Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 34D0991769	**(X3) Date Survey Completed** 08/11/2022
Name of Provider or Supplier Comprehensive Cancer Center Of Wfuhs At Mt Airy	**Street Address, City, State** 450 Price Street, Mount Airy, 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	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 review of 2020, 2021, and 2022 service and calibration records and interview with the GS (general supervisor) 8/11/22, the laboratory failed to perform and document calibration of the Coulter AcT diff 2 after replacement of critical parts. Review of Coulter AcT diff 2 service records revealed the service representative replaced the hemoglobin lamp, the white blood cell bath, and the photometer on 5/27/22. There was no documentation to indicate that the analyzer was calibrated by the service representative. Review of calibration records revealed the laboratory failed to calibrate the analyzer after the service was performed on 5/27/22. The last calibration for the AcT diff 2 hematology analyzer was documented 4/14/22. During interview approximately 11:40 a.m., the GS confirmed that the analyzer was not calibrated after the service was performed on 5/27/22.