Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1082475	09/12/2022
Name of Provider or Supplier	**Street Address, City, State**	
All Childrens Pediatric Clinic Pa	4221 North Conway Suite D, Palmhurst, 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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on surveyor observation, review of manufacturer's instructions, and confirmed in interview of laboratory personnel, the laboratory failed to follow manufacturer's instructions to discard unused test strips for 1 of 1 vial of True Metrix Blood Glucose test strips observed in the laboratory on September 12, 2022. The findings included: 1. Surveyor observation made on September 12, 2022 at 15:20 hours in the laboratory found 1 vial of True Metrix Blood Glucose test strips available for use in the laboratory. Lot Number: MX4429S Expiration Date: 07-31-2022 2. Review of the manufacturer's instructions for the True Metrix Blood Glucose test strips (RF3TVH03 Rev. 52) stated, "Caring for Test Strips ...Discard all unused test strips in vial after either date printed next to EXP on the test strip vial label or 4 months after date opened, whichever comes first. Using test strips past these dates may cause inaccurate results." 3. The findings were confirmed in interview with the technical consultant on September 12, 2022 at 15:22 hours in the laboratory.
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory

	that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on review of the laboratory's test menu, review of manufacturer's instructions, patient test records, and staff interview, the laboratory failed to provide documentation of reporting 133 SARS-CoV-2 antigen positive results from April 1, 2022 to September 12, 2022 (the day of the survey) as required. The findings included: 1. A review of the laboratory's test menu found the laboratory utilized the Quidel QuickVue antigen SARS-CoV-2 kit for patient testing. 2. A review of the manufacturer's instructions for use for the Quidel Quick-Vue antigen SARS-CoV-2 antigen assay under the section titled "Conditions for Authorization for the Laboratory and Patient Care Settings" stated, "Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate." 3. A review of laboratory policies found no documentation of a policy or procedure related to SARS-CoV-2 test reporting to public health authorities. 4. Review of patient test records found the following SARS-CoV-2 antigen positive results were not reported to any public health authority (patient alias list provided to technical consultant the day of the survey on September 12, 2022). 5. An interview with testing personnel #1 (as listed on Form CMS-209) on September 12, 2022 via telephone confirmed the findings. Key: SARS-CoV-2 - Coronavirus that causes COVID-19 CMS - Centers for Medicare and Medicaid Services
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory's test menu, laboratory policies, review of the laboratory's instrument verification records, and staff interview, the laboratory failed to provide documentation of verifying patient normal ranges when it changed hematology analyzers in May 2022. The findings included: 1. A review of the laboratory's test menu found the laboratory placed the Horiba hematology analyzer into use in May 2022. 2. Review of the laboratory's policy titled 'Validation of a New Test System' (no approval date by the laboratory director) stated, "Purpose: The purpose of this policy is to ensure that prior to performing tests on patients, every new test system will have studies performed to validate the accuracy, precision, reportable range of test results, and verify manufacturer's normal values." 3. Review of the verification study performed for the Horiba hematology analyzer in May 2022 found no patient normal verification studies. 4. The laboratory was asked to provide documentation of performing patient normal verification studies for the new analyzer.

	No documentation was provided. 5. An interview with the technical consultant on September 12, 2022 at 1700 hours in the office confirmed the findings.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records, and staff interview, the laboratory failed to have documentation of verifying 1 of 1 lots of Horiba Minotrol hematology controls. The findings included: 1. A review of the laboratory's quality control records found the following lot number of Horiba Minotrol hematology controls was not verified prior to putting into use. Lot: MX435 Expiration date: 07-25-2022 2. The laboratory was asked to provide documentation of verifying the lot number of quality control prior to putting it into use. No documentation was provided. 3. An interview with the technical consultant on September 12, 2022 at 1645 hours in the office found the laboratory did not verify the controls. This confirmed the findings.
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 laboratory policy, review of patient test records, and interview with laboratory personnel, the laboratory failed to ensure test reports were complete for 8 of 8 patient results randomly selected from July 23, 2022 to August 30, 2022. The findings included: 1. Review of the laboratory's policy titled, "Policy for handling flagged CBC Differentials" approved by the laboratory director on March 28, 2018 stated, " ...It is the policy of this laboratory to return [SIC] flagged CBC results. If the second run still shows flags, then lab will evaluate flagged differentials according to

	the procedures in the unit's operator manual ..." 2. Review of 8 randomly selected patient test records from July 23, 2022 to August 30, 2022 found the following samples that were incomplete. There was no documentation that the laboratory resolved flags. Therefore, the CBC results were incomplete. Date: 07-23-2022 Patient ID: See patient alias list Flags: M2, G1 Date: 07-23-2022 Patient ID: See patient alias list Flags: M2, G1 Date: 07-25-2022 Patient ID: See patient alias list Flags: G1, G2 Date: 07-25-2022 Patient ID: See patient alias list Flags: M2, G1, G2 Date: 07-25-2022 Patient ID: See patient alias list Flags: M2, G1, G2 Date: 08-26-2022 Patient ID: See patient alias list Flags: G1 Date: 08-27-2022 Patient ID: See patient list Flags: G1 3. The laboratory was asked to provide documentation of ensuring the CBC results were complete prior to their release to the healthcare provider. No documentation was provided. 4. The findings were confirmed in interview with the technical consultant on September 12, 2022 at 16:09 hours in the laboratory. Key: CBC - Complete Blood Count
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 on review of quality control records, patient test records, technical consultant quality assurance review, and confirmed in interview of laboratory personnel, the laboratory director failed to ensure a quality assurance plan was established and maintained for 20 of 20 patient results for CBCs from August 22, 2022. The findings included: 1. Review of the laboratory's hematology quality control records for August 22, 2022 found the laboratory could not provide documentation of at least two passing levels of hematology quality controls. 2. Review of technical consultant's quality assurance review for August 2022 found she instructed the laboratory to invalidate 20 of 20 patient results performed on August 22, 2022 since there was no passing quality control. 3. Review of the 20 patient charts found the results had not been invalidated and were available for review on their medical record. 4. The findings were confirmed in an interview with the technical consultant on September 12, 2022 at 1715 hours in the laboratory after her review of the records. Key: CBC - complete blood count