Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D2095272	05/28/2025
Name of Provider or Supplier	**Street Address, City, State**	
Kbmo Diagnostics	4 Business Way, Hopedale, MA	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and confirmed through an interview with the Technical Supervisor (TS) the laboratory did not have an ongoing mechanism to evaluate the TS and General Supervisor (GS) based on their CLIA responsibilities. Findings Include: 1. Record review on 5/28/2025 of the laboratory's 2023, 2024 and 2025 to date personnel competency records revealed the laboratory did not have documented competency evaluation for the TS and GS based on their CLIA responsibilities. 2. Record review on 5/28/2025 of the laboratory's, Policy and Procedure Manual revealed, the laboratory did not have a policy in place to evaluate the TS and GS based on their CLIA responsibilities. 3. During staff interview on 5/28/2025 at 11:30 AM with the TS, the TS confirmed the laboratory does not have a policy to evaluate the TS and GS based on their CLIA responsibilities and they were not assessed. 4. The laboratory performs 4,452,170 tests annually in the specialty of Diagnostic Immunology.
D5821	TEST REPORT CFR(s): 493.1291(k) (k)When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the

	original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on record review and interview with the Technical Supervisor (TS) the laboratory failed to indicate the final patient test report was a corrected report. Finding include: 1. Record review on 5/28/2025 of the laboratory's documentation of 2 incorrect patient reports revealed; "Patient 1 and Patient 2 had the wrong FIT-132 blood spot reports on August 16, 2024." 2. Record review on 5/28/2025 of the two final patient test reports of the above patients, containing corrected test results revealed the test report did not indicate the fact that the results were corrected. 3. Staff interview on 5/28/2025 at 12:15 PM with the TS confirmed the above findings. 4. The laboratory performs 4,452,179 tests annually in the specialty of Diagnostic Immunology.