

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D1013507	(X3) Date Survey Completed 05/24/2019
Name of Provider or Supplier Tennessee Oncology Pllc	Street Address, City, State 300 Stonecrest Blvd, Suite 400, Smyrna, TN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D6030	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;</p> <p>This STANDARD is not met as evidenced by: Based on review of the Quality Assessment policy for monitoring competency of testing personnel and an interview with the quality review supervisor determined the laboratory failed to follow its own policy for performing annual competency assessments for the two year period. The findings include: 1) A review of the Quality Assessment policy for the laboratory stated annual competency assessments for each testing person will be performed. 2) There were no documents available to show annual competency assessments were performed since 2017. 3) Interview with the quality review supervisor at 10:30 AM on May 24, 2019, confirmed there were no annual competency assessments documented ensuring their own policy was being followed from 2017-2019.</p>
D6046	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of</p>

all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on review of employee personnel records for 2017-2019 and interview with the quality review supervisor, the laboratory's technical consultant failed to document the six required criteria for assessing personnel competency. The findings include: 1) There were no TC reviews on-site of employee personnel records for 2017-2019 did not reveal documentation of the six required criteria of competency that include: direct observation of routine patient test performance; monitoring the recording and reporting of test results; review of intermediate test results or worksheets, quality control records, proficiency testing results and preventative maintenance records; direct observation of performance of instrument maintenance and function checks; assessment of test performance through previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and, assessment of problem solving skills. 2) An interview with the quality review supervisor on May 24, 2019, at 11:30am confirmed 2 of 2 testing personnel evaluated during 2017- 2019 were not evaluated using the six criteria for competency required by Centers for Medicare and Medicaid (CMS).