Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1082475	03/07/2024
Name of Provider or Supplier	**Street Address, City, State**	
All Childrens Pediatric Clinic Pa	4221 North Conway Suite D, Palmhurst, 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
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 upon review of the laboratory's verification study for the Horiba Micros (Serial number 111CS99869) hematology analyzer (completed May 19,2022), the laboratory's own written policy, the manufacturer specifications, patient test records and interview of facility personnel, the laboratory failed to verify the reference ranges for the parameters of the Complete Blood Count (CBC) were appropriate for the patient population before testing patient specimens. The laboratory reported an annual volume of 36,000 Hematology tests. The findings included: 1. Review of the Horiba Test System Validation form (signed by the laboratory director on 05/19/2024) found written next to Reference Range a note that read In Progress) with no documentation of approval. 2. Review of the laboratory's own written policy titled Validation of a New Test System (signed by the laboratory director with no date) found on page 1: "It is the policy of this lab to validate a new test system prior to using it to report patient results." 3. Review of the manufacturer specifications found on page 11 in Table 1-11 under the heading normal Ranges: WBC (White Blood Cells): Male 4.7 - 9.6 10 3/ mm3 Female 4.9 - 12.3 10 3/ mm3 RBC (Red Blood Cells): Male 4.7-6.1 10 6/ mm3 Female 4.2-5.4 10 6/ mm3 HGB (Hemoglobin): Male 13.5 - 16.5 g/dl Female 12.0 - 15.0 g/dl Hct (Hematocrit): Male 41-50% Female 37-45% MCV (Mean Corpuscular Volume): Male 83 - 101 um3 Female 84-96 um3 MCH (Mean Corpuscular

	Hemoglobin): Male 26-34 pg Female 27 - 34 pg MCHC(Mean Corpuscular Hemoglobin Concentration): 32-35 g/dl RDW(Red Cell Distribution Width): Male 12 - 16 % Female 12 - 14 % Plt (Platelet): Male 145 - 355 10 3/mm/3 Female 150 - 330 10 3/mm/3 MPV(Mean Platelet Volume) 7.3 - 9.0 um3 Granulocyte %: Male 49 - 74 Female 53 - 79 Lymphocyte%: Male 23 - 47 Female 19 - 41 Monocyte%: Male 3 - 6 Female 2 - 6 3. Review of 4 final patient reports for male and female patients between the ages of 1 and 15 years found the following reference ranges: Male: WBC 3.5 - 10 x10^3 RBC 3.8 - 5.8 x10^6 Hgb 11.0 - 16.5 g/dL Hct 35 - 50 % MCV 6.5 -11 um^3 MCH 26.5.0 - 33.5 pg MCHC 31.5 - 35.0 g/dL RDW 10 - 15 % Plt 150 - 450 x10^3 MPV 6.5 - 11.0 um^3 Gran % 43 - 76 % Lymph% 17 - 48 % Mono% 4 - 6% 4. During interview of the technical consultant conducted March 7, 2024 at 10:21 AM, she confirmed the laboratory had not verified the reference ranges for pediatric populations. She went on to say that the laboratory should have verified 3 different reference ranges for patients between the ages of newborn and 18 years of age.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based upon review of the laboratory's verification study for the Horiba Micros (Serial number 111CS99869) hematology analyzer (completed May 19,2022), the laboratory's own written policy, the manufacturer specifications, patient test records and interview of facility personnel, the laboratory director failed to ensure the reference ranges for the parameters of the Complete Blood Count (CBC) were appropriate for the patient population before testing patient specimens. (See D 5421)