Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0857401	08/12/2021
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
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 surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to maintain Work Records (WR) and Attestation Statements (AS) signed by the laboratory director for Hematology tests performed with the American Proficiency Institute (API) in 2020 and 2021. The findings include: 1. There was no AS for API - Hematology - 3rd event 2020. 2. There was no WR for API - Hematology - 1st event 2021. 3 . The TP #1 listed on CMS form 209 confirmed on 8/12/21 at 2:15 pm that the laboratory did not maintain complete records for PT.
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 surveyor review of Competency Assessment (CA) records and interview with the Testing Personnel (TP), the laboratory failed to follow written procedures to perform a CA on one of one Technical Consultants for the calendar year 2020. The TP #1 listed on CMS from 209 confirmed on 8/12/21 at 1:40 pm that the CA procedure was not followed.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP) the laboratory failed to review and evaluate results when they received an unacceptable score in Hematology tests performed with the American Association of Bioanalysts (AAB), for the offcycle event 10/25/19. The findings include: 1. The laboratory received an 60% Grade for Hematocrit. 2. There was no documented evidence that the laboratory investigated the failure. 3. The TP #1 listed on CMS form 209 confirmed on 8/12/21 at 2:45 pm that the laboratory did not review and document an evaluation of unacceptable PT results.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(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: a) Based on surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to follow their PM policy for flagging of Hematology results run on the Beckman Coulter AcT Diff 2 from 2/28/19 to the date of survey. The findings include: 1) The PM stated "X,+, and * flags will be rerun once" but a review of results with X, + and * revealed 20 out of 20 samples were not repeated. 2) The PM stated "1,2,3,4 or M differential flags are to be rerun once. If the parameter flagged is deemed unnecessary for treatment, the ordering physician may elect to forgo a rerun and have that result crossed out on the raw data print-out with a comment that says "not for diagnostic use". but a review of 20 out of 20 samples were not repeated or documented with the statement "not for diagnostic use". 3) The TP #1 listed on CMS form 209 confirmed on 8/12/21 at 2:20 pm the PM was not followed. Note: This deficiency was cited on surveys performed 2/8/17 and 2/28/19. b) Based on surveyor review of the PM, Quality Control (QC) records and interview with the TP, the laboratory failed to follow their policy for "Quality Control" performed on the Beckman Coulter AcT Diff 2 analyzer from 2/28/19 to the date of survey. The findings include: 1) The PM stated "Quality control value Levy Jennings (LJ) charts are reviewed by the technician on a weekly basis" 2) There was no documented evidence that LJ charts were reviewed on a weekly basis. 3) The PM stated "Quality

	control Levy Jennings charts are reviewed by the Technical Consultant (TC) and the Laboratory Director (LD) on a monthly basis." 4) There was no documented evidence that LJ charts were reviewed by the LD. 5) There was no documented evidence that LJ charts were reviewed by the TC from 8/17/19 through December 2020. 6). The TP #1 listed on CMS form 209 confirmed on 8/12/21 at 2:50 pm the QC procedure was not being followed.
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 surveyor review of Calibration Verification(CV) records, Operators Manual (OM) and interview with the Testing Personnel (TP), the laboratory failed to perform and document Calibration procedures at least once every six months for Hematology Tests performed on the Beckman Coulter Act2 Diff analyzer from 2/28/19 to the date of the survey. The finding includes: 1. A review of CV records revealed that the laboratory did not perform Carryover or Calibration on the dates CV was documented. 2. The TP #1 of CMS form 209 confirmed on 8/12/21 at 2:30 pm that the laboratory failed to perform and document CV.
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 surveyor review of Quality Control records and interview with the Testing Personnel (TP), the laboratory failed to verify commercially assayed QC material with each new lot and/or shipment of Hematology QC used on the Beckman Coulter Act

	Diff 2 analyzer from April 2021 to July 2021. The findings include: 1. Coulter 4C-ES Cell Controls lot 067600 put in use in April 2021 had no documented evidence that QC verification was performed. 2. Coulter 4C-ES Cell Control lots expire every three months. 3. The TP#1 listed on CMS form 209 confirmed on 8/12/21 at 2:00 pm that all assayed QC material was not verified before putting in use.
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 surveyor review of the Laboratory records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to provide overall management and direction to the laboratory from 2/28/19 to the date of survey. The findings include: 1. The LD failed to ensure that the QC program is maintained. Cross refer to D6020. 2. The Laboratory failed to follow their PM policy for flagging of Hematology results. Cross refer D5401. a) Note: This deficiency was cited on surveys performed 2/8/17 and 2/28/19. b) The Allegation Of Compliance(AOC) for the survey performed 2/8/17 stated: "The TP was briefed to perform repeat testing on patient specimens that have results with a asterisk (*). This will be reviewed by the TC at the end of each calendar month and after reviewed and signed by the LD. " c) The AOC for the survey performed 2/28/19 stated: Evaluation of analyzer flags: As part of the QA plan to be implemented by new TC, reference ranges and flags will be reviewed at least annually. As part of competency assessment, follow-up of flags will be reviewed when results are reviewed " d) There was no evidence the laboratory followed the AOC's
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 surveyor review of the Quality Control (QC) records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure that the QC program is maintained for laboratory services provided from 2/28/19 to the date of the survey. The findings include: 1. There was no documented evidence that the LD reviewed Complete Blood Count (CBC) QC. 2. The TP # 1 listed on CMS form 209 confirmed on 8/12/21 at 2:00 pm the LD did not ensure the QC program was maintained.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409

	The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on surveyor review of laboratory records, Quality Control (QC), Procedure Manual (PM) and personnel records and interview with the Testing Personnel (TP), the Technical Consultant (TC) failed to provide oversight and fulfill the requirements listed with 493.1413. 1. The TC failed to ensure that the QC programs were maintained. Cross refer to D6042 2. The TC failed to properly train staff. Cross refer to D6045 3. The TC failed to unsure TP followed the PM. Cross refer to D5401
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on surveyor review the Quality Control (QC) records, Calibration records, Package Inserts (PI) and interview with the Testing Personnel (TP), the Technical Consultant (TC) failed to ensure that the QC programs were maintained from 8/14/19 to the date of survey. The findings include: 1. There was no evidence of QC review from 8/14/19 to January 2021. 2. QC verification was not run on Coulter 4C-ES Cell Controls lot 067600. 3. The laboratory did not perform Carryover or Calibration on the dates CV was documented. 4. The TP #1 listed on CMS from 209 confirmed on 8 /12/21 at 2:30 pm that the QC programs were not maintained.
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: Based on surveyor review of the Training Records (TR) and interview with the Testing Personnel (TP), the Technical Consultant failed to have appropriate training on one out of one TP performing patient testing from 8/14/19 to the date of the survey. The findings include: 1) The TP was not trained properly on how to perform Calibration Verification (CV). a) A review of CV records revealed that the laboratory did not perform Carryover or Calibration on the dates CV was documented. 2) The TP#1 on CMS form 209 confirmed on 8/12/21 at 2:05 pm that the TC did not appropriately train TP on CV.

D6074	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(5) Each individual performing moderate complexity testing must be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the technical consultant, clinical consultant or director. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the Testing Personnel (TP), the TP failed to identify problems that may affect test performance by not reviewing and evaluating trends and/or shifts for tests performed on the Beckman Coulter AcT diff 2 analyzer from 2/28/19 to the date of survey. The TP #1 listed on CMS form 209 confirmed on 8/12/21 at 1:35 pm that trends and shifts were not reviewed.