

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 34D0895443	<b>(X3) Date Survey Completed</b> 01/26/2023
<b>Name of Provider or Supplier</b> Ah Wfb Hematology And Oncology - Elkin	<b>Street Address, City, State</b> 401 Eldon Parks Drive, Elkin, NC	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5437</b>	<p><b>CALIBRATION AND CALIBRATION VERIFICATION</b> 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 2022 hematology records and interview with the TS (technical supervisor) 1/26/23, the laboratory failed to ensure calibration was performed and documented at least once every 6 months for the Coulter DxH 520 hematology analyzer. Review of 2022 DxH 520 hematology records revealed the laboratory performed calibration procedures 10/25/22, 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 performed at installation, 1/24/22. During interview at approximately 12:20 p.m., the TS stated they did not realize the calibration was incomplete.</p>
<b>D6127</b>	<p><b>TECHNICAL SUPERVISOR RESPONSIBILITIES</b> CFR(s): 493.1451(b)(9)</p> <p>The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least</p>

semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies and procedures, review of personnel records, and interview with the TS (technical supervisor) 1/26/23, the TS failed to perform and document competency evaluations semiannually during the first year of testing for 1 of 7 testing personnel (TP #4). Review of the laboratory's "Quality Assurance Policies" revealed on pages 1-2 "Personnel ... Personnel are evaluated semi-annually in the first year of employment and annually thereafter. ..." Review of personnel records revealed TP #4 was hired in March 2021. Training for TP #4 was documented in April 2021, and a 6 month competency evaluation was documented in December 2021. TP #4's next competency was documented in January 2023, approximately 13 months later. During interview at approximately 9:30 a.m., the TS confirmed that TP #4 did not have two competency evaluations during the first year of testing patient specimens. She stated the annual competency evaluation due in June 2022 must have been overlooked.