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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 31D0857401 | (X3) Date Survey Completed 02/28/2024 |
| Name of Provider or Supplier Ehpn - Hematology Oncology | Street Address, City, State 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 |
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| D5401 | <p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), Work Records (WR) and interview with the Technical Consultant (TC), the laboratory failed to have a procedure for Complete Blood Count (CBC) results with flags from 8/20/22 to the date of survey. The TC confirmed on 2/28/24 at 11:30 am that the laboratory failed to have the aforementioned procedure.</p> |
| D5421 | <p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Complete Blood Cell (CBC) and automated differential Performance Specification (PS) records and interview with the Technical Consultant</p> |

(TC), the laboratory failed to ensure that all PS records were adequate for all analytes run on the Beckman Coulter DxH520 Analyzer from 8/20/22 to the date of survey. The findings include: 1. There was no source cited for Normal Patient Range. 2. There was no documented evidence that Linearity was performed. 3. The TC confirmed on 2/28/24 at 11:30 am that the laboratory failed to ensure that all PS records were adequate.

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 Technical Consultant (TC), the laboratory failed to perform and document Calibration procedures at least once every six months for Hematology Tests performed on the Beckman Coulter DxH520 analyzer from 8/20/22 to the date of the survey. The finding includes: 1. A review of CV records revealed that the laboratory did not perform Carryover or reproducibility on the dates CV was documented. 2. The TC confirmed on 2/28 at 10:30 am that the laboratory failed to perform Carryover or reproducibility. Note: This was previously cited 8/12/21

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 (QC) records and interview with the Technical 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 July 2021 to the date of survey. The findings include:
1. There is no documented evidence that QC material was verified. 2. The TC confirmed on 2/28/24 at 11:00 am that all assayed QC material was not verified before putting in use. Note: This was previously cited 8/12/21