Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0978941	(X3) Date Survey Completed 03/24/2021
Name of Provider or Supplier Texas Children's Pediatrics University Association	**Street Address, City, State** 1602 Rock Prairie Road Suite # 1100, College Station, 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
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 policies, review of the laboratory's American Proficiency Testing (API) proficiency testing (PT) records, and confirmed in interview of facility personnel, the laboratory failed to provide documentation of 3 of 6 attestation statements being signed by those who were required to sign them. The findings were: 1. Review of the laboratory's policy titled, "Proficiency Testing" (not approved by the current laboratory director) stated, "8. Sign the attestation statements." 2. Review of API's attestation statement form 2019 Hematology /Coagulation (events 1, 2, and 3) and 2020 Hematology (Coagulation (events 1, 2, 3) stated, "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 the laboratory's API proficiency testing records from 2019 Hematology/Coagulation (events 1, 2, and 3) and 2020 Hematology/Coagulation (events 1, 2, and 3) found the following attestation statements were not signed: 2020 (event 1) not signed by laboratory director 2020 (event 2) not signed by laboratory director not signed by testing person 2020 (event 3) not signed by laboratory director 4. An interview with testing personnel #1 (as listed on Form CMS-209) on March 24, 2021 at 10:45 hours in the break room confirmed the findings
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: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records and confirmed in interview, the laboratory failed to attain a score of at least 80% for each analyte in a testing event. The findings were: 1. Review of the laboratory's PT records for hematology from 2018 (event 3), 2019 (events 1, 2, and 3) and 2020 (events 1, 2, and 3) found the laboratory received the following scores: 2018 Hematology (event 3) RBC (Red Blood Cell) Score: 20% 2020 Hematology (event 2) PLT (Platelet) Score: 60% 2. Failure to achieve a score of at least 80% is unsatisfactory performance for each analyte. 3. The findings were confirmed in interview with testing personnel #1 (as listed on Form CMS-209) on March 24, 2021 at 09:30 hours in the break room. Key: CMS - Centers for Medicare and Medicaid Services
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 review of quality control (QC) records and interview, the laboratory failed to retain the QC package inserts used on the CELL-DYN Emerald hematology analyzer for 2020. Findings follow. 1. Review of the QC records from 2020 showed the Cell-Dyn 18 Plus quality control package inserts containing Lot number, Expiration date, target means, and ranges were not retained for 2020. 2. Interview with testing personnel #1, on the CMS Form 209, on March 24, 2021 at 1325 hours in the breakroom confirmed QC package inserts for 2020 were not retained.
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 review of the laboratory's policy and procedure and interview, the laboratory failed to perform calibrations every 6 months for the CELL-DYN Emerald hematology analyzer used to test Complete Blood Counts. Findings follow. 1. Review of the laboratory's policy and procedure titled CBC CELL DYN Emerald, effective 10 /01/2015 (see D5407), under CALIBRATION stated, "Calibration of the Cell-Dyn Emerald should occur at least once every 6 months or any time quality control values indicate that the instrument is 'out' of calibration." 2. Review of the maintenance log

	report printed from the instrument showed calibrations had been performed: a. 03/21 /2019, and b. 09/24/2019 (19 months had elapsed). 3. Interview with testing personnel #1, on the CMS Form 209, on March 24, 2021 at 1015 in the breakroom acknowledged they probably did not do calibrations in 2020, and confirmed they were due for another calibration.
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 the laboratory's policy and procedures, interview, and CMS Form 116, the current laboratory director failed to approve, sign and date the laboratory procedures prior to use. Findings follow. 1. Review of the laboratory's policy and procedure titled General Laboratory Policies, effective 03/07/2001, under Procedure Manual Review stated, "the procedure manual will be reviewed at least annually by the laboratory director." 2. Review of the Policy and Procedure Manual Documentation of Review stated, "all procedures in this manual are approved by the Director at the time of adoption and/or revision. Additionally, the Laboratory Director reviews the manual on an annual basis to ensure that all policies and procedures reflect the current testing and operating practices of the laboratory..." showed the last review by the previous Laboratory Director was on 10/25/2017. 3. Review of the laboratory's policy and procedure titled CBC CELL-DYN Emerald, showed the Technical Consultant signed the procedure on 10/01/2015, and the previous Laboratory Director had signed the procedure. 4. Interview with testing personnel #1 on March 24, 2021 at 1500 confirmed the current laboratory director had not signed the laboratory's policies and procedures. 5. Review of CMS Form 116 submitted by the laboratory for a change in Laboratory Director was signed by the current Laboratory Director on 03/06/2020.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory policy and procedures, test reports, and interview, the laboratory failed to follow the manufacturer's instructions for verifying the Complete Blood Count (CBC) indicies with flags tested on the CELL-DYN Emerald on 1 of 1 test reports reviewed with flags. Findings follow. 1. Review of the CELL-DYN Emerald Operator's Manual, 9140846F April 2012, under Section 3 Instrument alarms, Operational Alerts, and Measured Data Flags section WBC Measurand Flags starting on page 3-13 stated, "An Asterisk (*) for count invalidation of (s) suspect measurand flags are displayed with the corresponding results. These flags are generated after the instrument evaluates the measured data for a particular measurand or group of measurands. The result may be

	suspect due to interfering substances or the inability of the instrument to measure a measurand due to a sample abnormality. The name of each flag, how it is displayed, the cause of the flag, and the action to be taken are given in the following explanations." Multiple error flags were listed, including WBC (White Blood Cell) and Differential for the "*" which stated under "Action": "Check the specimen for clots or agglutination. Follow your laboratory's review criteria or review a stained smear to confirm the differential results and verify the WBC count. Redraw and retest the specimen as required." 2. Review of the laboratory's policy and procedure titled CBC CELL-DYN Emerald, effective 10/01/2015 (see D5407), on page 2 under Patient Testing stated, "5. When the cycle is complete, check results for alerts or flags, abnormal results and critical values. 6. Scan the CBC report in the Electronic Medical Record according to the laboratory's EMR reporting policy." 3. Review of instrument printouts from the patient's chart showed a. ID # 00001, at sequence 00009, tested on 10/02/2020 reported the White Blood Cell Differential results including Lymphocytes %, Mids %, Granulocytes %, absolute Lymphocytes, absolute Mids, and absolute Granulocytes, with the * flag. No other test reports were available to verify the counts. 4. Interview with testing personnel #1 on March 24, 2021 at 1340 hours in the breakroom confirmed the testing person should have rerun the sample and redraws if necessary. KEY EMR= Electronic Medical Record
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, temperature charts and interview, the laboratory failed to perform and document corrective action when the laboratory's room temperature exceeded the acceptable range for the CELL-DYN Emerald hematology analyzer used for testing Complete Blood Counts. Findings follow. 1. Review of the CELL-DYN Emerald Operator's Manual, 9140846F - April 2012, for Site Requirements on page 2-3 under Space Requirements stated, "To ensure the instrument and reagents function properly, it is important to maintain the temperature between 64-90 degrees Fahrenheit (18- 32 degrees Celsius)." 2. Review of the Room Temperature/Humidity Log From 01/04/2021 to 03/24/2021 showed the acceptable temperature range was 68 - 86 degrees Fahrenheit (20-30 degrees Celsius)". The following are dates with the laboratory room temperatures recorded in Fahrenheit: 01 /12/2021: 63.6 01/13/2021: 62.5 02/11/2021: 63.5. No documentation of corrective action was documented for the out of range temperatures. 3. Interview with testing personnel #1, on the CMS Form 209, on March 24, 2021 at 0935 hours in the breakroom acknowledged they were unable to adjust the thermostat because it controls all the rooms and one room may be cooler or warmer, and confirmed there was no documentation of corrective action taken for the out of range temperatures.

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 the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of annual competencies being performed by the technical consultant in 2019 and 2020. The findings were: 1. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of the technical consultant performing annual competency assessments for 8 of 8 testing personnel in 2019 and 2020. The assessments were performed by testing personnel #1 who did not qualify as a technical consultant. 2. The laboratory was asked to provide documentation of its designated technical consultant (as listed on CMS Form-209) performing the annual competencies in 2019 and 2020. No documentation was provided. 3. An interview with testing personnel #1 (as listed on CMS Form-209) on March 24, 2021 at 13:30 hours in the break room confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services