

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0670712	(X3) Date Survey Completed 08/26/2026
Name of Provider or Supplier Pediatric Associates At Ridge Road	Street Address, City, State 1200 East Ridge Road # 12, 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
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the Sysmex hematology analyzer, review of patient test records from July 2026 and August 2026, and staff interview, the laboratory failed to identify that 5 of 15 flagged CBC (complete blood count) results were reported to the provider. The findings included: 1. The manufacturer's instructions for the Sysmex XN-330 hematology analyzer (Revised June 2017) stated: "If an Positive or Error judgment occurs, check the data and repeat the analysis, or examine carefully in accordance with the protocol of the laboratory." 2. "A review of patient test records from June 2026 and August 2026 identified 5 of 5 "positive results" which were reported to the provider. They were: a) Date: 07/08 /2026 Order number: 2607080005 Flagged result: White blood cell b) Date: 07/10 /2026 Order number: 2607100020 Flagged result: White blood cell c) Date: 07/17 /2026 Order number: 2607170017 Flagged result: White blood cell d) Date: 07/21 /2026 Order number: 2607210010 Flagged results: White blood cell Neutrophils absolute Neutrophils percent Lymphocytes absolute Lymphocytes percent Monocytes absolute Monocytes percent Eosinophils absolute Eosinophils percent Basophils absolute Basophils percent IG absolute IG percent e) Date: 08/24/2026 Order number: 2608240025 Flagged result: Mean Platelet Volume 3. The technical consultant confirmed the findings in an interview conducted on 08/26/2026 at 1115 hours in the of
D5813	TEST REPORT CFR(s): 493.1291(g)

(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 procedures, review of patient test records from June 2026, and staff interview, the laboratory failed to have documentation of the notification of 1 of 1 critical values. The findings included: 1. The laboratory's procedure titled "Medical Alert Values" defined hematology critical values as: White blood cells less than 2.0 greater than 20 Hemoglobin less than 6.0 greater than 18.0 Hematocrit less than 18.0 greater than 60.0 Platelets less than 50 greater than 700 2. The laboratory's procedure titled "Reporting Critical Values" stated: "It is the policy of this laboratory to document the reporting of Critical Values. Document: Who was notified When was the person notified By whom was the person notified" 3. A sampling of critical values from June 2026 identified 1 of 1 critical values, however the laboratory failed to document the required information: a) Date: 06/01/2026 Order Number: 2606010019 White Blood Cell: 22.36 4. The technical consultant confirmed the findings in an interview conducted on 08/27/2026 at 1000 hours in the office.