

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0969102	(X3) Date Survey Completed 04/16/2019
Name of Provider or Supplier Tennessee Oncology, Pllc	Street Address, City, State 776 Weatherly Drive, Ste A, Clarksville, 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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the procedure manual, patient number one report and interview with the laboratory liaison, the laboratory failed to provide a procedure for the sodium citrate platelet aggregation testing. The findings include: 1) Observation of the laboratory on April 16, 2019 at 1:30 p.m. revealed the Sysmex XN-430 complete blood count (CBC) instrument serial number 11125 and the Sysmex XN-550 CBC instrument serial number 16001, in use for patient testing. 2) Review of the laboratory procedure manual revealed no procedure for the sodium citrate platelet aggregation testing. 3) Review of patient number one report and CBC instrument printout revealed the following:the final reported as Platelet Count, Sodium Citrate Tube, dated 01-10-19, result L 96 K/uL; the CBC instrument printout is 88 K/uL. 4) Interview on April 16, 2019 at 2: 30 p.m. with the laboratory liaison confirmed the laboratory collects patient samples using the sodium citrate tubes, performs testing on the CBC instruments and multiplies the answer by 1.1. The laboratory procedure and manufacturer's instructions for sodium citrate could not be located.</p>
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>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</p>

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 verification of performance specification records and interview with the laboratory liaison, the laboratory failed to verify the sodium citrate platelet aggregation procedure, prior to testing in 2018. The findings include: 1) Observation of the laboratory on April 16, 2019 at 1:30 p.m. revealed the Sysmex XN-430 complete blood count (CBC) instrument serial number 11125 and the Sysmex XN-550 CBC instrument serial number 16001, in use for patient testing. 2) Review of the verification of performance specification records revealed the sodium citrate platelet aggregation procedure was not included in the verification process, signed by the laboratory director on 12-24-18. 3) Interview on April 16, 2019 at 3:45 p.m. with the laboratory liaison confirmed the sodium citrate platelet aggregation procedure was not included in the verification procedure, with continued patient testing.

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 observation of the laboratory, review of the 2018 and 2019 laboratory records and interview with the laboratory liaison, the laboratory failed to compare the two CBC instruments for the sodium citrate platelet aggregation procedure at least two times per year, in 2018 and 2019. The findings include: 1) Observation of the laboratory on April 16, 2019 at 1:30 p.m. revealed the Sysmex XN-430 complete blood count (CBC) instrument serial number 11125 and the Sysmex XN-550 CBC instrument serial number 16001, in use for patient testing. 2) Review of the 2018 and 2019 laboratory records revealed no comparison between the two instruments for the sodium citrate platelet aggregation procedure in 2018 and 2019. 3) Interview on April 16, 2019 at 4:30 p.m. with the laboratory liaison confirmed the sodium citrate platelet aggregation procedure was in use for patient testing in 2018 and 2019. The laboratory did not evaluate and define the relationship between the two instruments performing the sodium citrate platelet aggregation procedure in 2018 and 2019.

D6011

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(2)

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)(2) and provide a safe environment in which employees are protected from physical, chemical, and biological hazards.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory and interview with the laboratory liaison, the laboratory director failed to provide a safe environment from biological hazards. The findings include: 1) Observation of the laboratory on April 16, 2019 at 1:30 p.m. revealed no biohazard signs in the laboratory where patient testing is performed. 2) Interview on April 16, 2019 at 1: 35 p.m. with the laboratory liaison confirmed there are no biohazard signs in the laboratory.