Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0646585	07/11/2024
Name of Provider or Supplier	**Street Address, City, State**	
Unilab, Inc	418 N Austin Blvd, Oak Park, IL	

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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of laboratory policy and procedure manuals and interview with the technical supervisor (TS); the laboratory failed to have two of five policy and procedure manuals reviewed, approved, signed, and dated by the current laboratory director (as noted on the CMS-209 Laboratory Personnel Form) as required per 493. 1251. Findings include: 1. Review of laboratory policy and procedure manuals revealed no laboratory director approval, including signature and date, by the current laboratory director on the following laboratory policy and procedure manuals: a. Quality Assurance Manual for the specialties of Microbiology, Diagnostic Immunology, Chemistry, and Hematology b. Individual Quality Control Plans (IQCPs): i. Exempt Media Quality Controls for the subspecialty of Bacteriology ii. Minimum Inhibitory Concentration (MIC) Quality Controls for the subspecialty of Bacteriology 2. An interview with the TS at 10:52 am on 07/11/2024 confirmed the above findings.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

	This STANDARD is not met as evidenced by: Based on lack of documentation, direct observation, and interview with the technical supervisor (TS); the laboratory failed to have a system in place that twice a year evaluates and defines the comparison of test results between 16 of 16 Routine Chemistry analytes performed on two Roche Cobas Mira Plus testing instruments utilized for Routine Chemistry testing in the years reviewed, 2022 through the date of survey 07/11/2024. Findings include: 1. Direct observation on 7/10/2024 at 01:40 PM, during the tour of the laboratory, identified two Roche Cobas Mira Plus analyzers (Serial Numbers: 36-9009 & 36-9114), both of which were used to perform the following Routine Chemistry analytes. Routine Chemistry Analytes: A. Alanine Amino Tranferase [ALT] B. Albumin C. Alkaline Phosphatase D. Amylase E. Aspartate Amino Tranferase [AST] F. Total Bilirubin G. Blood Urea Nitrogen [BUN] H. Calcium I. Cholesterol Total J. Cholesterol HDL K. Creatinine [blood] L. Creatinine Phospho-Kinase M. Ferritin N. Glucose O. Protein Total P. Triglycerides 2. The laboratory lacked documentation of instrument-to-instrument test result comparisons for all analytes listed above which were performed on the two Roche Cobas Mira Plus analyzers. 3. An interview with the TS at 1:51 pm on 07/10/2024 confirmed that the above analytes had been performed on both analyzers since 2022 but no instrument-to-instrument test result comparisons were available nor had been performed from 2022 through the date of the survey 7/11/2024.