

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1003967	(X3) Date Survey Completed 09/01/2022
Name of Provider or Supplier Ridgewood Medical Clinic	Street Address, City, State 219 W Kingsley Rd Ste 336, Garland, 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 was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. .
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE 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 a review of the laboratory's verification records, the laboratory's reference ranges, and staff interview, it was revealed that the laboratory failed to have documentation of verifying 3 of 3 patient normal ranges for Complete Blood Count (CBC) testing on the Drew Scientific D3 hematology analyzer. Findings include: 1. A review of the laboratory's verification records for the Drew Scientific D3 hematology analyzer revealed verification studies were performed in October 2021. 2. Further review of the laboratory's verification records revealed the laboratory failed to have documentation of verifying the following 3 patient normal ranges for CBC testing on the Drew Scientific D3 hematology analyzer: a) Pediatric (age 0-2 years): WBC 6.0 - 14.0 LYM# 1.8 - 6.6 MID# 0.1 - 1.0 GRA# 1.1 - 8.0 LYM% 25.0 - 50.0 MID% 2.0 - 10.0 GRA% 45.0 - 65.0 RBC 3.80 - 5.40 HGB 10.5 - 14.0 HCT 32.0 - 42.0 MCV 72.0 - 88.0 MCH 30.0 - 30.0 MCHC 32.0 - 36.0 RDW 11.5 - 16.0 PLT 150 - 400 MPV 6.0 - 9.5 b) Pediatric (age 2-18 years): WBC 4.0 - 10.5 LYM# 1.0 - 3.5 MID# 0.1 - 1.0</p>

GRA# 1.5 - 6.6 LYM% 25.0 - 40.0 MID% 2.0 - 10.0 GRA% 45.0 - 70.0 RBC 4.20 - 5.60 HGB 12.0 - 16.0 HCT 35.0 - 47.0 MCV 78.0 - 95.0 MCH 26.0 - 32.0 MCHC 32.0 - 36.0 RDW 11.5 - 14.0 PLT 150 - 400 MPV 6.0 - 9.5 c) Adult: WBC 4.0 - 12.0 LYM# 1.0 - 5.0 MID# 0.1 - 1.0 GRA# 2.0 - 8.0 LYM% 25.0 - 50.0 MID% 2.0 - 10.0 GRA% 50.0 - 80.0 RBC 4.00 - 6.20 HGB 11.0 - 17.0 HCT 35.0 - 55.0 MCV 80.0 - 100.0 MCH 26.0 - 34.0 MCHC 31.0 - 35.5 RDW 10.0 - 16.0 PLT 150 - 400 MPV 7.0 - 11.0 3. An interview with the technical consultant on 9/1/22 at 10:10 a.m. in the break room, after review of the records, confirmed the above findings. Key: WBC - white blood cell RBC - red blood cell HGB - hemoglobin HCT - hematocrit MCV - mean corpuscular volume MCH - mean corpuscular hemoglobin MCHC - mean corpuscular hemoglobin concentration RDW- red cell distribution width PLT - platelet MPV - mean platelet volume LYM - lymphocytes MID - monocytes, basophils, eosinophils GRAN - granulocytes