Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0496149	07/11/2018
Name of Provider or Supplier	**Street Address, City, State**	
Texas Childrens Pediatric Associates, Inc	4949 Fairmont Parkway, Pasadena, 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
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Review of the CMS Report 155, proficiency testing records and interview of facility personnel found that the laboratory failed to achieve satisfactory performance (a score of 80% or higher) for the analyte Red Blood Cell (RBC) in one of five Hematology proficiency testing events between the 3rd testing event of 2016 and the 1st testing event of 2018. The findings included: 1. Review of the CMS report 155 Individual Laboratory Profile found a result of 60% submitted by the proficiency testing agency for the analyte RBC in the 2017 3rd testing event. 2. Review of the American Proficiency Institute (API) proficiency testing records for 2016, 2017 and 2018 (three events per year) found that the laboratory attained a score of 60% for the analyte RBC in the 2017 Hematology 3rd testing event. The laboratory submitted unacceptable results for specimens HEM-12 and HEM-14. 2. Interview of Testing person one on the CMS report 209 Laboratory Personnel report 209 confirmed the above scores were attained and that the laboratory consulted with the manufacturer regarding service once the failure was identified.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Review of proficiency testing records and interview of facility personnel found that

	the laboratory failed to retain all proficiency testing records for at least two years. The findings included: 1. Review of the American Proficiency Institute (API) proficiency testing records for Chemistry found that the laboratory failed to retain results for five of six testing events between the 2016 3rd Chemistry testing event and the 2018 2nd testing event. The laboratory failed to retain the original results for Bilirubin tested on the Reichart Unistat bilirubinometer. 2. Interview of testing person one on the CMS report 209 Laboratory Personnel Report conducted on July 11, 2018 at 09:40 AM confirmed that the Reichert Unistat did not have a printer. The laboratory did not record proficiency results on the patient log used to record patient results, and did not retain the result submission form used to record the proficiency testing results.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Review of proficiency testing records policies and procedures and interview of facility personnel found that the laboratory failed to document proficiency testing evaluation and verification activities when Red blood cell (RBC) analyte failures occurred in the 2017 Hematology 3rd testing event. The findings included: 1. Review of the American Proficiency Institute (API) proficiency testing records between 2016 3rd testing event and 2018 1st testing event (three testing events per year) found that the laboratory failed to document the evaluation of test results and corrective actions taken when proficiency testing failures (A score of less than 80%)occurred in one of five testing events reviewed . The laboratory obtained a score of 60% for the analyte RBC in the 2016 3rd testing event for Hematology. Review of the performance evaluation found a note "To call and have CBC serviced by Horiba". No other documentation was made regarding the assessment of patient results or other corrective actions. 2. Interview of testing person one listed on the CMS report 209 Laboratory Personnel Report conducted on July 11, 2018 at 10:00 AM confirmed that the laboratory had no other documentation available for the proficiency testing failure. Further discussion found that the laboratory tested 216 patient specimens between November 2017 and February 2018 without assessment of patient results during the time that proficiency testing failures occurred.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of proficiency testing records from Hematology 2016 3rd event through the 2018 1st event, patient test records, and staff interview, the laboratory director failed to ensure that corrective action was taken when proficiency testing failures occurred in the 2017 3rd testing event for RBC. (See D2021)