

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D1103837	<b>(X3) Date Survey Completed</b>  07/25/2019
<b>Name of Provider or Supplier</b>  Thompson Oncology Group Lenoir City	<b>Street Address, City, State</b>  576 Fort Loudoun Medical Center Dr, Suite 203, Lenoir City, 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>D5429</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: ===== Based on observation of Hematology refrigerator thermometers, review of thermometer maintenance, lack of accuracy verification prior to expiration dates and upon interview with the Nurse Manager, determined the laboratory failed to perform and document required maintenance to ensure accuracy of thermometers prior to expiration dates. The findings include: 1. Observation of two of two thermometers in Hematology refrigerator at 9:10 a.m. July 25, 2019. 2. Review of thermometer maintenance requires accuracy verification to be performed prior to expiration dates. 3. Lack of thermometer maintenance for accuracy verification prior to expiration dates for digital thermometer reading at 7.3 degrees Celsius with expiry date of 6/27/19 and for internal bottle thermometer reading at 4 degrees Celsius with expiry date of 12/9/16 set within the same Hematology refrigerator. 4. Interview at approximately 1:30 p.m. July 25, 2019 with Nurse Manager confirmed the thermometer maintenance for accuracy verification was not performed prior to expiration dates for the two of two thermometers in Hematology refrigerator with temperatures of thermometers not matching. =====</p>
<b>D6000</b>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.</p>

1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

===== This condition level deficiency is due to Laboratory Director position not filled since July 31, 2018 to include lack of proficiency testing review for 2018 and 2019 (D6018), lack of quality control review for 2018 and 2019 (D6020) and lack of personnel competency reviews for 2018 (D6029). =====

**D6018**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)(iii)

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;

This STANDARD is not met as evidenced by:

===== Based on review of Proficiency Testing (PT) policy, lack of PT results review from January 2018 to July 2018, lack of PT results review from August 2018 to July 2019 due to lack of Laboratory Director position not filled and upon interview with the Clinical Supervisor, determined there was no director review of PT results for 2018 and 2019 and lack of Laboratory Director position not filled from July 31st, 2018 to July 25th, 2019. The findings include: 1. Review of PT policy states that Laboratory Director is to review Proficiency Testing results with date and signature. 2. Lack of Proficiency Testing results review by previous Laboratory Director from January 2018 to July 2018. 3. Lack of Proficiency Testing results review from August 2018 to July 2019 due to Laboratory Director position not filled. 4. Interview at approximately 1:30 p.m. 7/25 /19 with Clinical Supervisor confirmed that Proficiency Testing results had not been reviewed by Laboratory Director for 2018 and 2019 and Laboratory Director Position was not filled since July 31, 2018.

**D6020**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(5)

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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

===== Based on review of Quality

Control (QC) Program, lack of Laboratory Director review of Peer Value Quality Control (QC) reports for 2018 and 2019, lack of Laboratory Director position not filled after July 31, 2018 and upon interview with the Clinical Supervisor, determined the previous Laboratory Director failed to review QC reports monthly from January 2018 through July 2018 and lack of QC reports review from August 2018 to July 25, 2019 due to Laboratory Director position not filled. The findings include: 1. Review of Quality Control program states that Laboratory Director will review Quality Control (QC) Peer Value reports monthly. 2. Lack of monthly review of Peer Value QC reports from January 2018 to July 2018 by previous Laboratory Director. 3. Lack of monthly review of Peer Value QC reports from August 2018 to July 25, 2019 due to Laboratory Director position not filled. 4. Interview at approximately 1:30 p.m. July 25, 2019 with the Clinical Supervisor confirmed there was no review of monthly Peer Review QC reports from January 2018 to July 2018 by previous Laboratory Director and no monthly QC reports review from August 2018 to July 25, 2019 due to Laboratory Director position not filled.

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**D6029**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

===== Based on review of personnel policy, lack of 2018 competencies for 5 of 6 testing personnel, failure to fill Laboratory Director position after July 31, 2018 and upon interview with Clinical Supervisor, determined there were no 2018 annual competency reviews for 5 of 6 testing personnel and there was no Laboratory Director position filled after July 31, 2018. The findings include: 1. Review of personnel policy states that Laboratory Director is to review all training and competencies. 2. Lack of 2018 annual competencies for 5 of 6 testing personnel who perform Complete Blood Count (CBC) testing. 3. Failure to fill Laboratory Director position after July 31, 2018. 4. Interview at approximately 1:30 p.m. July 25, 2019 with the Clinical Supervisor confirmed the Laboratory Director failed to ensure that 2018 competencies for 5 of 6 testing personnel were performed and documented for CBC testing and failure to fill Laboratory Director position since July 31, 2018.

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