

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2143578	<b>(X3) Date Survey Completed</b>  06/09/2021
<b>Name of Provider or Supplier</b>  Vitalmd Group Holding, Llc DbA Rainbow Pediatrics	<b>Street Address, City, State</b>  9980 N Central Park Blvd Ste 108a, Boca Raton, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A recertification survey conducted on 06/09/2021 found that RAINBOW PEDIATRICS OF PALM BEACH COUNTY, LLC clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories.
<b>D5439</b>	<p><b>CALIBRATION AND CALIBRATION VERIFICATION</b> CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with laboratory director (LD), the laboratory failed to perform calibration verification procedures of the Beckman Coulter AC-</p>

Tdiff2 analyzer at least every 6 months from 4/9/2019 to 06/09/2021. Findings include: -Review of the Beckman Coulter AC-Tdiff2 Analyzer records revealed that the laboratory performed calibration on 4/09/2019. No other calibration records were found. During an interview on 06/09/2021 at 12:00 p.m., the LD confirmed that the laboratory failed to perform instrument calibration every 6 months in the period of 4/9/2019 to 06/09/2021.

**D5791**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:  
Based on record review and laboratory director (LD) interview, the facility's quality assessment (QA) procedure failed to ensure the laboratory performed blood cell analyzer (CBC) analyzer calibration verification every 6 months from 4/9/19 to 6/9/21. Findings include: Record review of CBC analyzer records revealed that the laboratory failed to do the CBC analyzer calibrations at least every 6 months. Refer to D5439 Review of Monthly Quality Audit Review Form (MQARF) revealed that on section 3 stated that "Calibration and or Calibration verification has been performed (every 6 months) and meet the manufacturer requirement". Review of the MQARF records from August 2019 to March 2021, revealed that the QA failed to correct the deficiency. During an interview on 06/9/2021 at 12:30 PM, with the LD, she confirmed that the QA failed to ensure that the the laboratory performed the CBC analyzer calibrations at least every 6 months.

**D6021**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(5)

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. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:  
Based on record review and interview with the Laboratory Director (LD), the LD failed to ensure that the Quality Assurance (QA) corrected the laboratory deficiency of not performing the cell blood counter (CBC) calibrations at least every 6 months from August 2019 to March 2021. Findings include: -Review of the Monthly Quality Audit Review Form (MQARF) records, revealed that the LD failed to sign and date the forms from August 2019 to March 2021 and failed to ensure the laboratory QA corrected the deficiency of not performing calibrations for CBC at least every 6 months. During an interview on 06/09/2021 at 12:00 PM, with the LD, she confirmed that she failed to sign and date the MQARF for the time of reference and failed to ensure the QA corrected the failure to perform calibration for the CBC for the period of reference.