Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0310302	10/02/2018
Name of Provider or Supplier	**Street Address, City, State**	
Tennessee Oncology, Pllc	605 Glenwood Drive, Suite 200, Chattanooga, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) 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. This STANDARD is not met as evidenced by: Based on a review of 2016-2018 proficiency testing (PT) records and an interview with the general supervisor, the laboratory director (LD) failed to document signed eight of eight attestation statements for chemistry, immunolgy, endocrinology, and hematology PT Events (A, B, C) from 2016-2018. Findings include: 1. The laboratory director (LD) did not sign 8 of 8 PT attestation statements from 2016-2018 PT Events A, B, and/or C. 2. In an interview, on October 2, 2018, at 11:00 AM, the general supervisor confirmed she had signed all 8 of 8 PT attestation statements instead of the lab director for PT Events (A, B, C) in 2016-2018.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

	This STANDARD is not met as evidenced by: Based on a review of records for 2018 personnel records, quality assurance plan, and an interview with the general supervisor, the laboratory director failed to ensure job descriptions with duties and responsibilities for the positions of Laboratory Director (LD), Clinical Consultant (CC), Technical Consultant/Supervisor (TC/TS), and Testing Personnel (TP). Findings include: 1. There were no job descriptions with duties and responsibilities available to review in personnel records during 2016-2018. 2. There were no job descriptions with duties and responsibilities available to review in the lab quality assurance plan during 2016-2018. 3. Interview with the general supervisor on October 2, 2018, at 10:00am, confirmed the laboratory director did not ensure job descriptions were available with duties and responsibilities for the LD, CC, TCTS, and TP during 2016-2018.