

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D0680723	<b>(X3) Date Survey Completed</b>  09/27/2021
<b>Name of Provider or Supplier</b>  Alice Pediatric Clinic	<b>Street Address, City, State</b>  305 E 3rd, Alice, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The laboratory was surveyed and found to be in compliance with the conditions of participation found in the CLIA regulations at 42 CFR 493 and recertification is recommended.
<b>D5421</b>	<p><b>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE</b> CFR(s): 493.1253(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's verification studies, review of patient test records and staff interview, it was revealed the laboratory failed to have documentation of verifying patient normal ranges for 3 of 3 patient normal range used for testing CBCs (complete blood count). The findings included: 1. A review of the laboratory's verification studies revealed the laboratory failed to have documentation of verifying patient normal ranges for the following three patient CBC normal ranges: Age 1: WBC 6 - 14 RBC 3.8 - 6 HGB 10.5 - 14 HCT 26 - 60 MCV 72 - 88 MCH 24 - 30 MCHC 32 - 36 RDW 11.5 - 14.5 PLT 150 - 440 MPV 0 - 99.8 LYM % 24 - 72 LYM# 0.6 - 4.9 MON% 0.1 - 24 MON# 0 - 1.8 GRA% 37 - 92 GRA# 1.5 - 7.5 Age 14 Female: WBC 4 - 10 RBC 3.8 - 6 HGB 12.5 - 18 HCT 36.1 - 51 MCV 78 - 97 MCH 27 - 31 MCHC 32 - 36 RDW 11.5 - 14.5 PLT 150 - 440 MPV 0 - 99.8 LYM % 10 - 58.5 LYM# 0.6 - 4.9 MON% 0.1 - 24 MON# 0 - 1.8 GRA% 37 - 92 GRA# 1.5 - 8 Age 19 Male: WBC 3.5 - 10 RBC 3.8 - 5.8 HGB 11 - 16.5 HCT 35 - 50 MCV 80 - 97 MCH 26.5 - 33.5 MCHC 31.5 - 35 RDW 10 - 15 PLT 150 - 450 MPV 6.5 - 11 LYM</p>

% 17 - 48 LYM# 1.2 - 3.2 MON% 4 - 10 MON# 0.3 - 0.8 GRA% 43 - 76 GRA# 1.5 - 8 2. Review of patient records revealed the listed CBC ranges were in use for patient testing. 3. The laboratory was asked to provide documentation of verifying the patient normal ranges currently in use. No documentation was provided. 4. An interview with the technical consultant on 09/27/2021 at 11:00 hours in the break room - after his review of the records- confirmed the findings.