Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0864535	05/10/2018
Name of Provider or Supplier	**Street Address, City, State**	
Tennessee Oncology Pllc	2004 Hayes Street, Suite 350, Nashville, 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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Hematology: The laboratory failed to maintain satisfactory participation in three out of three events for the Cell I.D. or white blood cell (WBC) differential, resulting in the first unsuccessful proficiency testing (PT) occurrence for the Cell I.D. or WBC differential analyte. (Refer to D2130)
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive

	events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a review of the Casper 155 report and the laboratory's 2017 Medical Laboratory Evaluation (MLE) Proficiency Test (PT) records, and interview with the laboratory supervisor the laboratory failed to maintain satisfactory performance for the Cell ID analyte in 2017 events one, two and three, resulting in the second unsuccessful occurrence in 2017. The findings include: 1) Review of the Casper 155 report revealed the Cell ID 2017 event one score is 40%, event two score is 60% and event three is 0%. 2) Review of the laboratory's 2017 MLE-M1 PT records event one cell BC-1, BC-2, BC-5 had unacceptable grades, resulting in a score of 40%, event two 2017 MLE-M2 cell BC-9, BC-10 had unacceptable grades, resulting in a score of 60%, event three cell BC-13-18 had unacceptable grades resulting in a score of 0%. 3) Interviw with the laboratory supervisor on May 10, 2018 at 13:00 PM confirmed the laboratory had unsuccessful score on Cell I.D. event one score of 40%, event two score of 60% and event three score of 0% for 2017.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the Temperature and Humidity Chart for Laboratory Equipment log and interview with the Laboratory Supervisor, it was determined that the laboratory failed to ensure the freezer temperature where maintained at -18-0 Centigrade (C) /0.4-32 Fahrenheit (F) in 2016 and 2017 The Findings include: 1. Review of theTemperature and Humidity Chart for Laboratory Equipment log revealed the freezer temperatures were out of range in 2016 for the following months: June - 12 of 21 days; July - 8 out of 19 days, August - 13 out of 22 days, September - 8 out of 20 days, October - 16 out of 21 days, November - 20 out of 21 days, December - 20 out of 21 days: Year 2017- January - 11 out of 21 days, February - 13 out of 20 days, March - 13 out of 23 days, April - 16 out of 20 days, May - 9 out of 20 days, June -14 out of 22 days, July - 10 out of 20 days, September - 8 out of 21 days, 2. An interview with the Laboratory Supervisor on May 10, 2018 at approximately 13: 10 PM confirmed the laboratory failed to ensure the freezer temperatures were in acceptable range in 2016 and 2017.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (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. This STANDARD is not met as evidenced by: Based on lack of record review for comparison of test resuls 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 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 in 2016 and 2017. During this time both analyzers where in use. 2. Interview with the Laboratory Supervisor on May 10, 2018 at 13:20 PM confirmed the laboratory failed to perform comparison of test results in 2016 and 2017.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the Temperature and Humidity Chart for Laboratory Equpment log and interview with the Laboratory Supervisor determined that the laboratory failed to document corrective action for the freezer temperature out of range for 2016 and 2017. The Findings Include: 1. Review of the Temperature and Humidity Chart for Laboratory Equpment log revealed the laboratory failed to document corrective action for out of range freezer temperature for February through December 2016 and January through December 2017. 2. Interview with the Laboratory Supervisor on May 10, 2018 at 13:15 PM confirmed the laboratory failed to document corrective action for out of range freezer temperature for February through December 2016 and January through December 2017.