Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0163250	03/07/2024
Name of Provider or Supplier	**Street Address, City, State**	
Hudson Valley Hematology/Oncology Associates Rllp	400 Westage Business Center Drive, Suite 103, Fishkill, 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
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 review of the current, approved standard operating procedures (SOPs), lack of personnel competency evaluation records, as well as interview with the testing person (TP), the Laboratory Director (LD) failed to perform and document clinical consultant (CC) competency evaluations. FINDINGS: 1. There was no documentation of CC competency performance or evaluation. 2. This is contrary to instructions indicated in the current, approved "Laboratory Personnel Policies" SOP. 3. The TP confirmed the findings on March 7, 2024, at 12:30 P.M.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) summary reports and interview with the TP, the laboratory failed to perform and document corrective action for unacceptable PT scores. FINDINGS: 1. There was no documentation of corrective action for Cell

	Identification (Cell I.D.) American Proficiency Institute (API) 2023 third event PT score of 60%. 2. There was no documentation of corrective action for Red Blood Cell (RBC) API 2022 second event score of 40%.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the current, approved Quality Assurance (QA) policy, lack of QA documentation, and interview with the TP, the laboratory failed to identify and correct ABX Horiba Micros 60 analyzer calibration failures. FINDINGS: 1. There was no documentation of QA review from 2022 through date of survey. 2. There was no documentation of corrective action for ABX Horiba Micros 60 analyzer calibration failures. 3. These are contrary to instructions indicated in the current, approved QA policy and review calendar. 4. The TP confirmed the findings on March 7, 2024, at 12: 30 P.M.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of current, approved SOPs, temperature and humidity records, as well as interview with the TP, the laboratory failed to monitor and document room temperature and humidity in the area where laboratory testing occurred. FINDINGS: 1. There was no documentation of room temperature and humidity in the area where laboratory testing occurred from 2022 through the date of the survey. 2. The current, approved SOPs did not include instructions for performing such activities. 3. It was noted that a refrigerator utilized for the storage of analyzer control and calibrator reagents included a temperature log. 4. The TP confirmed the findings on March 7, 2024, at 12:30 P.M.
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 ABX Horiba Micros 60 analyzer calibration records, manufacturer's requirements, and interview with the TP, the laboratory failed to perform, document, and comply with analyzer calibration requirements. FINDINGS: 1. There was no documentation of hemoglobin (Hgb) out-of-range corrective action resulting from ABX Horiba Micros 60 analyzer calibration performed September 13, 2022. 2. There were no records of analyzer calibration from September 13, 2022, through July 14, 2023. 3. These are contrary to instructions indicated in the ABX Horiba Micros 60 analyzer manufacturer's calibration instructions. 4. Approximately 4710 patient specimens were tested and results reported. 5. The TP confirmed the findings on March 7, 2024, at 12:30 P.M.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of the ABX Horiba Micros 60 analyzer calibration records, manufacturer's requirements, and interview with the TP, the laboratory failed to perform and document corrective action resulting from analyzer calibration failure. FINDINGS: 1. There was no documentation of Hgb out-of-range corrective action resulting from ABX Horiba Micros 60 analyzer calibration performed September 13, 2022. 2. This is contrary to ABX Horiba Micros 60 analyzer manufacturer's calibration instructions. 3. The TP confirmed the findings on March 7, 2024, at 12:30 P.M.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

	This STANDARD is not met as evidenced by: Based on review of PT summary records and interview with the TP, the LD failed to perform and document corrective action for unacceptable PT scores. Refer to D5211.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the current, approved the QA policy, lack of QA documentation, and interview with the TP, the LD failed to facilitate and comply with an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory system. Refer to D5291, D5783, and D5437.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of the current, approved SOPs, lack of personnel competency evaluation records, as well as interview with the LD, the LD failed to perform and document CC competency evaluations. Refer to D5209.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

	This STANDARD is not met as evidenced by: Based on review of the current, approved SOPs, lack of personnel competency evaluation records, as well as interview with the TP, the LD failed to draft, approve written description of TP and CC responsibilities and duties. FINDINGS: 1. There was no documentation of CC competency performance or evaluation. 2. The current, approved SOPs did not include a description of TP and CC responsibilities and duties. 3. The TP confirmed the findings on March 7, 2024, at 12:30 P.M.