

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1018588	(X3) Date Survey Completed 07/25/2022
Name of Provider or Supplier All Childrens Pediatric Clinic	Street Address, City, State 626 North Texas Blvd, 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
D0000	<p>Noted deficiencies and plans of correction were discussed with the laboratory representatives at the entrance and exit conferences. The facility representatives were given an opportunity to provide evidence of compliance with the noted deficiency, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and certification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.</p>
D5405	<p>PROCEDURE MANUAL CFR(s): 493.1251(c)</p> <p>Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory.</p> <p>This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the Horiba hematology analyzer, review of patient test results, and staff interview, the laboratory failed to have documentation of a policy for resolving flags on CBC (complete blood count) results for 15 of 15 random patient results that required follow up from April 2022 to May 2022. The findings were: 1. A review of the manufacturer's instructions for the Horiba hematology analyzer (Document No. D00A00212) under the section titled 'Flags' listed the following morphological alerts: L1 - abnormal cell number on the left side (30-60 fl) of WBC distribution curve. Possible platelet aggregates or nucleated</p>

RBC's. M2 - excessive cell number in the 130-160 fl zone. Possible lymphoblasts, myelocytes, atypical lymphocytes or basophilia. G1 - excessive cell number in the 160-200 fl zone. Possible eosinophilia, myelocytes or polynucleated neutrophils. G2 - excessive cell number in 220-250 fl zone. This flag follows abnormal granulocyte peak displacement. Possible granulocyte membrane anomalies, lyse flow problem, old blood or granulocyte cell size than 250 fl. G3 - excessive cell number larger than 400 fl. Possible metamyelocytes or large immature cells. SCH - excessive cell number between 18-25 fl, suspect presence of schizocytes or platelet aggregates. Verify platelet on a stained smear. 2. A sampling of patient test results from April 2022 to May 2022 identified the following patient results which were reported to the provider with flags on the differential portion of the results: Date Last 4 digits of ID Flag(s) 04-30-2022 H007 G1, G2 05-01-2022 A008 G1 05-02-2022 A005 G2 05-02-2022 U001 G1, G2 05-02-2022 O003 M2, G1, G2 05-02-2022 E012 G1, G2 05-02-2022 E013 M2, G1, G2 05-02-2022 L042 M2, G1, G2 05-02-2022 A012 G1 05-02-2022 T001 G1 05-02-2022 Y001 M2, G1, G2 05-02-2022 I000 G1, G2 05-02-2022 S000 M2,G1, G2, SCH 05-02-2022 A007 G2 05-02-2022 A000 G1,G2 3. The laboratory was asked to provide documentation of a policy to resolve flags prior to their release to the healthcare provider. No documentation was provided. 4. An interview with the laboratory owner on July 27, 2022 at 1430 hours in the patient exam room confirmed the findings.

D5469

CONTROL PROCEDURES
CFR(s): 493.1256(d)(10)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's quality control records and staff interview, it was revealed the laboratory failed to have documentation of verifying 2 of 4 lot numbers of Pentra hematology quality controls from October 2021 to July 2022. The findings included: 1. A review of the laboratory's quality control records from October 2021 to July 2022 found the following 2 of 4 lot numbers had no documentation of being verified prior to use: Lot: M434 Lot: M436 2. The laboratory was asked to provide documentation of verifying each new lot prior to placing it into use. No documentation was provided. 3. An interview with the technical consultant on 07/25 /2022 at 15:00 hours - after her review of the records- confirmed the findings.

D5803

TEST REPORT
CFR(s): 493.1291(b)

Test report information maintained as part of the patient's chart or medical record

must be readily available to the laboratory and to CMS or a CMS agent upon request.

This STANDARD is not met as evidenced by:

Based on review of final patient results and confirmed in interview of facility personnel, the laboratory failed to ensure 15 of 15 randomly reviewed final patient results was available in the patient's medical record from April 2022 to May 2022. The findings were: 1. Review of the following 15 of 15 patient final reports found patients results were not available in the patient's medical record: Date Last 4 digits of ID 04-30-2022 H007 05-01-2022 A008 05-02-2022 A005 05-02-2022 U001 05-02-2022 O003 05-02-2022 E012 05-02-2022 E013 05-02-2022 L042 05-02-2022 A012 05-02-2022 T001 05-02-2022 Y001 05-02-2022 I000 05-02-2022 S000 05-02-2022 A007 05-02-2022 A000 2. The findings were confirmed in interview with the primary testing person at 15:00 in the office. She confirmed that they were scanning results to a file but not the patient chart.