Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0882938	04/16/2025
Name of Provider or Supplier	**Street Address, City, State**	
Tennessee Oncology, Pllc	397 Wallace Road Bldg C Suite 201, Nashville, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of laboratory policy, the Centers for Medicare and Medicaid Services form CMS-209, laboratory personnel records and staff interview, the laboratory failed to assess and document interim competency for two of eight testing personnel (TP) and annual competency for one of eight testing personnel (TP) in 2024. The findings include: 1. A review of the policy "Competency Testing on Laboratory Personnel" revealed the following requirement: "During the first year of an individual's duties, competency must be assessed after initial training and semiannually. After an individual has performed their duties for one year, competency must be assessed annually." 2. A review of the form CMS-209 revealed eight testing personnel listed for moderately complex testing. 3. A review of the laboratory's personnel records revealed the following: - TP 3- no documented annual competency in 2024 - TP 5- no documented interim competency in 2024 - TP 6- no documented interim competency in 2024 4. An interview with the Laboratory Regional Operations Manager on April 16, 2025 at 12:45 pm confirmed the above survey findings.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic

	examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on laboratory observation, a review of instrument printouts, a review of the laboratory procedure manual, and staff interviews, the laboratory failed to include in its policies and procedures a protocol for verifying flagged complete blood count (CBC) test results. The findings include: 1. An observation of the laboratory on 04/16 /2025 at 08:45 am revealed a Sysmex XN-430 (Serial Number 12031) analyzer in use for CBC patient testing. 2. During a random review of patient results, a review of instrument printouts from the Sysmex XN-430 for Patient #3 revealed a Positive CBC interpretation indicating "Morph. Count". The following "WBC IP Message" flags were listed: - IG Present - Left Shift - NRBC The following flagging instructions were listed: - #43: Confirm HBG by repeat testing - #47: Confirm HCT by repeat testing - #14: Make smr, scan, follow lab SOP - #26: If indicated, make smear and scan - #56: Scan smear for abnormal RBC morph 3. A review of the laboratory's procedure manual revealed no protocol for verifying flagged CBC test results. 4. An interview with the Laboratory Regional Operations Manager on April 16, 2025 at 12:45 pm confirmed the laboratory procedures failed to include a protocol for confirming flagged CBC results obtained from the Sysmex XN-430 analyzer.