Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0857401	03/10/2026
Name of Provider or Supplier	**Street Address, City, State**	
Ehpn - Hematology Oncology	2 Journal Square Plaza, Jersey City, NJ	

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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), and interview with the Techincal Consultant (TC), the laboratory failed to have a procedure for Corrective Action (CA) for flagged hematology results run on the Beckman Coulter DxH -520 analyzer from 2/28/24 to 3/10/26. The finding includes: 1. The laboratory did not have a CA procedure for flagged hematology results. 2. The TC confirmed on 3/10/26 at 11: 00 am that the aforementioned procedure was missing.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on surveyor review of patient work records, review of the Beckman Coulter DxH 520 Instructions for Use (IFU) and interview with the Techincal Consultant (TC), the laboratory failed to follow the IFU for the Hematology testing performed on the Beckman Coulter DxH 520 from 7/10/25 to 3/10/26. The findings include: 1. 2 out

	of 10 patient work records had flags but there was no corrective action taken per the IFU. 2. For the R flag, manufacturer states, "Review results". a. Patient specimen Sequence # 23383 from 7/10/25 had the R flag with PLT3 PLT/RBC Overlap message, but those results were reported without further action being taken and/or documented. b. Patient specimen Sequence # 22444 had the R flag with PLT3 PLT /RBC Overlap message, but those results were reported without further action being taken and/or documented. 3. The TC confirmed on 3/10/26 at 11:00 am that the laboratory failed to take correction action for any of the aforementioned flags and/or messages based on the IFU.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(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. (d)(10)(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. (d)(10)(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. This STANDARD is not met as evidenced by: Based on surveyor review of Quality Control (QC) records and interview with the Techincal Consultant (TC), the laboratory failed to verify commercially assayed QC material with each new lot and/or shipment of Hematology QC used on the Beckman Coulter DxH520 analyzer from 2/28/24 to 3/10/26. The findings include: 1. There is no documented evidence that QC material was verified. 2. The TC confirmed on 3/10 /26 at 11:00 am that all assayed QC material was not verified before putting in use. Note: This was previously cited 8/12/21 and 2/28/24
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) (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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), Electronic Medical Records (EMR) and interview with the Techincal Consultant (TC), the laboratory failed to establish a procedure for verifying manually entered results from 2/28/24 to 3/10/26. The findings include 1. The laboratory manually enters patient test results into the Electronic Medical Records (EMR) system. 2. There was no procedure to verify that the patient results where correctly entered into the EMR. 3. The TC confirmed on 3/10 /26 at 11:30 am that the laboratory did not have the procedure mentioned above.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)

	(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records, Procedure Manual (PM) and interview with the Techincal Consultant (TC), the Laboratory Director (LD) failed to ensure that the QC program was maintained for laboratory services provided from 2/28/24 to the 3/10/26. The findings include: 1. The PM states "Levey Jennings charts are reviewed by the techician on a weekly basis.". 2. The PM states "Levey Jennings charts are reviewed by the Techician Consultant and the LD on a monthly basis.". 3. There was no documented evidence that the above mentioned procedures were performed. 4. The TC confirmed on 3/10/26 at 11:30 am the LD did not ensure the QC plan was maintained. .
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) (e)(11) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results; This STANDARD is not met as evidenced by: Based on surveyor review of the Personnel Files (PF) and interview with the Techincal Consultant (TC), the Laboratory Director (LD) failed to have appropriate education and training documentation on all TP performing laboratory testing from 2 /28/2024 to 3/10/26. The findings include: 1. The laboratory did not have education records for five out of five TP listed on the CMS form 209. 2. There was no documented evidence that five out of five TP were trained to perform Hematology testing performed on the Beckman Coulter DXH-520 analyzer. 3. The TC confirmed on 3/10/26 at 11:0 am the above records were not on file.