

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0950912	(X3) Date Survey Completed 03/23/2023
Name of Provider or Supplier Vita Medical Associates Pc	Street Address, City, State Gateway At Greenway Park, Bethlehem, PA	
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
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, lack of documentation, and interview with testing personnel #1 (TP), the laboratory failed to assess the maintenance/ function checks for 4 of 4 pipettes used for chemistry and hematology testing in the laboratory from 1/29/2021 to the day of survey. Findings Include: 1. On the day of survey, 03/23/2023 at 01:25 pm, the laboratory could not provide maintenance/function check records for the following 4 of 4 pipettes used from 01/29/2021 to 03/23/2023: - Diamond Pro 1000 microliter pipette S/N: RC694399. -Eppendorf Research 1000 microliter pipette S/N: 2252649 - Eppendorf Research 100-1000 microliter pipette S/N: RE768387. -Eppendorf Research 100 microliter pipette S/N: 3756329. 2. The laboratory performed 67,500 tests in 2022 (CMS 116 annual volume). 3. TP #1 confirmed the findings above on 03/23/2023 around 2:30 pm.</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 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)</p>

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 upon review of the Beckman Coulter DxH 520 calibration records, laboratory procedure manual, and interview with testing personnel #1 (TP), the laboratory failed to perform calibrations on the Beckman Coulter DxH 520 analyzer used to perform complete blood count (CBC) tests from 02/23/2022 to the date of the survey. Findings Include: 1. The laboratory's Hematology Procedure states, "calibration is performed every 6 months or when advised by Coulter representative". 2. On the day of the survey, 03/17/2023 at 12:30 pm, review of the Beckman Coulter DxH 520 analyzer calibration records revealed the laboratory did not perform calibrations every 6 months as per their policy on the Beckman Coulter DxH 520 analyzer from 02/23/2022 to 03/17/2023. 3. TP #1 confirmed the finding above on 03/17/2023 around 02:30 pm.

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 a review of the laboratory's quality assurance (QA) documents and interview with testing personnel #1 (TP), the laboratory director (LD) failed to ensure QA programs were maintained and documented to assure the quality of laboratory services provided from September 2022 to the date of the survey. Findings Include: 1. On the day of survey, 03/23/2022 at 01:19 pm, the laboratory could not provide QA documentation of the periodic evaluation used by the laboratory to assess its preanalytical, analytical, and postanalytical processes from September 2022 to March 2023. 2. TP #1 confirmed the findings above on 03/23/2023 around 02:30 pm.