

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 44D0969102	<b>(X3) Date Survey Completed</b> 03/11/2024
<b>Name of Provider or Supplier</b> Tennessee Oncology, Pllc	<b>Street Address, City, State</b> 776 Weatherly Drive, Ste A, Clarksville, TN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	During a recertification survey performed on 03/11/24, the laboratory was found out of compliance with the following condition: 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel
<b>D5775</b>	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of instrument comparison records, and staff interview, the laboratory failed to compare results for the automated white blood cell count performed on the two Sysmex Complete Blood Count (CBC) instruments twice a year in 2022, 2023, and 2024. The findings include: 1. Observation of the laboratory on March 11, 2024, at 8:45 am revealed two Sysmex Complete Blood Count (CBC) instruments in use for performing patient testing for CBC with automated White Blood Cell (WBC) differential (serial numbers 11125 and 16001). 2. Review of instrument comparison records revealed the laboratory did not compare results for automated WBC differential between the two instruments in 2022, 2023, or 2024. 3. The laboratory liaison confirmed the survey findings during interview on 03 /16/24 at 12:45 pm.</p>
<b>D6063</b>	<p>LABORATORY TESTING PERSONNEL CFR(s): 493.1421</p> <p>The laboratory must have a sufficient number of individuals who meet the</p>

qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:

Based on observation of the laboratory, review of patient test reports, personnel qualifications, and staff interview, testing person number three did not meet the regulatory education requirements for moderately complex testing personnel (Refer to D6065).

**D6065**

**TESTING PERSONNEL QUALIFICATIONS**

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, review of patient test reports, review of testing personnel records, and staff interview, testing person number three failed to qualify as a testing person due to lack of documentation. The findings include: 1. Observation of the laboratory on March 11, 2024, at 8:45 am revealed two Sysmex Complete Blood Count (CBC) instruments used for performing patient testing for CBC with automated White Blood Cell differential (CBC w/Diff). 2. Testing person three reported two patients for CBC w/Diff on 12/21/23 (Sample ID 23704541 and Sample ID 23706150). 3. Qualifications for testing person three were reviewed. The diploma on file did not indicate the degree. 4. The laboratory liaison stated the following during an interview on 03/11/24 at 12:00 pm: Testing person three graduated from a certificate degree Medical Laboratory Technician program. The high school diploma was not maintained as part of the employee file. This confirmed the survey findings.