

<p>Statement of Deficiencies</p>	<p>(X1) Provider/Supplier/CLIA Identification Number</p> <p>44D0992181</p>	<p>(X3) Date Survey Completed</p> <p>05/02/2023</p>
<p>Name of Provider or Supplier</p> <p>Tennessee Oncology Pllc</p>	<p>Street Address, City, State</p> <p>Russell Plaza 120 Frank Martin Road, Suite 102, Shelbyville, TN</p>	
<p>For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.</p>		

<p>(X4) ID Prefix Tag</p>	<p>Summary Statement of Deficiencies</p>
<p>D6004</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b)</p> <p>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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.</p> <p>This STANDARD is not met as evidenced by: Based on a phone interview, review of the Aspen Web 116 database, virtual observation, review of patient test reports and staff interview, the laboratory director failed to ensure compliance with 493.49 (g) (1) Requirements for a Certificate of Compliance, which requires the renewal application be sent to HHS 9 to 12 months prior to the expiration of the certificate, resulting in the laboratory operating on an expired Clinical Laboratory Improvements Amendments (CLIA) certificate from 04/01/23 to the date of the survey on 05/02/23. The findings include: 1. Phone interview with the technical consultant on 04/25/23 at 2:45 pm revealed the laboratory failed to return the CLIA renewal application which had allowed the laboratory's CLIA certificate to expire. 2. Review of the Aspen Web 116 database revealed the laboratory's CLIA certificate expired on 03/31/23. 3. Virtual observation of the laboratory on 05/02/23 at 8am revealed the Sysmex XN430 (serial # 11093) in use for patient testing for Complete Blood Count (CBC). 4. Review of patient number MRN 448429 revealed patient testing for CBC reported on 05/02/23. 5. Virtual interview with the laboratory lead on 05/02/23 at 10:35 am confirmed the laboratory director</p>

failed to ensure the laboratory's CLIA renewal application was returned in a timely manner resulting in the laboratory operating on an expired CLIA certificate.