Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1034142	11/21/2018
Name of Provider or Supplier	**Street Address, City, State**	
Tyler Office Of Pediatrics	4801 Troup Hwy South, Suite 301, Tyler, 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	Based on the survey conducted 06-21-2018, the laboratory was found to be out of compliance with the following conditions of 42 CFR: 493.1441 Laboratory Director .
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 American Association of Family Practice (AAFP) proficiency testing (PT) documentation for 2017 and 2018 and staff interview, the laboratory failed to test PT samples using personnel who routinely perform paitient testing. Findings: 1. Review of the signatures on attestation statements for AAFP PT events 1-3 in 2017 and events 1-3 in 2018 revealed that all sample testing for those events was performed by testing person 1 (CMS form 209). 2. In an interview at the site on 11-21-2018, testing person 2 stated that she routinely performed patient testing in the laboratory. In the same interview, testing person 2 confirmed that all proficiency testing in 2017 and 2018 was performed by testing person 1. .
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: . Based on review of laboratory PT documentation for 2017 and 2018, confirmed by

	staff interview, the laboratory failed to verify the accuracy of immunology testing performed using the Hitachi CLA luminometer at least twice annually. Findings: 1. Laboratory documentation included materials indicating use of a Hitachi CLA-1 luminometer for allergen-specific IgE testing beginning in May of 2017 and continuing to the date of the survey. 2. No documentation of accuracy verification concurrent with patient testing for 2017 or 2018 was found or could be made available during the survey. In an interview at the time of the survey, testing person 2 stated that no accuracy verification testing had been performed during that time. 3. Review of patient testing records revealed that from 03-01-2017 to 11-21-2018, a total of 39 patients had been tested using the system. .
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory 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 general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: . Based on review of laboratory policies and testing records for 2017 and 2018, confirmed by staff interview, the laboratory failed to utilize or document effective general laboratory systems quality assessment activities. Findings: 1. Laboratory policies and procedures included a document titled "Quality Assurance Plan." This was a generic template from an unknown source that did not indicate to what laboratory it applied or to the effective date of the plan. The document was not dated or signed by the laboratory director. 2. The above document included a section titled "Quality Assurance Reviews" stating: "QA reviews should be conducted on a regular basis for the purpose of monitoring and improving the quality of the testing process. Our reviews are conducted: (Check One) __Monthly __Bi-Monthly __Quarterly __Bi-anually __Annually" No review interval was selected. 3. Also included was a section titled "Quality Assurance Records" stating: "Quality Assurance Reviews should be filed with this plan and are available for periodical review by the Director of the laboratory, or surveyors. All records are dated and initialed by the Staff performing the reviews, and the Laboratory Director." No such documentation was found or could be made available at the time of the survey. 4. In an interview at the site on the date of the survey, testing person 2 stated that documentation and periodic review of quality assurance activities had not been implemented in the laboratory. .
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 surveyor observation and review of written procedures, confirmed by staff interview, the laboratory failed to define reference intervals for hematology testing using the Sysmex XP-300 analyzer, put in service 3-1-2017. Findings: 1. Laboratory procedures for hematology testing were reviewed. No listing of reference ranges for the population served was available. On request, a copy of a patient report was reviewed. No reference ranges were shown. 2. In an interview at the site on 11-21-2018, testing person 2 stated that results were interpreted according to individual patient age by the provider, who also serves as laboratory director and technical consultant. .
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 procedures and staff interview, the laboratory director failed to approve, date and sign the updated procedure for hematology testing using the Sysmex XP-300 analyzer, put in service 03-01-2017. Findings: 1. Laboratory procedures were reviewed. The procedure for hematology testing had been updated with the replacement of an Abbott Emerald hematology analyzer with a Sysmex XP-300. The updated procedure did not bear the signature of the laboratory director or date of revision. 2. In an interview at the site on the date of the survey, testing person 2 stated she was not aware that procedure updates required signed, dated approval by the laboratory director. .
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 performance verification documents for the Sysmex XP-300

	hematology analyzer and staff interview, the laboratory failed to verify that the manufacturer's reference intervals were appropriate for the laboratory's patient population. Findings: 1. Performance verification documents for the Sysmex XP-300 were reviewed. No information on studies for appropriate normal patient values was included or could be offered at the time of the survey. 2. In an interview at the site on 11-21-2018, testing person 2 stated that to her knowledge no such studies had been performed. .
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: . Based on review of patient test results for 2018 and analyzer settings, confirmed by staff interview, the laboratory failed to include reference intervals in test reports for hematology testing performed on the Sysmex XP-300 analyzer. Findings: 1. Patient test reports were reviewed. It was noted that, for hematology testing, no reference ranges were included. In an interview at the site on 11-21-2018, testing person 2 stated that she was unaware of the need to display this information on patient test reports, and to her knowledge no reference ranges had been established in the laboratory information system. 2. Upon request, analyzer settings were examined. No limits for hematology parameters had been entered. .
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 laboratory policy and staff interview, the laboratory director failed to establish and maintain an effective quality assessment program for the laboratory. Refer to D 5293. .
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) 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)(8) Ensure that reports of test results include pertinent information required for interpretation.

	This STANDARD is not met as evidenced by: . Based on review of patient testing reports, confirmed by staff interview, the laboratory director failed to ensure that reports for hematology testing using the Sysmex XP-300 analyzer included normal ranges required for interpretation. Refer to D 5807 (1) .
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 laboratory testing personnel competency verification documentation and staff interview, the technical consultant failed to evaluate the competency of testing personnel using all required methods. Findings: 1. Testing personnel education and competency verification documents were reviewed. Included were checklists for testing persons 1 and 2 marked "Personnel Assessment" in which the following was stated: "The following notations will be used to designate the assessment tool used. OBS: direct observation of test performance. RR: Review of patient testing records iincluding intermediate worksheets or logs and final reports. QC: Review of quality control activities including performance and recording. RA: Assessment of problem solving skills via review of instrument maintenance and function checks. PT or SS: Assessment of test performance through analysis of Proficiency PT or previously analyzed specimens (SS). Indicate below." 2. For both testing personnel, the only method indicated for competency assessment was OBS, or observation. .
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: . Based on surveyor observation, review of laboratory policy and procedure, performance verification documentation and staff interview, the laboratory director, who also serves as technical consultant, failed to provide overall management and direction of the laboratory. Refer to D 6021, D6026, D 6046 and D 6094 . .
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

	This STANDARD is not met as evidenced by: . Based on review of laboratory quality assessment policy and staff interview, the laboratory director failed to establish and maintain a quality assessment program for laboratory services. Refer to D 5293. .