

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D1073404	(X3) Date Survey Completed 09/19/2024
Name of Provider or Supplier Dr Bills Kids	Street Address, City, State 426 Highway, 26 East, Cochran, GA	
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	A recertification survey was performed on , September 19, 2024. The facility was found to be NOT in compliance with the CLIA conditions and standards for specialties /subspecialties for 42 CFR. CONDITION LEVELS: D5024 - Hematology - 493.1215 D6000 - Moterately Complexity Laboratory Director - 493.1403 NOTE: The CMS-2567 (Statement of Deficiencies) is an official , legal document,. All information must remain unchanged except for entering the Plan Of Correction (POC), correction dates, and the signature space. Any discrepancy n the original deficiency citation(s) will be reported the the Georgia Regional Office (RO) for referral the Office of the Inspector General (OIG) for possible fraud if the information is inadvertently changed by the provide/supplier, the State Survey Agency (SA) should be notified immediately.
D5024	<p>HEMATOLOGY CFR(s): 493.1215</p> <p>If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on review of the manufacturers calibration requirements and interview with the Laboratory Manager confirmed that the laboratory failed to perform calibration procedures every 6 months as required in the Emerald Operations Manual.. There was no documented calibrations for 23 months from 09/07/22 to 08/07/2024 on the Abbott Emerald Hematology Analyzer. Reference: D 5437 - Calibration Calibration Verification - 493.1255(a)</p>
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the</p>

laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:
Based on review of the manufacturers calibration requirements and interview with the Laboratory Manager it was revealed that the laboratory failed to perform calibration procedures every 6 months on the Hematology Analyzer-Abbott Emerald Hematology Analyzer (Emerald) as described in the Emerald Operations Manual. Findings 1. Review of the Emerald "Log Report" daily maintenance report revealed the Emerald was calibrated on 9/7/2022 and was not calibrated again until 8/7/2024, a period of 23 months. 2. Interview with the Laboratory Manager (LM) at 1:30 pm, on 09/19/2024 in the LM 's office confirmed the aforementioned statements.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:
Based on review of the Calibration Documents revealed the Laboratory Director failed to provide overall management and direction of the laboratroty. This is a condition level Reference: D 6005 Laboratory Director Responsibilites 493.1407(c)

D6005

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(c)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (c) The laboratory director must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed.

This STANDARD is not met as evidenced by:
Based on calibration records and staff interview the Laboratory Director (LD) failed to verify that the testing personnel were performing the calibration procedure on the Abbott Emerald Hematology Analyser (Emerald) as required in the Operators Manual. Findings: 1. Review of the daily Emerald log, the laboratory performed the calibration on 09/07/2022 and then was not calibrated again until 8/07/2024, 23 months apart. 2. Interview with the lab manager, on 09/19/2024 at approximately 1:30 pm in the lab manager's office, confirmed the aforementioned statement