

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D0312477	<b>(X3) Date Survey Completed</b>  01/22/2024
<b>Name of Provider or Supplier</b>  Tennessee Cancer Specialists	<b>Street Address, City, State</b>  7650 Dannaher Lane Suite 100, Powell, 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>D5793</b>	<p><b>ANALYTIC SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1289(b)(c)</p> <p>(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assessment plan, review of environmental records, review of monthly quality assurance records and interview with the Technical Consultant, the laboratory's quality assessment process was ineffective when it failed to identify and correct problems in November 2022 and December 2022. The findings include: 1. Review of the laboratory's quality assessment plan revealed the quality assurance plan is designed to identify and eliminate sources of error and problems and to provide a mechanism for corrective action. 2. Review of laboratory's humidity records revealed laboratory humidities recorded were outside the stated acceptable range (20%-85%) for the following days with no documented corrective action: Date Humidity -11.17.2022: 16% -11.18.2022: 16% -11.21.2022: 16% -11.22.2022: 16% -12.02.2022: 16% -12.19.2022: 16% -12.27.2022: 16% -12.28.2022: 16% 3. Review of November 2022 and December 2022 monthly quality assurance review records revealed the following statement and answer, "Was humidity recorded and in range every day? Yes List any values out of range and corrective action". No out of range values listed and no corrective action documented. 4. Interview on 01.22.2024 at 12:00 p.m. with the Technical Consultant confirmed the laboratory's quality assessment process was ineffective when it failed to identify and correct problems when unacceptable laboratory humidities were recorded with no documented corrective action in November 2022 and December 2022.</p>