Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0994691	12/22/2021
Name of Provider or Supplier	**Street Address, City, State**	
All Children's Pediatric Clinic P A	6900 N 10th Ste 8, Mcallen, 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 representatives at the entrance and exit conferences. The facility representatives were given an opportunity to provide evidence of compliance with the noted deficiency, 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 certification 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.
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 policies, review of patient test records, and staff interview, it was revealed the laboratory failed to follow it policies for repeating complete blood count (CBC) results. The findings include: 1. A review of the laboratory's policy titled "Policy for Repeating CBC Tests" (approved by the laboratory director on 10/01/2015 and posted in the laboratory above the analyzer) revealed: "In an effort to ensure accuracy in patient CBC testing, it is the policy of this laboratory to repeat tests when patient results are outside the following range: RBC Less than 3.5 or greater than 7.0 million WBC Less than 2.5 or greater than 22

	thousand HCT Less than 27% or greater than 48% HBG Less than 9 or greater than 16 mg/% PLT Less than 100 or greater than 450 thousand" 2. A sampling of patient test results from December 14, 2021 to December 17, 2021 identified the following patient results which met the laboratory's criteria for repeat testing, however the laboratory failed to have documentation of repeat testing being performed: a) Date: 12 /14/2021 Specimen ID: 3-30-07 HGB: 17.2 HCT: 51.0 b) Date: 12/16/2021 Specimen ID: 4-18-20 WBC: 24.8 c) Date: 12/17/2021 Specimen ID: 4-18-20 WBC: 23.5 d) Date: 12/17/2021 Specimen ID: 11-12-4 HGB: 16.6 HCT: 50.2 e) Date: 12/17/2021 Specimen ID: 6-14-7 HGB: 16.5 HCT: 51.2 3. The laboratory was asked to provide documentation of repeat testing as required by its policy. No documentation was provided. 4. An interview with the technical consultant on 12/22/2021 at 1500 hours in exam room 4 - after her review of the records- confirmed the findings. KEY RBC - red blood cell WBC- white blood cell HGB- hemoglobin HCT- hematocrit
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the Sysmex XP-300, review of patient test records, and staff interview, it was revealed the laboratory failed to have documentation of performing corrective actions on flagged complete blood cell (CBC) results. The findings include: 1. A review of the manufacturer's instructions for the Sysmex XP-300 (XP-300 Quick Guide- Document Number 1051-CFL, Revision 2, June 2014) revealed the manufacturer identified a list of error flags which were possible on CBC results which would indicate possible incorrect values. An example is: AG - The particle count equal to or less than the LD exceeds a prescribed range. Probable cause is platelet agglutination, which does not alter the WBC count, but may results in decrease platelet count. 2. A sampling of patient test records from 12/17 /2021 to 12/22/2021 identified the following patient results with AG flags however the laboratory failed to perform corrective actions prior to reporting the results to the provider: a) Date: 12/17/2021 Specimen ID: 6-2-21 b) Date: 12/17/2021 Specimen ID: 09-23-15 c) Date: 12/18/2021 Specimen ID: 1-7-18 d) Date: 12/18/2021 Specimen ID: 1-23-21 e) Date: 12/18/2021 Specimen ID: 9-8-9 f) Date: 12/19/2021 Specimen ID: 9-22-19 g) Date: 12/19/2021 Specimen ID: 9-11-20 h) Date: 12/19 /2021 Specimen ID: 7-6-21 i) Date: 12/20/2021 Specimen ID: 7-8-15 j) Date: 12/20 /2021 Specimen ID: 8-13-17 k) Date: 12/20/2021 Specimen ID: 8-23-11 l) Date: 12/21 /2021 Specimen ID: 10-9-10 m) Date: 12/21/2021 Specimen ID: 7-30-3 n) Date: 12/21 /2021 Specimen ID: 8-26-11 3. The laboratory was asked to provide documentation of performing corrective actions to resolve the flagged results prior to reporting the results to the providers. No documentation was given. 4. An interview with the technical consultant on 12/22/2021 at 1545 hours in exam room 4 - after her review of the records- confirmed the findings.
D5813	TEST REPORT CFR(s): 493.1291(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result

	indicates an imminently life-threatening condition, or panic or alert values. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, review of patient test records, and staff interview, it was revealed the laboratory failed to have documentation of documenting the notification of critical values. The findings were: 1. A review of the laboratory's policy titled "Reporting Critical Values" (approved by the laboratory director on 9/1 /2014) stated: "It is the policy of this laboratory to document the reporting of Critical Values. Document: 1. Who was notified 2. When was the person notified 3. By whom was the person notified 2. A review of the laboratory's policy titled "Critical Values" (approved by the laboratory director on 9/1/2014) revealed the laboratory defined the following values as 'critical': WBC under 2 or over 22 HGB under 7.5 or over 18 HCT under 25 or over 55 Platelets under 50 or over 800 3. A sampling of patient results from December 2021 identified the following patient results with critical values for which the laboratory did not have documentation of the reporting of the critical values: a) Date: 12/16/2021 Specimen ID: 4-18-20 WBC: 24.8 b) Date: 12/17/2021 Specimen ID: 4-18-20 WBC: 23.5 4. The laboratory was asked to provide documentation of the notification of the critical values as required by its policy. No documentation was provided. 5. An interview with the technical consultant on 12/22 /2021 at 1530 hours in exam room 4 - after her review of the records- confirmed the findings. KEY WBC - white blood cell HGB - hemoglobin HCT - hematocrit
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: Based on review of laboratory records, manufacturer's instructions, patient reports, and confirmed in interview of laboratory personnel, the technical consultant failed to identify training needs of testing personnel. The findings include: Testing personnel were not: 1. Following the laboratory's policies (refer to D5401 and D5813). 2. Resolving flags on complete blood count. (refer to D5779).