

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 44D1088998	<b>(X3) Date Survey Completed</b> 12/15/2022
<b>Name of Provider or Supplier</b> Ut Erlanger Women's Oncology	<b>Street Address, City, State</b> 102 Central Avenue, Chattanooga, 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>D2009</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review and request of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records and interview with the office manager and lead testing person, it was determined the testing personnel and/or the laboratory director failed to sign the attestation sheets for 11 of 12 PT events for 2021 and 2022. The findings include: 1. Request of the laboratory's PT records revealed the following: -No attestation pages available for the following: Hematology/Coagulation 2021 event one and two and 2022 event one Chemistry 2021 event one, two and three and 2022 event one -Attestation pages not signed by the testing personnel and/or laboratory director for the following: Hematology/Coagulation 2022 event two and three Chemistry 2022 event two and three 2. Interview with the office manager and lead testing person on 12.15.2022 at 1pm confirmed the above findings.</p>
<b>D6018</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)(iii)</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. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;</p>

This STANDARD is not met as evidenced by:

Based on review and request of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records and interview with the office manager and lead testing person, the laboratory director failed to ensure proficiency testing results were available and/or reviewed for 8 of 12 proficiency testing performance evaluation reports in 2021 and 2022. The findings include: 1. Request of the laboratory's PT records revealed the following: -No performance evaluation reports available for review for the following: Hematology/Coagulation 2021 event one and two and 2022 event one Chemistry 2021 event two and three and 2022 event one -Performance evaluation reports not reviewed/signed by laboratory director for the following: Hematology/Coagulation 2021 event three Chemistry 2022 event two 2. Interview with the office manager and lead testing person on 12.15.2022 at 1pm confirmed the above findings.