Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D1033664	(X3) Date Survey Completed 04/20/2023
Name of Provider or Supplier Tennessee Oncology Pllc	**Street Address, City, State** 4220 Harding Rd, S&E Bldg Ste 200, 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 review of the laboratory's personnel records, personnel policy, and staff interview, the laboratory personnel policy did not include assessing technical consultant (TC) competency, as required. The findings include: 1. Review of the laboratory personnel records revealed the following: Delegation of technical consultant duties by the lab director to one TC. There were no records for documentation of technical consultant competency by the director of the lab for 2021, 2022, and 2023. 2. Review of the laboratory personnel competency policy revealed no requirement for assessment of technical consultant competency. 3. Interview with the laboratory lead on 04/20/23 at 2:25 pm confirmed the laboratory personnel competency policy did not include a requirement for technical consultant competency assessment performed by the lab director.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

	This STANDARD is not met as evidenced by: Based on observation of the lab, review of patient test reports, instrument validation records and staff interview, the laboratory director failed to approve validation studies for Sysmex XN 430 serial number 11072 complete blood count instrument (CBC) prior to patient testing in 2018. The findings include: 1. Observation of laboratory on 4 /20/2023 at 8:45 a.m. revealed a Sysmex XN 430 instrument serial number 11072 on the counter in use for performing patient CBCs. 2. Review of the first patient reported (MRN #131649) revealed testing on the instrument began on 11/29/2018. 3. Review of the instrument validation records revealed an install date of 11/29/2018. Lab director approval was not performed until 10/29/2020. 4. Interview with the laboratory lead on 4/20/2023 at 2:15 p.m. confirmed that the laboratory began patient testing on the Sysmex XN 430 Serial number 11072 on 11/29/18 without lab director approval.