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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 45D0503928 | (X3) Date Survey Completed 09/23/2025 |
| Name of Provider or Supplier Rainbow Pediatric Clinic | Street Address, City, State 902 S Airport Drive Ste 1, Weslaco, 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 |
|---------------------------|--|
| D5401 | <p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the manufacturer instructions, review of the laboratory's procedures, review of patient test records from May 2025 and August 2025, and staff interview, the laboratory failed to following its procedures for: A) Flagged Complete Blood Count results B) Repeat Complete Blood Count results The findings included: A) Flagged Results 1. A review of the the manufacturer's instructions for the Sysmex XN-330 hematology analyzer (Code no. AK803790, Revision: June 2017) under the section titled "5.11.2 Display of analysis result data" determined: Display: [*] Meaning: Low Reliability Description: Indicates that the reliability of the data is low 2. A review of the laboratory's procedure titled "Policy for Handling Abnormal CBC's and their Flags" (approved 12/30/2020) determined: "It will be the policy if [sic] this laboratory to evaluate every CBC and handle any flags displayed prior to releasing the result. Post evaluating the CBC, the lab staff can repeat the analysis if enough sample is collected or performed a re-collection. A normal CBC will include normal cells: Lymphocytes, Monocytes, Basophils, Neutrophils, Eosinophils and normal size and shape RBC's and Platelets. If you CBC instrumentation is showing alarms or flags, it will be considered abnormal. The lab will send out the specimen for peripheral smear or manual diff if quantity is sufficient to the Reference Lab. All abnormal flagged results will be crossed out." 3. A sampling of patient test results from May 2025 and August 2025 identified the following patient results reported the provider with flags (see patient alias list): a) May 30, 2025 Patient 1 Flag: [*] Analytes: White blood cell Neutrophil count Neutrophil percent Lymphocyte count Lymphocyte percent</p> |

Monocyte count Monocyte percent Eosinophil count Eosinophil percent Basophil count Basophil percent Immature granulocyte count Immature granulocyte percent Patient 2 Flag: [*] Analytes: White blood cell Neutrophil count Neutrophil percent Lymphocyte count Lymphocyte percent Monocyte count Monocyte percent Eosinophil count Eosinophil percent Basophil count Basophil percent Immature granulocyte count Immature granulocyte percent b) August 21, 2025 Patient 3 Flag: [*] Analytes: Platelet Mean Platelet Volume c) August 22, 2025 Patient 4 Flag: [*] Analytes: Platelet Mean Platelet Volume d) August 26, 2025 Patient 5 Flag: [*] Analytes: Neutrophil count Neutrophil percent Lymphocyte count Lymphocyte percent Monocyte count Monocyte percent Immature granulocyte count Immature granulocyte percent e) August 29, 2025 Patient 6 Flag: [*] Analytes: Platelet Mean Platelet Volume Patient 7 Flag: [*] Analytes: Neutrophil count Neutrophil percent Lymphocyte count Lymphocyte percent Monocyte count Monocyte percent Immature granulocyte count Immature granulocyte percent Patient 8 Flag: [*] Analytes: White blood cell Platelet Mean Platelet Volume Neutrophil count Neutrophil percent Lymphocyte count Lymphocyte percent Monocyte count Monocyte percent Immature granulocyte count Immature granulocyte percent 4. The technical consultant confirmed the findings in an interview conducted on 09/23/2025 at 1015 hours in the break room. B) Repeat CBC results 1. A review of the laboratory's procedure titled "Policy for repeating CBC's and Communicating Critical Values" (approved 12/30/2020) determined: "In an effort to ensure accuracy in patient CBC testing, it is the policy of this laboratory to repeat tests when these are critical." The procedure then defined the follow ranges for repeat testing: WBC: less than 2 or greater than 20 HGB: less than 7.5 or greater than 18 HCT: less than 25 or greater than 55 PLT: less than 50 or greater than 800 2. A review of patient test records from August 2025 identified the following result which met the laboratory's criteria for repeat testing, however the laboratory failed to have documentation of repeating the test (see patient alias list: a) August 25, 2025 Patient 9 Analytes: HGB: 24.5 HCT: 70.4 3. The technical consultant confirmed the findings in an interview conducted on 09/23/2025 at 1015 hours in the break room. Key WBC: white blood cell HGB: hemoglobin HCT: hematocrit PLT: platelet

D5779

CORRECTIVE ACTIONS
CFR(s): 493.1282(a)

(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 laboratory's room temperature records from February 2025, and staff interview, the laboratory failed to have documentation of performing corrective actions on 15 of 24 days when room temperatures were documented outside the laboratory's acceptable range. The findings included: 1. A review of the laboratory's room temperature records from February 2025 determined the laboratory defined the acceptable room temperature range as 68-77 F. 2. Further review of the laboratory's room temperature records from February 2025 identified the following 15 of 24 work days when the room temperature was documented outside the laboratory's acceptable range, however the laboratory failed to have documentation of performing corrective actions. Date Temp 2/1 67 F 2/3 67 F 2/4 67 F 2/5 67 F 2/6 67 F 2/7 67 F 2

/8 67 F 2/10 66 F 2/11 67 F 2/12 67 F 2/24 67 F 2/25 67 F 2/26 67 F 2/27 67 F 2/28 67 F 3. The technical consultant confirmed the findings in an interview conducted on 09/23/2025 at 1030 hours in the break room. Key F - Fahrenheit

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 August 2025 and staff interview, the laboratory failed to have documentation of the notification of 1 of 1 critical results. 1. A review of the laboratory's procedure titled "Policy for repeating CBC's and Communicating Critical Values" (approved 12/30 /2020) determined: "In an effort to ensure accuracy in patient CBC testing, it is the policy of this laboratory to repeat tests when these are critical. The laboratory will immediately notify the requestor or user about lab results in the CRITICAL range." The laboratory's procedure then defined the following result ranges requiring repeat testing: WBC: less than 2 or greater than 20 HGB: less than 7.5 or greater than 18 HCT: less than 25 or greater than 55 PLT: less than 50 or greater than 800 2. A review of the laboratory's procedure titled "Reporting Panic Values" (approved 3/2/2000) determined: "It is the policy of this laboratory to document the reporting of panic values. Document: - who was notified - when was the person notified - by whom was the person notified" 3. A review of patient test results from August 2025 identified the following patient sample which met the laboratory's criteria for a critical value, however the laboratory failed to have documentation of the notification to the provider: a) Date: 08/25/2025 Patient 9 HGB: 24.5 HCT: 70.4 4. The technical consultant confirmed the findings in an interview conducted on 09/23/2025 at 1015 hours in the break room. Key: WBC: white blood cell HGB: hemoglobin HCT: hematocrit PLT: platelet