Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0107146	09/18/2024
Name of Provider or Supplier	**Street Address, City, State**	
Union Internal Medicine Group Pa	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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Clinical Consultant (CC), the laboratory failed to have complete attestation records for all College of American Pathologists (CAP) PT events for Endocrinology, Chemistry and hematology tests for events one and two 2024. The findings include: 1. The attestation records for PT events one and two 2024 did not have the name of the analyst that performed PT. 2. The CC confirmed on 9/18/24 at 1:35 pm the attestation records were not complete.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

	This STANDARD is not met as evidenced by: a) Based on surveyor review of the Procedure Manual (PM), and interview with the Clinical Consultant (CC)), the laboratory failed to follow the PM for "Control Range verification procedure" from 1/17/23 to the date of the survey. The finding includes: 1. The PM stated "Before a new lot number of controls is started the controls are to be run in triplicate. The values are to be compared to the affiliated control ranges", "These are to be kept in a separate log book". 2. There was no documented evidence that the aforementioned procedures were performed. 3. The CC confirmed on 9/18/24 at 12:00pm the laboratory did not follow the PM. b) Based on surveyor review of the Procedure Manual (PM), and interview with the Clinical Consultant (CC), the laboratory failed to include new shipments of control material as part of the laboratories Quality Control Verification (QCV) procedure from 1/17/23 to the date of survey. The CC confirmed on 9/18/24 at 12:00pm the laboratory failed to have the aforementioned procedure.
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 surveyor review of Quality Control Verification (QCV) records and interview with the Clinical Consultant (CC), the laboratory failed to verify QC material before use for Alfa Wassweman Ace Alera from 1/17/23 to the date of survey. The findings include. 1) There was no documented evidenced that the QCV was performed on the current lot of Alfa Wassermsan Controls. 2) The CC confirmed 9/18/24 at 11:15 am that QC material was not verified before putting in use. Note: this was previously cited 1/7/23
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the

	reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the Clinical Consultant (CC), the laboratory failed to document all Corrective Actions (CA) taken when QC was out of range for the Cell Dyn emerald analyzer from 2/5/24 to the date of survey. The findings include: 1. There was no document when control were repeated as follow: a)Low level controls run six times 2/9/24 b)Low level controls run three times 2/13/24 c) Low level control run twice 2/21/24 d) Low level controls run five times 2/22/24 e) Low level controls run three times 2/26/24 f) Low level controls fun five time 2/28/24 2. The CC confirmed on 9/18/24 at 1:30 pm the laboratory did not document CA when QC was out of range.
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 surveyor review of the Procedure Manual and interview with Clinical Consultant (CC) the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems from 1/17/23 to the date of survey. The findings include: 1. The Laboratory failed to have a Corrective Action (CA) procedure for Quality Control (QC). 2. The CC confirmed on 9/18/24 at 11:45 am that the laboratory failed to have a CA procedure for QC.