Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D1098945	02/28/2024
Name of Provider or Supplier	**Street Address, City, State**	
Hudson Valley Hematology-Oncology Associates	2649 Strang Blvd Suite 208, Yorktown Heights, NY	

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	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) 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. This STANDARD is not met as evidenced by: Based on review of the monthly, yearly analyte calibration logs and interview with the general supervisor (GS), the laboratory failed to comply with instructions indicated in the current, approved Hudson Valley Hematology Oncology Associates Quality Control SOP-23 standard operating procedure. FINDINGS: 1. The laboratory failed to document June 2022 monthly approval and date review for the Siemens Immulite 2000 Immunoassay System (serial: F1247) vitamin B12 analyte. 2. The laboratory failed to document 2022 yearly approval and date review for Siemens Immulite 2000 Immunoassay System ferritin analyte. 3. The laboratory failed to document 2022 and 2023 calibration tracking worksheet review for the Roche Diagnostics Cobas c 501 analyzer (serial: 15H9-11) direct bilirubin analyte. 4. The GS confirmed the findings on February 28, 2024, at approximately 12:45 P.M. 5. It was noted that the respective documentation was completed during the survey in partial satisfaction of this requirement.