

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0995218	(X3) Date Survey Completed 08/23/2023
Name of Provider or Supplier G Athanasi Orfanos Md Pediatrics	Street Address, City, State 2703 W Trenton, 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
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the Boule Con-Diff Tri-Level hematology controls, surveyor observation of control material currently in use, and staff interview, the laboratory failed to document expiration dates for three of three opened hematology controls currently in use. The findings included: 1. Review of the manufacturer's instructions for the Boule Con-Diff Tri-Level hematology controls hematology control (201043L R03.31.15) found under the heading STORAGE AND STABILITY: "Open vial stability 14 days after opening when returned to refrigerator after each use." 2. Observations made during the inspection found three vials of controls in a cup in the refrigerator. Low control lot 22305-01 expiration 2023-09-2023 with an opened date of 08/21/2023 Normal control lot 22305-02 expiration 2023-09-26 with an opened date of 08/24/2023 High control level 22305-03 expiration 2023-09-28 with an opened date of 8/23/2023 The controls did not have a date documented for the new expiration date defined by the open date on the vials in use. 3. During interview of testing person two conducted on August 23, 2023 at 10:35 AM, she confirmed the lab had not documented the new open vial expiration date and used no other means of documenting how long the controls were used.</p>
D5481	<p>CONTROL PROCEDURES CFR(s): 493.1256(f)(g)</p>

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based upon review of policies and procedures, quality control records and interview of facility personnel, the laboratory reported eighteen patient specimens when Hematology controls failed to meet the laboratory's acceptable limits on nine of thirteen days in June 2023. The findings included: 1. Review of the policy titled CONTROL POLICY (dated 1/4/11) found: "Control results shall be recorded and if controls are beyond the expected range then remedial actions must also be recorded. All control results and remedial actions must be recorded and records kept for at least two (2) years. Patient testing must not be performed or reported when control test results are outside the expected range. Use the "QC Out-Of-Limits Log Sheet" to record controls and remedial actions when controls are outside the expected range. Additionally, use the "Daily Sample Troubleshooting Checklist" found in this section, to help you resolve daily control problems. All control records and Remedial Action Sheets will be reviewed, signed/initialed and dated monthly by the Laboratory Technical Consultant. Every month the Technical Consultant will report to the Laboratory Director and the Testing Personnel his findings about the laboratory's performance of quality control, quality assurance, and proficiency testing." 2. Review of Hematology Quality Control records for June 1, 2023 through June 13, 2023 found: a. The laboratory had control failures for Boule Con-Diff Tri-Level lot 2230201 on six of thirteen days : I. June 7, 2023 - White Blood Cell (WBC)- the lab obtained a result of 3.0, with an acceptable result of 3.1 - 3.7 and no documentation of corrective actions. II. June 8, 2023 - Lymphocyte % (LYM%) - The lab obtained a result of 36.81, with an acceptable result of 37.4 - 51.4 and no documentation of corrective actions. III. June 9, 2023 - Lymphocyte % (LYM%) - The lab obtained a result of 35.91, with an acceptable result of 37.4 - 51.4 and no documentation of corrective actions. GRA% - The lab obtained a result of 57.4, with an acceptable result of 43.2-57.2 and no documentation of corrective actions. IV. June 11, 2023 - Lymphocyte % (LYM%) - The lab obtained a result of 36.2, with an acceptable result of 37.4 - 51.4 and no documentation of corrective actions. GRA% - The lab obtained a result of 57.3, with an acceptable result of 43.2-57.2 and no documentation of corrective actions. V. June 12, 2023 - White Blood Cell (WBC)- The lab obtained a result of 3.0, with an acceptable result of 3.1 - 3.7 and no documentation of corrective actions. Lymphocyte % (LYM%) - The lab obtained a result of 35.5, with an acceptable result of 37.4 - 51.4 and no documentation of corrective actions. GRA% - The lab obtained a result of 58.4, with an acceptable result of 43.2-57.2 and no documentation of corrective actions. VI. June 13, 2023 - Red Blood Cell (RBC) - The lab obtained a result of 2.39, with an acceptable result of 2.10 - 2.34 and no documentation of corrective actions. Hemoglobin (HGB) - The lab obtained a result of 5.9 with an acceptable result of 5.2-5.8 and no documentation of corrective actions. b. The laboratory had control failures for Boule Con-Diff Tri-Level lot 2230202 on seven of thirteen days as follows: I. June 5, 2023 - The laboratory obtained a result of 11.3 for HGB, with an acceptable result between 11.4 - 12.2 and no documentation of corrective actions. The laboratory obtained a result of 8.1 for WBC, with an acceptable result of 8.3-9.5 and no documentation of corrective actions. II. June 6, 2023 - The laboratory obtained a result of 8.2 for WBC, with an acceptable result of 8.3-9.5 and no documentation of corrective actions. III. June 9, 2023 -The laboratory obtained a result of 11.3 for HGB, with an acceptable result between 11.4 - 12.2 and no documentation of corrective actions. The laboratory obtained a result of 8.1 for

WBC, with an acceptable result of 8.3-9.5 and no documentation of corrective actions. IV. June 10, 2023 - The laboratory obtained a result of 3.91 for RBC, with an acceptable result of 3.97- 4.33 and no documentation of corrective actions. The laboratory obtained a result of 11.3 for HGB, with an acceptable result between 11.4 - 12.2 and no documentation of corrective actions. The laboratory obtained a result of 8.1 for WBC, with an acceptable result of 8.3-9.5 and no documentation of corrective actions. V. June 11, 2023 - The laboratory obtained a result of 11.0 for HGB, with an acceptable result between 11.4 - 12.2 and no documentation of corrective actions. The laboratory obtained a result of 7.6 for WBC, with an acceptable result of 8.3-9.5 and no documentation of corrective actions. VI. June 12, 2023 - The laboratory obtained a result of 11.1 for HGB, with an acceptable result between 11.4 - 12.2 and no documentation of corrective actions. The laboratory obtained a result of 7.2 for WBC, with an acceptable result of 8.3-9.5 and no documentation of corrective actions. VI. The laboratory obtained a result of 10.9 for HGB, with an acceptable result between 11.4 - 12.2 and no documentation of corrective actions. The laboratory obtained a result of 7.1 for WBC, with an acceptable result of 8.3-9.5 and no documentation of corrective actions. 5. During interview of the technical consultant conducted August 23, 2023 at 10:47 AM she confirmed that the laboratory tested and reported patient specimens when controls failed to meet the acceptable criteria on nine of thirteen days between June 1, 2023 and June 13, 2023.

D5781

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
Based upon review of policies and procedures, quality control records and interview of facility personnel, the laboratory failed to document corrective actions when Hematology controls failed to meet the laboratory's acceptable limits on nine of thirteen days in June 2023. The findings included: 1. Review of the policy titled CONTROL POLICY (dated 1/4/11) found: "Control results shall be recorded and if controls are beyond the expected range then remedial actions must also be recorded. All control results and remedial actions must be recorded and records kept for at least two (2) years. Patient testing must not be performed or reported when control test results are outside the expected range. Use the "QC Out-Of-Limits Log Sheet" to record controls and remedial actions when controls are outside the expected range. Additionally, use the "Daily Sample Troubleshooting Checklist" found in this section, to help you resolve daily control problems. All control records and Remedial Action Sheets will be reviewed, signed/initialed and dated monthly by the Laboratory Technical Consultant. Every month the Technical Consultant will report to the Laboratory Director and the Testing Personnel his findings about the laboratory's performance of quality control, quality assurance, and proficiency testing." 2. Review of Hematology Quality Control records for June 1, 2023 through June 13, 2023 found:

a. The laboratory had control failures for Boule Con-Diff Tri-Level lot 2230201 on six of thirteen days : I. June 7, 2023 - White Blood Cell (WBC)- the lab obtained a result of 3.0, with an acceptable result of 3.1 - 3.7 and no documentation of corrective actions. II. June 8, 2023 - Lymphocyte % (LYM%) - The lab obtained a result of 36.81, with an acceptable result of 37.4 - 51.4 and no documentation of corrective actions. III. June 9, 2023 - Lymphocyte % (LYM%) - The lab obtained a result of 35.91, with an acceptable result of 37.4 - 51.4 and no documentation of corrective actions. GRA% - The lab obtained a result of 57.4, with an acceptable result of 43.2-57.2 and no documentation of corrective actions. IV. June 11, 2023 - Lymphocyte % (LYM%) - The lab obtained a result of 36.2, with an acceptable result of 37.4 - 51.4 and no documentation of corrective actions. GRA% - The lab obtained a result of 57.3, with an acceptable result of 43.2-57.2 and no documentation of corrective actions. V. June 12, 2023 - White Blood Cell (WBC)- The lab obtained a result of 3.0, with an acceptable result of 3.1 - 3.7 and no documentation of corrective actions. Lymphocyte % (LYM%) - The lab obtained a result of 35.5, with an acceptable result of 37.4 - 51.4 and no documentation of corrective actions. GRA% - The lab obtained a result of 58.4, with an acceptable result of 43.2-57.2 and no documentation of corrective actions. VI. June 13, 2023 - Red Blood Cell (RBC) - The lab obtained a result of 2.39, with an acceptable result of 2.10 - 2.34 and no documentation of corrective actions. Hemoglobin (HGB) - The lab obtained a result of 5.9 with an acceptable result of 5.2-5.8 and no documentation of corrective actions. b. The laboratory had control failures for Boule Con-Diff Tri-Level lot 2230202 on seven of thirteen days as follows: I. June 5, 2023 - The laboratory obtained a result of 11.3 for HGB, with an acceptable result between 11.4 - 12.2 and no documentation of corrective actions. The laboratory obtained a result of 8.1 for WBC, with an acceptable result of 8.3-9.5 and no documentation of corrective actions. II. June 6, 2023 - The laboratory obtained a result of 8.2 for WBC, with an acceptable result of 8.3-9.5 and no documentation of corrective actions. III. June 9, 2023 -The laboratory obtained a result of 11.3 for HGB, with an acceptable result between 11.4 - 12.2 and no documentation of corrective actions. The laboratory obtained a result of 8.1 for WBC, with an acceptable result of 8.3-9.5 and no documentation of corrective actions. IV. June 10, 2023 - The laboratory obtained a result of of 3.91 for RBC, with an acceptable result of 3.97- 4.33 and no documentation of corrective actions. The laboratory obtained a result of 11.3 for HGB, with an acceptable result between 11.4 - 12.2 and no documentation of corrective actions. The laboratory obtained a result of 8.1 for WBC, with an acceptable result of 8.3-9.5 and no documentation of corrective actions. V. June 11, 2023 - The laboratory obtained a result of 11.0 for HGB, with an acceptable result between 11.4 - 12.2 and no documentation of corrective actions. The laboratory obtained a result of 7.6 for WBC, with an acceptable result of 8.3-9.5 and no documentation of corrective actions. VI. June 12, 2023 - The laboratory obtained a result of 11.1 for HGB, with an acceptable result between 11.4 - 12.2 and no documentation of corrective actions. The laboratory obtained a result of 7.2 for WBC, with an acceptable result of 8.3-9.5 and no documentation of corrective actions. VI. The laboratory obtained a result of 10.9 for HGB, with an acceptable result between 11.4 - 12.2 and no documentation of corrective actions. The laboratory obtained a result of 7.1 for WBC, with an acceptable result of 8.3-9.5 and no documentation of corrective actions. 5. During interview of the technical consultant conducted August 23, 2023 at 10:47 AM she confirmed that the laboratory tested patient specimens when controls failed to meet the acceptable criteria and failed to document remedial actions using the "QC Out Of Limits Log Sheet" on nine of thirteen days between June 1, 2023 and June 13, 2023.

D6042

TECHNICAL CONSULTANT RESPONSIBILITIES

	<p>CFR(s): 493.1413(b)(4)</p> <p>(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;</p> <p>This STANDARD is not met as evidenced by: Based upon review of policies and procedures, the quality control policy and quality control records, the technical consultant failed to ensure testing personnel were documenting corrective actions and and not performing patient testing when quality control failures occurred as defined in the laboratory policy titled CONTROL POLICY. (See D5481 and D5781)</p>
<p>D6049</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.</p> <p>This STANDARD is not met as evidenced by: Based upon review of policies and procedures, the quality control policy and quality control records, the technical consultant failed to ensure testing personnel were documenting corrective actions and and not performing patient testing when quality control failures occurred as defined in the laboratory policy titled CONTROL POLICY. (See D5481 and D5781)</p>
<p>D6072</p>	<p>TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3)</p> <p>Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.</p> <p>This STANDARD is not met as evidenced by: Based upon review of policies and procedures, the quality control policy and quality control records, testing personnel failed to document corrective actions and not perform patient testing when quality control failures occurred as defined in the laboratory policy titled CONTROL POLICY. (See D5481 and D5781)</p>