| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 23D0719399 | 04/11/2024 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Corewell Health Dearborn Hospital Hem & Oncology | 19725 Allen Rd, Brownstown, MI | |

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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| **D5417** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(d)<br><br>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.<br><br>This STANDARD is not met as evidenced by:<br>. Based on observation and interview with the Technical Consultant, the laboratory failed to ensure sodium citrate blood collection tubes were not used beyond their expiration dates for 84 of 84 sodium citrate tubes observed. Findings include: 1. The surveyor observed a flat of 84 blue-top sodium citrate tubes in the clinic infusion area with other phlebotomy supplies on 4/10/24 at 10:06 am. The tubes had expired on 3/31 /24. 2. An interview on 4/10/24 at 10:15 am with the Technical Consultant confirmed the sodium citrate tubes had exceeded their expiration dates. |
| **D5439** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(b)<br><br>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless |

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| | the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.<br><br>This STANDARD is not met as evidenced by:<br>. Based on record review and interview with the Technical Consultant, the laboratory failed to perform calibrations for the Beckman Coulter DxH 520 analyzer at least every 6 months in 2023 (1/20/23 to 11/3/23). Findings include: 1. A review of the laboratory's "Calibration of Hematology Analyzer" procedure revealed a section stating, "All automated analyzers are to be calibrated under the following conditions (including but not limited too) a. Replacement of a major part b. Unacceptable quality control results c. Every 6 months or sooner if needed." 2. A review of the laboratory's Beckman Coulter DxH 520 hematology analyzer's calibration documentation revealed a lack of calibration performed between the 1/20/23 and 11/2/23 calibration dates. 3. An interview on 4/10/24 at 12:05 pm with the Technical Consultant confirmed the laboratory had not performed a calibration between the 1/20/23 and 11/2/23 calibration dates. |