Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0931719	09/22/2023
Name of Provider or Supplier	**Street Address, City, State**	
Hudson Valley Hematology-Oncology Associates Rllp	159 Barnegat Road, Suite 101, Poughkeepsie, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on direct observation, review of the American Proficiency Institute (API) 2022 results, first event result of 2023, and interview with the primary laboratory testing person (TP#1), the laboratory failed to enroll in the correct API hematology specialty module. FINDINGS: 1. System for processing manual differentials was not present in the laboratory at the time of the survey. 2. The laboratory was enrolled in the API hematology specialty cell identification module. 3. The laboratory TP#1 confirmed on September 22, 2023, at approximately 11:30 A.M. that the laboratory did not perform manual differentials and/or cell identification. It was noted that automated Complete Blood cell Count (CBC) was performed on the Micros 60 hematology analyzer.
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 review of the API records for all three events in 2022; first and second event results of 2023; attestation forms, analyzer printouts, API test result forms, and API summary test reports; the laboratory failed to maintain completed, signed copies of the attestation forms. FINDINGS: 1. The laboratory director (LD) and Testing Personnel (TP) did not sign and date the attestation forms for the three events in 2022 as well as the first and second events of 2023. a. It was noted that the laboratory TP signed and dated the CBC Proficiency Testing (PT) sample attestation forms. b. The attestation forms did not however include TP identification responsible for performing test event cell identifications and manual differentials. 2. TP#1 confirmed on September 22, 2023, at 11:00 A.M. that the TP responsible for performing the color chrome slide review failed to sign and date the attestation forms for all three events in 2022 as well as the first and second events of 2023.
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of the API PT summary reports for 2022 as well as the first and second event results of 2023, the laboratory failed to successfully participate in analyte cell identification PT. The following score was assigned for slides BC-06, BC-08, BC-09: 2022 second event = 40%. This was considered unsatisfactory PT performance.
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 six testing personnel education records, the three new laboratory personnel training records, lack of competency assessment policy, and interview with TP#1, the laboratory failed to establish a written, approved policy for laboratory personnel competency assessment. FINDINGS: 1. Training for three of six testing personnel was performed by the LD in 2022, however there was no

	documentation of six-month evaluations. a. Hire dates were not documented in the personnel files. b. It was noted that annual competency assessments were performed for the six testing personnel in May 2023. Refer to D6032.
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 API PT summary reports and interview with TP#1, the laboratory failed to evaluate and document corrective action for cell identification PT scores less than 100%. FINDINGS: 1. 2021 third event = 80% (BC-15). 2. 2023 first event = 80%. (BC-05).
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 Quality Assessment (QA) procedure/policy and an interview with TP#1, the laboratory failed to follow the approved QA procedure/policy for monitoring and, when indicated, correct problems identified for both technical and non-technical systems in the laboratory. FINDINGS: 1. It was noted that the laboratory submitted a QA policy as part of the plan of correction (POC) for the on-site survey conducted January 4, 2022. The referred to QA policy indicated the following: Quality Systems Assessment Plan: The director has the responsibility for monitoring the requirements for patient test management and ensures that the established procedures for the pre-analytic through the post analytic stages of testing have been followed. The quality assessment reviews are conducted when indicated and /or on an annual basis. The assessment includes a periodic evaluation of the following areas: Patient Test Management/Relationship of Patient, Information to Patient Test Results: Procedure Manual: Quality Control (QC) and Calibration: Quality Assessment Review and Records: Pre-Analytical phases: Analytical phase Post-analytical phase Communications and Complaints. THIS IS A RECITED STANDARD DEFICIENCY FROM THE SURVEY CONDUCTED ON JANUARY 4, 2022. Refer to D2000, D2015, D2121, D5209, D5211, D6000, and D6021.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step

	performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on the review of laboratory's Standard Operating Procedure (SOP) manual and interview with TP#1, the laboratory failed to draft and approve the following SOPs: a. Laboratory's criteria for control acceptability. b. Corrective action when control and calibration results failed. c. Course of action if the test system became inoperable. 1. The TP#1 confirmed on September 22, 2023, at approximately 12:30 P.M. that the laboratory's SOPs did not include such policies.
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 the Horiba ABX Micros 60 temperature requirements, lack of room temperature and humidity records, as well as interview with TP#1, the laboratory failed to monitor and document room temperatures and humidity for the area where the Micros 60 hematology analyzer was located. FINDINGS: 1. The laboratory failed to monitor and document room temperatures and humidity for the calendar year 2022 through the survey date. 2. The Horiba ABX Micros 60 hematology analyzer manufacturer's requirements specify temperature ranges of 18 to 32C (65 to 90F) and a maximum relative humidity of 80%.
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 review of the laboratory's Quality Control (QC) records and an interview with TP#1, the laboratory failed to perform lot to lot reagent verifications for the Micros 60 hematology analyzer. FINDINGS: 1. Documentation of hematology analyzer reagent QC lot to lot validation was not available at the time of the survey. 2. The laboratory failed to perform and document QC verification for the following lots: For 2022: MX432, MX433, MX434, MX435, MX436, and MX437. For 2023: MX438, MX439, MX440, MX441, and MX443 (lot in use at the time of the survey). 3. The TP#1 confirmed on September 22, 2023, at approximately 1:00 P.M., that lot to lot reagent verifications for the Micros 60 hematology analyzer were not performed.
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 Micros 60 Mintrol-16 control material daily QC printouts and interview with TP#1, the laboratory failed to document Mintrol-16 control ranges on the control reports for all three levels of QC material. FINDINGS: 1. The 2022 and 2023 daily QC printed reports did not include documented Mintrol-16 control ranges for the following lots: For: 2022 MX432, MX433, MX434, MX435, MX436, and MX437. For 2023: MX438, MX439, MX440, MX441, and MX443 (lot in use at the time of the survey). 2. It was noted that the 2022 and 2023 daily start-ups/function checks were acceptable. 3. According to the daily QC printouts for MX438, the lot was implemented November 4, 2022. The printout data indicated an end of use date of March 6, 2023, however the respective lot expiration was January 5, 2023. Furthermore, lot MX442 was implemented July 6, 2023, with end of use date of September 13, 2023, and an expiration date September 5, 2023. 4. According to TP#1, the control files were sent automatically to the main laboratory where the technical consultant (TC) downloaded the results, control files, for generation of the Levy-Jennings graphs. The documents were subsequently submitted to the LD to review and sign. 5. According to TP#1, control files were saved to the main laboratory's information system. However, the surveyed facility was unable to save the respective control files to Micros 60 laptop computer. 6. According to the TC, the TP#1 should be saving the control files to the Micros 60 laptop computer and the information contained in the files included control ranges, control lots, and expiration dates. 7. According to the TC, control files were downloaded to the main laboratory's

	information system for data processing. Data and the Levy-Jennings graphs were subsequently generated and forwarded to the LD to review and sign. 8. No documentation of corrective action was available for review.
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 review of the SOPs, review of laboratory records, and interview with TP#1, the laboratory failed to draft and approve written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems in the analytic phases of hematology testing. Refer to D5413, D5783, and D5637.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of the Horiba ABX Micros 60 SOP manual, laboratory QC records, lack of QA documentation, and interview with TP#1, the LD failed to provide overall management of the laboratory. FINDINGS: The LD failed to ensure: 1. That the submitted, approved POC was implemented and maintained in response to the deficiencies cited for the on-site survey conducted January 4, 2022. 2. That the laboratory was enrolled in the correct API PT module. Refer to D6015. 3. Review and evaluation of the API PT summary reports. Refer to D6018. 4. Corrective action performance and documentation for PT analytes that scored less than 100%. Refer to D6019. 5. Establishment and maintenance of a QC program. Refer to D6020. 6. Establishment and maintenance of a QA program for all phases of laboratory testing. Refer to D6021. 7. Drafting and approving testing personnel duty and responsibility policies and protocols. Refer to D6032. 8. Documented testing personnel initial training and six-month competency assessments. Refer to D6053.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

	This STANDARD is not met as evidenced by: Based on direct observation, review of the API 2022 results, first event result of 2023, and interview with the primary laboratory testing person (TP#1), the laboratory failed to enroll in the correct API hematology specialty module. Refer to D2000.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of the API PT records, reports, and confirmed by interview with TP#1, the LD failed to ensure that the TP responsible for performing the color chrome slide review signed and dated the attestation forms for all three events in 2022 as well as the first and second events of 2023. Refer to D2015.
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 the laboratory's API PT records and an interview with TP#1, the LD failed to evaluate and document corrective action for cell identification PT scores less than 100%. Refer to D5211.
D6020	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 the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by:

	Based on review of hematology QC records and interview with TP#1, the LD failed to ensure compliance with the laboratory's hematology QC program to assure the quality of laboratory services. Refer to D5403, D5413, D5469, D5783, and D5791.
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 QA policy, review of the POC from the survey conducted on January 4, 2022, lack of QA review records, and interviews with LD and TP#1, the LD failed to ensure documentation of TP identification responsible for performing patient testing. Refer to D5291 and D6000.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and 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 results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the personnel records and confirmed by interview with TP#1, the LD failed to draft, approve, and document the hematology testing personnel job duties and responsibilities. Refer to D5209.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the six testing personnel education records, the three new

	laboratory personnel training records, and interview with TP#1, the LD failed to perform the six-month evaluations for the three new testing personnel after the training was completed.