Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2274543	05/26/2023
Name of Provider or Supplier	**Street Address, City, State**	
Tennessee Oncology, Pllc	315 Washington Ave Ste 230, Cookeville, TN	

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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of patient test reports, laboratory procedures and staff interview, the laboratory failed to ensure procedures for Complete Blood Count (CBC) testing were approved by the laboratory director prior to patient reporting which began on 01/20/23. The findings include: 1. Observation of the laboratory on 05/26/23 at 9:00 am revealed a Sysmex XN 430 instrument (SN: 11748) in use for performing CBC patient testing. 2. Review of patient test reports revealed patient reporting for CBC began on 01/20/23 (patient: 379726). 3. Review of the Laboratory Standard Operating Procedure and Policy Guide revealed the procedure titled "Sysmex Hematology Analyzer" was approved on 02/10/23 by the current laboratory director. 4. Interview with the laboratory clinical operations manager on 05/26/23 at 12:00 pm confirmed the laboratory began CBC patient testing prior to laboratory director approval of procedures.