 of 4 Testing Persons (TP-1, TP-2, TP-3, and TP-5) who perform moderate complexity testing. Refer to D6054 8. The laboratory failed to have documentation that 1 of 6 testing persons met the qualifications required to perform moderate complexity testing. Refer to D6065. 9. The laboratory record titled "Monthly Quality Assurance Checklist" stated the following to be reviewed each month: "Our Personnel policies were followed: All personnel who perform tests have documented training for these tests ... All personnel who perform tests have read the procedure manual for those tests .... Personnel evaluations were performed as necessary ...Our Proficiency testing policies have been followed: Proficiency tests were handled in the same manner as patient specimens. Proficiency test results were evaluated, failures were investigated, and remedial action was taken ...Our Quality Control policies were performed as specified: All required temperatures were taken and recorded ...All required instrument maintenance was performed and documented ...Any necessary remedial action was performed and documented ...Our Quality Assurance Program is monitored for compliance: The above information has been reviewed to determine whether errors that occurred could have been prevented by changing our policies and procedures." Further review of this laboratory record from 01/2019 through 11/2020 revealed each month the review was inquiries were answered "yes". The laboratory failed to ensure their QA (quality assessment) system effectively monitored, assessed, and corrected problems in the laboratory.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel

	meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of laboratory policy and confirmed in staff interview, the Laboratory Director failed to ensure laboratory overall operations and test systems were in compliance with regulations as evidenced by: 1. The current laboratory director failed to approve, sign or date procedures or changes in procedures. Refer to D5407.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on review of Centers for Medicare and Medicaid (CMS) 209 submitted form, manufacturer's instructions, personnel records, and staff interview, the technical consultant failed to provide technical oversight, as evidenced by: 1. The technical consultant failed to evaluate and document annual competency in 2018 for 4 of 4 Testing Persons (TP-1, TP-2, TP-3, and TP-5) who perform moderate complexity testing. Refer to D6046. 2. The technical consultant failed to perform testing personnel competency assessments at least twice the first year of patient testing for 1 of 6 testing persons listed on Form CMS-209. Refer to D6053 3. The technical consultant failed to evaluate competency annually in 2019 for 4 of 4 Testing Persons (TP-1, TP-2, TP-3, and TP-5) who perform moderate complexity testing. Refer to D6054.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the CMS-209 form, personnel records, and staff interview, the technical consultant failed to evaluate and document annual competency in 2018 for 4 of 4 Testing Persons (TP-1, TP-2, TP-3, and TP-5) who perform moderate complexity testing. Findings included: 1. Review of CMS 209 form revealed moderate complexity complete blood count (CBC) testing was performed by Testing Persons 1, 2, 3, and 5 in 2018. 2. Review of personnel records from 2018 through 2020 revealed a form titled, "Laboratory Personnel Evaluation". The forms for TP-1, TP-2, TP-3, and TP-5 2018 annual CBC testing competency assessments, in the section titled "Reviewed by", were signed by the Head Nurse. The Head Nurse was NOT listed on the CMS-209 form as the Technical Consultant. The Technical Consultant had not performed and documented competency assessment for TP-1, TP-2, TP-3, and TP-5 to include: a) Direct observation of routine patient test performance, including patient

	preparation, specimen handling, processing and testing. b) Monitoring the recording and reporting of patient test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens or external proficiency testing samples. f) Assessment of problem solving skills. 3. In an interview on 12/15/2020 at 10:05 am in a facility office, Testing Person #5 confirmed the above findings.
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 review of the Centers for Medicare and Medicaid (CMS)-209 form, QBC hematology analyzer manufacturer's instructions, personnel records, and staff interview, the technical consultant failed to perform testing personnel competency assessments at least twice the first year of patient testing for 1 of 6 testing persons listed on Form CMS-209. Findings included: 1. Review of CMS 209 form revealed moderate complexity complete blood count (CBC) testing was performed by Testing Person #6. 2. Review of the QBC Autoread Plus Hematology system manufacturer's instructions (Rev. B 7/2007) revealed the following in the section titled "Personnel Training and Qualifications": "Personnel are evaluated semiannually during the first year of employment or when new methodologies are incorporated. Thereafter, evaluations are performed yearly." 3. Review of personnel records revealed Testing Person #6 initial training for the QBC hematology analyzer was performed 03/02 /2019. The next competency assessment was performed 12/14/2020. The Technical Consultant failed to perform testing personnel competency assessments at least twice the first year of patient testing for Testing Person #6. 4. In an interview on 12/15/2020 at 12:00 pm in a facility office, Testing Person #5 confirmed the above findings.
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 review of CMS 209 form, personnel records, and staff interview, the Technical Consultant (TC) failed to evaluate competency annually in 2019 for 4 of 4 Testing Persons (TP-1, TP-2, TP-3, and TP-5) who perform moderate complexity testing. Findings included: 1. Review of CMS 209 form revealed moderate complexity complete blood count (CBC) testing was performed by Testing Persons 1, 2, 3, and 5 in 2019. 2. Review of personnel records from 2018 through 2020 revealed no documentation of annual competency assessments in 2019. The Technical Consultant had not performed and documented competency assessment for TP-1, TP-2, TP-3, and TP-5 to include: a) Direct observation of routine patient test

	performance, including patient preparation, specimen handling, processing and testing. b) Monitoring the recording and reporting of patient test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens or external proficiency testing samples. f) Assessment of problem solving skills. 3. In an interview on 12/15/2020 at 10:05 am in a facility office, Testing Person 5 confirmed the above findings. This is a repeat deficiency from the survey conducted 1/11/2018.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services (CMS) 209 form and personnel records, it was revealed the laboratory failed to have documentation that 1 of 6 testing persons met the qualifications required to perform moderate complexity testing. Refer to D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of the CMS-209 form and personnel records, the laboratory failed to have documentation that 1 of 6 testing persons met the qualifications required to perform moderate complexity testing. Findings included: 1. Review of the CMS-209 form included Testing Person 1 through Testing Person 6 listed to perform moderate complexity testing. 2. A review of testing persons' personnel records revealed the laboratory did not have documentation to ensure the following 1 of 6 testing persons were qualified to perform moderate complexity testing: a. Testing person 6; No education documents provided 3. In an interview on 12/15/2020 at 12:00 pm in a facility office, Testing Person #5 was asked to provide educational documentation for Testing Person #6. No documentation was provided. This confirmed the above findings.