

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0107146	(X3) Date Survey Completed 01/17/2023
Name of Provider or Supplier Union Internal Medicine Group Pa	Street Address, City, State 2027 Morris Avenue, Union, NJ	
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
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) 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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Calibration Verification (CV) records, Operators Manual (OM) and interview with the Testing Personnel (TP), the laboratory failed to follow the manufacturer's test systems instructions for performing and documenting Calibration at least once every six months for Hematology Tests performed on the Abbott Cell Dyn Emerald analyzer in the calendar years 2021 and 2022. The findings include: 1. The the manufacturer's test systems instructions stated prior to calibration: "Verify instrument precision by running a fresh, normal whole blood specimen ten times into the PRECISION file. Refer to Section 9: Service and Maintenance, Subsection: Precision for information on using QC files. Ensure that CV% results are within the limits as provided in Section 4: Performance Characteristics and Specifications. Record the results below or attach a printout to this document". 2. A review of CV records revealed that the laboratory did not perform "Precision Check" as required prior to CV. 3. The TP confirmed on 1/17/23 at 11:30 am that the laboratory failed to follow the manufacturer's test systems instructions as stated above.</p>

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 the lack of Quality Control Verification (QCV) records and interview with the Testing Personnel (TP), the laboratory failed to verify QC material before use for Alfa Wassweman Ace Alera on the date of survey. The findings include. 1) There was no documented evidenced that the QCV was performed on the current lot of Alfa Wassermisan Chemistry Controls. 2) There was no documented evidenced that the QCV was performed on the current lot of Alfa Wassermisan Lipid Controls. 3) The TP confirmed 1/17/23 at 11:15 am that QC material was not verified before putting in use.

D5807

TEST REPORT

CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Final Report (FR), Manufacturer Package Insert (MPI) and interview with the Testing Personnel (TP), the laboratory failed to identify the source of the Reference Intervals (RI) used for Total Bilirubin (TBILI), and Albumin (ALB) tests on the date of survey. The findings include: 1. The TP stated the laboratory used the RI listed in the MPI. 2. The MPI RI for TBILI was .3-1.2 mg/dL but the FR had 0.0-1.0 mg/dL. 3. The MPI RI for ALB was 3.5-5.2 mg/dL but the FR had 3.5-5.0 mg/dL. 4. The TP confirmed on 1/17/23 at 11:32 am that the RI on the FR was not that of the RI in the MPI.