

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1032356	(X3) Date Survey Completed 06/12/2025
Name of Provider or Supplier All Children's Pediatric Clinic, Pa	Street Address, City, State 1313 S Closner Suite # A, Edinburg, 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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's proficiency testing records from 2023, 2024 and 2025, and staff interview, the laboratory failed to ensure 4 of 7 testing personnel participated in proficiency testing for hematology. The findings included: 1. A review of the laboratory's submitted Form CMS 209 determined the facility identified 7 personnel who performed hematology testing. 2. A review of the laboratory's American Proficiency Institute's proficiency testing records from 2023 (events 2 and 3), 2024 (events 1, 2, and 3) and 2025 (event 1) determined only testing personnel #3, #5 and #7 participated in proficiency testing. The records showed: a) 2023 Event 2 performed by testing personnel #3 b) 2023 Event 3 performed by testing personnel #7 c) 2024 Event 1 performed by testing personnel #3 d) 2024 Event 2 performed by testing personnel #5 e) 2024 Event 3 performed by testing personnel #3 f) 2025 Event 1 performed by testing personnel #3 3. The technical consultant confirmed the finding in an interview conducted on 06/12/2025 at 0903 hours in the manager's office.</p>
D2010	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples.</p>

This STANDARD is not met as evidenced by:
 Based on review of laboratory policy, review of the laboratory's American Proficiency Institute (API) proficiency testing records from 2023 and 2024, and staff interview, the laboratory failed to test proficiency testing samples the same number of times as patient samples for 11 of 30 samples. The findings were: 1. A review of the laboratory's policy titled, "Proficiency Testing" determined: "PT specimens are to be treated the same as patient samples." 2. A review of the laboratory's policy titled, "Critical Values" (approved on August 10, 2015) determined: "The laboratory Personnel will repeat all CBC's outside the critical/panic value range ..." It went on to list the following critical value ranges: WBC 2.0 - 22.0 cu.mm HGB 7.5 - 18 g/dL HCT 24 - 55 % PLT 50 - 800 cu.mm 3. Review of the laboratory's API proficiency testing records from 2023 (events 1, 2 and 3) and 2024 (events 1, 2 and 3) identified the laboratory tested the following proficiency testing samples twice even though they did not meet the laboratory's repeat criteria policy. a) 2023 Hematology (event 1) Sample ID: HSY-05 Run 1: 03/10/2023 @ 16:22 Run 2: 03/10/2023 @ 16:24 b) 2023 Hematology (event 2) Sample ID: HSY-06 Run 1: 07/12/2023 @ 11:31 Run 2: 07/12/2023 @ 11:32 Sample ID: HSY-09 Run 1: 07/12/2023 @ 11:38 Run 2: 07/12/2023 @ 11:45 Sample ID: HSY-10 Run 1: 07/12/2023 @ 11:43 Run 2: 07/12/2023 @ 11:44 c) 2023 Hematology (event 3) Sample ID: HSY-12 Run 1: 11/15/2023 @ 16:00 Run 2: 11/15/2023 @ 16:02 Sample ID: HSY-13 Run 1: 11/15/2023 @ 16:03 Run 2: 11/15/2023 @ 16:04 Sample ID: HSY-14 Run 1: 11/15/2023 @ 16:05 Run 2: 11/15/2023 @ 16:07 d) 2024 Hematology (event 1) Sample ID: HSY-04 Run 1: 03/20/2024 @ 10:51 Run 2: 03/20/2024 @ 16:48 e) 2024 Hematology (event 2) Sample ID: HSY-09 Run 1: 07/22/2024 @ 16:40 Run 2: 07/22/2024 @ 16:47 Sample ID: HSY-10 Run 1: 07/22/2024 @ 16:50 Run 2: 07/22/2024 @ 16:51 f) 2024 Hematology (event 3) Sample ID: HSY-11 Run 1: 11/19/2024 @ 12:19 Run 2: 11/19/2024 @ 12:21 4. The technical consultant confirmed the findings in an interview conducted on 06/12/2025 at 900 hours in the manager's office. Key: CBC - complete blood count WBC - white blood cell HGB - hemoglobin HCT - hematocrit PLT - platelet cu.mm - cubic millimeter g/dL - grams per deciliter CMS - Centers for Medicare and Medicaid Services

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 policies, review of the laboratory's critical value log from April 26, 2025 - June 9, 2025, review of patient test records from April 26, 2025 - June 9, 2025 and staff interview, the laboratory failed to have documentation of the notification of 4 of 11 critical values as required by its policy. The findings included: 1. A review of the laboratory's policy titled "Critical Values" (approved August 10, 2015) identified the laboratory's policy for the documentation of critical values as: "The Laboratory Personnel will repeat all CBC's outside the critical/panic value range and immediately notify provider. Documentation must include: Who was notified, when was the person notified, and by who was the person notified." The policy defined the laboratory's critical values as: WBC 2.0 - 22.0 cu.mm HGB 7.5 - 18 g/dL HCT 24 - 55 % PLT 50 - 800 cu.mm 2. A review of the laboratory's critical value log from April 26, 2025 - June 9, 2025 determined the laboratory documented the

notification of 7 critical values. 3. A review of patient test records from April 26, 2025 - June 9, 2025 identified 4 additional critical values which were not documented on the critical value log. They were: a) test date: 4/26/2025 patient ID: 12-15-18 WBC: 22.8 b) test date: 5/08/2025 patient ID: 10-29-17 WBC: 25.3 c) test date: 5/14/2025 patient ID: 4-25-20 WBC: 22.6 d) test date: 6/9/2025 patient ID: 12-22-13 WBC: 22.1

4. The technical consultant confirmed the finding in an interview conducted on 06/12/2025 at 10:16 hours in the manager's office.