Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0672600	05/30/2019
Name of Provider or Supplier	**Street Address, City, State**	
Oncology Specialties, Pc	1751 Veterans Dr, Suite190 B, Florence, AL	

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 reviews of the Horiba ABx 60C+ calibration procedure, calibration and quality control (QC) records, patient results in the Electronic Medical Record (EMR), and an interview with the Technical Consultant (also the Laboratory Manager), the surveyor determined the laboratory failed to follow the laboratory procedure to verify calibrations by running quality controls (QC) before patient CBC (Complete Blood Count) testing resumed, for one out of four calibrations of the Hematology analyzer performed in 2017 - 2018. The findings include: 1. A review of calibration records for the Horiba ABx 60C+ revealed the instrument was calibrated on 11/2/2017 at 12:12 PM. A review of Hematology records for this date revealed QC was performed only in the early morning. 2. During an interview on 5/30/2019 at 9:00 AM, the surveyor and the Technical Consultant reviewed the Horiba ABx 60C+ calibration procedure which required performance of three levels of QC to verify the calibration. The Technical Consultant confirmed the testing personnel had failed to run QC after the calibration, as per procedure. 3. As the interview continued, the surveyor then asked if patient CBC's were performed after the calibration on 11/2/2017. The Consultant

	reviewed patients in the Onco EMR, and stated eleven CBC's were performed after completion of the calibration. Thus the above noted findings were confirmed. SURVEYOR ID# 32558 Licensure and Certification Surveyor