Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0496149	09/28/2020
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
D0000	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were 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 in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. 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.
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, a review of the laboratory's American Proficiency Institute (API) proficiency testing records for 2019 and 2020, a review of the laboratory's New Flagging Protocol, and staff interview, it was revealed the laboratory failed to have documentation of testing proficiency samples in the same

	manner it tested patient samples for 5 of 5 events in 2019 and 2020 for Hematology testing. Findings include: 1. A review of the laboratory's policy titled 'Laboratory Quality Assurance TCP Policy' revealed the following: "Patient test materials will be processed in a manner that is identical to the testing procedures used for routine clinical samples. For example, samples will not be tested in duplicate, except for procedures where patient specimens are tested in duplicate. However, abnormal survey results can be repeated if patient specimens would routinely be repeated in similar situations." 2. A review of the laboratory's New Flagging Protocol revealed the following: "WBC Flags L1, M2, G1, G2, G3 For all WBC Flags, clinical staff will re-run sample." 3. A review of the laboratory's American Proficiency Institute (API) proficiency testing records for 2019 and 2020 revealed the following events/samples where the proficiency sample's results were flagged by the analyzer and not repeated per the laboratory's protocol: a) 2019 Hematology/Coagulation - 1st Event Samples: HEM -01 flag: G1 HEM -02 flag: G3 HEM -03 flag: G1 HEM -05 flag: G1 and G3 b) 2019 Hematology/Coagulation - 2nd Event Samples: HEM -07 flag: G1 HEM -08 flag: G1 c) 2019 Hematology/Coagulation - 3rd Event Samples: HEM -12 flag: G3 HEM -13 flag: G3 HEM -14 flag: G3 HEM -15 flag: G3 d) 2020 Hematology /Coagulation - 1st Event Samples: HEM -02 flag: G1 HEM -03 flag: G1 HEM -05 flag: G3 e) 2020 Hematology/Coagulation - 2nd Event Samples: HEM -07 flag: G3 HEM -09 flag: G3 HEM -10 flag: G3 4. The laboratory was asked to provide documentation of testing proficiency samples in the same manner it tested patient samples by repeating proficiency samples with flags. No documentation was provided. 5. An interview with testing person #1 (as indicated on the CMS 209 form, signed by the laboratory director on 9/24/20) on 9/29/20 at 10:25 a.m. in the break room, after review of the records, confirmed the above findings. Key: WBC= White blood cell
D2123	HEMATOLOGY CFR(s): 493.851(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on a review of the laboratory's American Proficiency Institute (API) proficiency testing records and staff interview, it was revealed the laboratory failed to participate in 1 of 3 proficiency testing events for 2018, resulting in unsatisfactory scores for all analytes in the specialty of Hematology. Findings include: 1. Review of the laboratory's American Proficiency Institute (API) proficiency testing records from 2018 revealed the laboratory failed to participate in the 2018 Hematology/Coagulation - 3rd Event, resulting in an unacceptable score of 0% for the following analytes: a) Erythrocyte Count b) Hematocrit c) Hemoglobin d) Leukocyte Count e) MCV f) Platelet Count g) RDW h) White Blood Cell Differential i) Granulocytes j) Lymphocytes k) Monocytes 2. An interview with testing person #1 (as indicated on the CMS 209 form, signed by the laboratory director on 9/24/20) on 9/28/20 at 10:25

	a.m. in the break room, after review of the records, confirmed that the API was not done. This confirmed the above findings. Key: MCV= Mean corpuscular volume RDW= red cell distribution width
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on a review of the laboratory's calibration records for the Horiba Micros 60 hematology analyzer and staff interview, it was revealed the laboratory failed to retain the documentation for 1 of 2 calibrations performed on the Horiba Micros 60 hematology analyzer. Findings include: 1. A review of the laboratory's calibration records for the Horiba Micros 60 hematology analyzer from October 2018 to August 2019 revealed the laboratory performed calibrations on the following days: October 23, 2018 August 1, 2019 2. Further review of the laboratory's calibration records revealed the laboratory performed a calibration on the Horiba Micros 60 hematology analyzer between October 23, 2018 and August 1, 2019, as evidenced by the change in calibration factors. 3. The laboratory was asked to provide documentation of the instrument printouts for the calibration performed between October 23, 2018 and August 1, 2019. No documentation was provided. 4. An interview with testing person #1 (as indicated on the CMS 209 form, signed by the laboratory director on 9/24/20) on 9/28/20 at 11:40 a.m. in the break room, after review of the records, confirmed the above findings.
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 New Flagging Protocol, a random review of patient test records from 2019 and 2020, and staff interview, it was revealed the laboratory failed to follow its procedure for addressing flags on patient's CBC (complete blood count) results. Findings include: 1. A review of the laboratory's New Flagging Protocol revealed: "WBC Flags L1, M2, G1, G2, G3 For all WBC Flags, clinical staff will re-run samples. If flags appear a second time, the report must be given to the ordering provider to decide if further testing is required." 2. A random review of patient test results from April 2019 to August 2020 revealed the following patient's results were flagged and there was no documentation of the sample being re-run as required by the laboratory's protocol: a) Patient: 3002264791 Resulted: 4/23/19 Flag: G1 b) Patient: 3002227840 Resulted: 5/1/19 Flag: G1 G2 c) Patient: 3002223476 Resulted: 6/11/19 Flag: G1 G2 d) Patient: 3000990793 Resulted: 9/7/19 Flag: G1 e) Patient: 3000167384 Resulted: 11/18/19 Flag: G1 f) Patient: 3002550449 Resulted: 2/17/20 Flag: G1 g) Patient: 3002515040 Resulted: 3/30/20 Flag: G1 h)

	Patient: 3002544508 Resulted: 5/5/20 Flag: G1 G2 i) Patient: 3001846211 Resulted: 8 /14/20 Flag: G1 j) Patient: 3002860723 Resulted: 8/28/20 Flag: G1 3. An interview with testing person #1 (as indicated on the CMS 209 form, signed by the laboratory director on 9/24/20) on 9/28/20 at 1:15 p.m. in the laboratory, after review of the records, confirmed the above findings. Key: WBC= white blood cell
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) 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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on a review of the laboratory's procedures, a review of patient test records, and staff interview, it was revealed that the laboratory director failed to ensure testing personnel followed the laboratory's procedures for addressing flags on patient's CBC (complete blood count) results. (refer to D5401)