

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 44D0882942	<b>(X3) Date Survey Completed</b> 05/23/2018
<b>Name of Provider or Supplier</b> Tennessee Oncology Pllc	<b>Street Address, City, State</b> 250 25th Ave N Suite 100, Nashville, 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>D2128</b>	<p>HEMATOLOGY CFR(s): 493.851(e)</p> <p>(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Medical Laboratory Evaluation (MLE) summary report for Hematocrit testing second event 2017 and interview with the Laboratory Supervisor revealed the laboratory failed to review and document remedial action for failed hematocrit analyte results second event 2017. Finding Include: 1. Review of the MLE summary report for Hematocrit testing second event 2017 revealed the laboartory failed to review and document remedial action for failed hematocrit analyte results second testing event 2017. 2. Interview with the Laboratory Supervisor on May 23,2018 at 13:25 pm confirmed the laboratory failed to review and document remedial action for failed hematocrit analyte results second testing event 2017.</p>
<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>

This STANDARD is not met as evidenced by:  
Based on lack of record review for comparison of test results using two of the same Complete Blood Count (CBC) analyzers and interview with the Laboratory Supervisor the laboratory failed to perform comparison of test results using two of the same CBC analyzers in 2016 and 2017. The Findings Include: 1. Lack of record review for comparison of test results using two of the same CBC analyzers the laboratory failed to perform comparison of test results for two of the same CBC analyzers in 2016 and 2017. 2. Interview with the Laboratory Supervisor on May 23, 2018 at 13:20 PM confirmed the laboratory failed to perform comparison of test results for two of the same CBC analyzers in 2016 and 2017.

**D6040**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(2)

The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

This STANDARD is not met as evidenced by:  
Based on review of validation records for Access-2 immunoassay analyzer and interview with the Technical Consultant failed to review and evaluate the verification data in July 2017. The Finding Include: 1. Review of the validation records for Access-2 immunoassay analyzer revealed the validation records were not reviewed for vitamin B-12, Vitamin-D and Folate analytes in July 2017 by the Technical Consultant. 2. Interview with the Laboratory Supervisor on May 23, 2018 at 1:15 pm confirmed the Technical Consultant failed to review the validation records for Vitamin B-12, Vitamim-D and Folate analytes in July 2017.