

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D1052600	(X3) Date Survey Completed 10/07/2024
Name of Provider or Supplier Tennessee Oncology, Pllc	Street Address, City, State 2200 E Third Street, Suite 100, 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
D6043	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(5)</p> <p>(b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;</p> <p>This STANDARD is not met as evidenced by: Based on laboratory observation, review of instrument validation records, quality control (QC) records, the laboratory's policies, monthly quality assurance (QA) reports, lack of documentation, and staff interviews, the technical consultant (TC) failed to identify, investigate, and follow-up on performance issues with one of four QC lots reviewed in 2023 and 2024. The findings include: 1. An observation of the laboratory on 09/07/2024 at 9:10 a.m. revealed that it used one Sysmex XN-430 (ID: 12002) and one Sysmex XN-550 (ID: 12419) to perform complete blood count (CBC) testing. The laboratory used three levels of Sysmex HN-L Check quality control material to verify each instrument's performance. 2. A review of instrument validation records revealed that the Sysmex XN-430 (ID: 12002) replaced a Sysmex XN-430 (ID: 11141) on 03/05/2024. 3. A review of the laboratory's 2023 and 2024 QC records revealed it used XN-L Check lots 4265, 4012, 3293, and 3209 to monitor test system performance. 4. A review of the laboratory's "Quality Assurance Program" (PolicyStat ID: 13180163) revealed the following: - Laboratory management will review quality assurance reports monthly for "quality outliers" and implement process improvement as needed. - The laboratory sends peer evaluations of monthly QC to the technical consultant for review and approval. 5. A review of the laboratory's monthly quality reports revealed that the laboratory used the Sysmex Insight report to monitor overall QC performance against peers. The January 2024 Insight report summary for Sysmex XN-430 (ID: 11141) using XN-L Check QC lot number 3293 stated there was an accuracy bias on the white blood cell (WBC) parameter. Further review revealed a "W" flag on the WBC parameter of the level two control due to a standard deviation</p>

interval (SDI) of 2.4. The report states that the flag means the parameter is "outside the established SDI range." 6. The laboratory could not provide documentation that showed the QC outlier was identified or monitored. 7. An interview with the Clinical Lab Operations Manager and Regional Operations Manager on 09/07/2024 at 1:00 p. m. confirmed the findings.