

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0107146	(X3) Date Survey Completed 08/25/2026
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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to verify the accuracy and reliability of all Hematology testing analytes performed on the Cell-Dyn Emerald from 9/18/24 to 8/25/26. The finding includes: 1. Surveyor review of PT records revealed all Hematology analytes tested by the laboratory were not included in PT events 1, 2 and 3 in 2024 and 2025 and PT event 1 in 2026 performed with PT provider American Association of Bioanalysts Medical Laboratory Evaluation (AAB/MLE). 2. The following analytes were not verified for accuracy twice annually on the Cell-Dyn Emerald analyzer: a) Lymphocytes (LYM) b) Monocyte Intermediate (MID) c) Granulocytes (GRA) 3. The TP#2 on CMS form 209 confirmed on 8/25/26 at 11:00 am, the laboratory did not verify the accuracy of all analytes performed on the Cell-Dyn Emerald.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Tstin Perosnnle (TP), the laboratory failed to document the evaluation of all unsatisfactory PT scores and corrective action taken for PT performed with American

	Association of Bioanalysts Medical Laboratory Evaluation (AAB/MLE) for the M2 2026. The findings include: 1. The laboratory received a 20% on Hematocrit (HCT). 2. There was no documented evidence for evaluation or corrective action performed for s. HCT M2 2026 3. The TP#2 on CMS form 209 confirmed on 8/25/26 at 11:15 am, that the laboratory failed to evaluate and perform corrective action for all unsatisfactory PT scores.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on surveyor review of analyzer calibration records, review of the Manufacture Operator Manual (OM) and interview with the Testing Personnel (TP), the laboratory failed to follow the OM for Hematology testing performed on the Cell-Dyn Emerald in the calendar years 2022 and 2023. The findings include: 1. The OM appendix E, worksheet E.1, pre-calibration procedure checklist, states "7. Verify instrument precision." 2. There was no documented evidence that precision was verified prior to running calibration material on 6/28/26. 3. The TP#2 on CMS form 209 confirmed on 8/25/26 at 11:40 am the laboratory failed to follow the OM.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor observation of Access 2 reagent kit for Uric Acid and Triglycerides, and interview with the Testing Personnel (TP), the laboratory failed to discard expired reagent from 6/ to 12/3/25. The findings include: 1. Alpha Wasserman reagent kit for Uric Acid Lot# SA1025 expired 6/30/26. 2. Alpha Wasserman reagent kit for Triglycerides Lot# SA1023 expired 6/30/26. 3. Approximately 700 patients run and reported. 4. The TP#2 on CMS form 209 confirmed on 8/25/26 at 1:30 pm that the laboratory failed to discard expired reagent.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (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.

This STANDARD is not met as evidenced by:

Based on the lack of Calibration Verification (CV) records and interview with the Testing Personnel (TP), the laboratory failed to perform and document CV procedures at least every six months on the Alfa Wassweman Ace Alera analyzer in the calendar year 2025. The findings include; 1) The laboratory is running two levels of Quality Control (QC) on the Alfa Wassweman Ace Alera for Routine Chemistry testing. 2) Linearity was done once on 4/21/25 in the calendar year 2025.. 3) The TP#2 on CMS form 209 confirmed on 8/25/26 at 12:00 pm that a linearity was not performed every six months on the Alfa Wassweman Ace Alera analyzer in the calendar year 2025.

D5469

CONTROL PROCEDURES

CFR(s): 493.1256(d)(10)(g)

(d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(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. (d)(10)(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. (d)(10)(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.

This STANDARD is not met as evidenced by:

Based on lack of 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 and Beckman Coulter Access 2 from 1/17/23 to the 8/25/26. The findings include. 1) There was no documented evidenced that the QCV was performed on the current lots of Alfa Wassermesan Controls Chemistry Control level 1 an level 2 run on the Alfa Wassweman Ace Alera analyzer. 2) There was no documented evidenced that the QCV was performed on the current lot Liquicheck Specialty Immunoassay Controls levels 1, 2 and 3 run on the Access 32 analyzer. 3) There was no documented evidenced that the QCV was performed on the current lot Liquicheck Immunoassay plus Contorls levels 1, 2 and 3 run on the Access 32 analyzer. 4) The TP#2 on CMS form 209 confirmed 8/25/26 at 11:15 am that QC material was not verified before putting in use. Note: this was previously cited 1/7/23

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.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Procedure Manual (PM), and interview with the Testing Personnel (TP), the PM lacked a Quality Control Verification (QCV) procedure for new lots of Quality Control (QC) used for Endocrinology and Routine Chemistry tests from 9/18/24 to 6/2/26. The findings include: 1. The laboratory did not establish a detailed procedure for performing QCV on new lots of QC material that included frequency and acceptability criteria. 2. The TP#2 on CMS form 209 as listed on the CMS 209 form confirmed on 8/25/26 at 12:05 pm, the laboratory did not establish a QCV procedure.

D6074

TESTING PERSONNEL RESPONSIBILITIES

CFR(s): 493.1425(b)(5)

(b)(5) Be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the technical consultant, clinical consultant or director; and

This STANDARD is not met as evidenced by:

Based on the surveyor review of Quality Control (QC) records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to identify problems that may affect test performance by not reviewing and evaluating trends and/or shifts for tests performed on the Alfa Wassweman Ace Alera and Access 2 analyzers from 9/18/24 to 8/25/26. The findings include: 1) The date ranges for monthly QC review for the Alfa Wassweman Ace Alera were as follows. a) May 2026 1/13/25 - 5/28/26. b) July 2026 11/16/24 - 7/30/26. 2) The Alfa Wassweman Ace Alera Levy Jennings chart can show a maximum of 67 data points. a) May 2026 had 218 data points as the N value for QC. b) July 2026 had 250 data points as the N value for QC. 3) The date ranges for monthly QC review for the Access 2 analyzer for the month of June 2026 was 6/11/26 - 7/12/26. 4) The date ranges for monthly QC review for the Access 2 analyzer for the month of May 2026 was 4/30/26 - 5/31/26. 5) There was no documented evidence that 6/1/26 - 6/10/26 was included in the monthly QC review. 6) The TP confirmed at 12:00pm on 8/25/26 that the LD failed to identify problems that may affect test performance by not reviewing and evaluating trends and/or shifts.