Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0310302	06/01/2023
Name of Provider or Supplier	**Street Address, City, State**	
Tennessee Oncology, Pllc	605 Glenwood Drive, Suite 200, Chattanooga, 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 CMS Laboratory Personnel Report (CLIA) (CMS 209), laboratory policy, testing personnel (TP) records, and interview with the technical consultant, the laboratory failed to follow the policy for personnel competency assessment for one of four testing personnel in 2022. The findings include: 1. Review of CMS 209 report revealed four testing personnel performing patient testing for complete blood counts and manual blood smear differentials. Testing personnel three was a new testing person since last survey with documented hire date of 01.10.2022. 2. Review of the laboratory's policy titled, "Competency Testing on Laboratory Personnel" stated, "During the first year of an individual's duties, competency must be assessed after initial training and semiannually". 3. Review of testing personnel competency assessment records revealed no documentation of semiannual competency assessment for testing personnel three in 2022. 4. Interview with the technical consultant on June 1, 2023 at 2:30 p.m. confirmed the laboratory failed to follow its policy for testing personnel competency assessment in 2022.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, laboratory records, interview with lead testing person, and interview with the technical consultant, the laboratory failed to follow the procedure for annual pipette calibration 2021. The findings include: 1. Review of the laboratory procedure titled, "Equipment - Pipette Calibration" stated, "All multiuse pipettes must be calibrated annually to confirm proper volume delivery." 2. Review of laboratory pipette calibration records revealed calibration was not performed on the laboratory's two pipettes (serial numbers 300309 and MK945421) in 2021. 3. Interview with the lead testing person on June 1, 2023 at 2:00 p.m. confirmed, two pipettes (serial numbers 300309 and MK945421) were calibrated 11.17.2020 and 05.24.2022, and were not calibrated in November 2021 when due for annual calibration. 4. Interview with technical consultant on June 1, 2023 at 2:30 p.m. confirmed the laboratory failed to follow the procedure for annual pipette calibration in 2021.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation of the laboratory and interviews with the technical consultant, the laboratory failed to label three staining dishes used for manual blood smear differential patient testing in 2023. The findings include: 1. Observation of the laboratory on June 1, 2023 at 12:30 p.m. revealed a microscope on the counter and three staining dishes, one containing QuickLink I Wright's Stain and two containing deionized water in use for performing manual blood smear differential patient testing that were not labeled. 2. Interview with the technical consultant on June 1, 2023 at 12: 45 p.m. confirmed the QuickLink I Wright's stain had been poured from the original bottle into the staining dish and the other two dishes had been filled with dionized water. 3. Interview with the technical consultant on June 1, 2023 at 2:30 p.m. confirmed the laboratory failed to label the three dishes (one containing QuickLink I Wright's Stain and two containing deionized water) with content, lot number and expiration date on the date of the survey (06.01.2023).