

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D1083231	(X3) Date Survey Completed 08/09/2018
Name of Provider or Supplier Cancer Care, Pllc	Street Address, City, State 274 Clear Sky Court, 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 laboratory procedure for CBC QC manual, the 2018 complete blood count (CBC) quality control (QC) records and interview with testing personnel number one, the laboratory failed to follow the CBC QC procedure for running concurrent old and new lot numbers prior to use. The findings include: 1) Observation of the laboratory on August 9, 2018 at 10:15 a.m. revealed the Horiba ABX Micros 60 CSB 16P "EN" instrument (serial number 302CS2497) in use for patient CBC testing. 2) Review of the laboratory procedure for the CBC QC manual revealed, "Assay values on a new lot of control should be confirmed before it is put into routine use. Test the new lot when the instrument is in good working order and QC results on the previous lot are acceptable." "Run each level of QC 10-20 times over multiple days using the manufacturer's means and limits." 3) Review of the 2018 CBC QC records revealed the CBC QC lot number MX411 expiration date 7-5-18 was in use from May 5, 2018 to July 5, 2018 with no concurrent runs of old and new lot numbers prior to patient testing. 4) Interview on August 9, 2018 at 12:30 p.m. with testing personnel number one confirmed the concurrent run of old and new lot numbers for CBC QC lot number MX411 expiration date 7-5-18 was not performed in May 2018 prior to patient testing.</p>