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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 34D0247244 | (X3) Date Survey Completed 02/02/2023 |
| Name of Provider or Supplier Ah Wfb Hematology Oncology Statesville | Street Address, City, State 365 Brookdale Drive, Statesville, NC | |
| 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 |
|---------------------------|---|
| D5437 | <p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of 2020, 2021, and 2022 hematology records and interview with the TC (technical consultant) 2/2/23, the laboratory failed to perform and document calibration procedures at least once every 6 months for the Coulter DxH 520 hematology analyzer. Review of 2020, 2021, and 2022 DxH 520 hematology records revealed the laboratory performed calibration procedures 8/25/21, but the calibration was not completed. Review of the post-calibration instrument printout revealed it showed the calibration date as the date of the previous calibration, 2/25/21. Review of calibration records revealed the laboratory's next successful calibration was performed 4/5/22. During interview at approximately 1:20 p.m., the TC confirmed that the 8/25 /21 calibration records showed the previous calibration date, 2/25/21.</p> |
| D6053 | <p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the</p> |

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 personnel records and interview with the TC (technical consultant) 2/2/23, the TC failed to perform and document competency evaluations semiannually during the first year of testing for 1 of 5 testing personnel (TP #2). Review of personnel records revealed TP #2 was hired in January 2020. Training for TP #2 was documented in June 2020, and a 6 month competency evaluation was documented in November 2020. TP #2's next competency was documented in November 2021, approximately 12 months later. During interview at approximately 10:15 a.m., the TC confirmed that TP #2 did not have two competency evaluations during the first year of testing patient specimens.