Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D1029009	(X3) Date Survey Completed 01/14/2019
Name of Provider or Supplier Tennessee Oncology Pllc	**Street Address, City, State** 103 Natchez Park Dr, Suite 103, Dickson, 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
D0000	493.51 Notification requirements for laboratories issued a certificate of compliance. Laboratories issued a certificate of compliance must meet the following conditions: (a) Notify HHS or its designee within 30 days of any change in -- (1) Ownership; (2) Name; (3) Location; (4) Director; or (5) Technical supervisor (laboratories performing high complexity only). This condition is not met as evidenced by: Based on review of the laboratory director of record in the Clinical Laboratory Improvement Amendments (CLIA) database and the current Clinical Laboratory Improvement Amendments (CLIA) Application for Certification form (CMS 116 form) and interview with the current laboratory director, the laboratory failed to notify CLIA of the change in laboratory director in 2017. The findings include: 1) Review of the CLIA database revealed the name of a laboratory director other than the one listed on the current CMS 116 form. 2) Interview with the current laboratory director on January 14, 2019 at 9:00 am confirmed the current laboratory director assumed the laboratory director position around May 2017. No documentation of notification of the change to CLIA could be located. The laboratory failed to notify CLIA of the change of laboratory director in 2017.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the validation studies for the

	Sysmex XN 430 complete blood count (CBC) instrument, patient number one test report and interview with the laboratory director, the laboratory failed to verify reference range for the Sysmex XN 430 CBC instrument in 2018. The findings include: 1) Observation of the laboratory on January 14, 2019 at 8:15 am revealed the Sysmex XN 430 CBC instrument (serial #11056) in use for patient testing. 2) Review of the validation studies performed for the Sysmex XN 430 CBC instrument in October 2018 revealed no verification of patient reference range (normal patient range). 3) Review of patient number one CBC test report revealed the laboratory began patient testing on the Sysmex XN 430 CBC instrument on December 4, 2018. 4) Interview with the laboratory director on January 14, 2019 at 11:30 am confirmed no reference range/normal range study had been performed for the Sysmex XN 430 in 2018.