Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2012798	06/15/2022
Name of Provider or Supplier	**Street Address, City, State**	
West Cancer Center	1290 Kelley Dr, Paris, 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	PROCEDURE MANUAL CFR(s): 493.1251(a) 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. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory procedure manual, review of selected patient testing dates, quality control (QC) records, and email communication, and interview with the technical consultant, the laboratory failed to follow its' own procedure for ensuring Complete Blood Count (CBC) QC was performed and acceptable prior to performing patient CBC testing in 2021 and 2022 with three patient affected on the dates selected. The findings include: 1. Observation of the laboratory on 06/15/2022 at 9 am revealed two CellDyn Emerald CBC instruments in use for patient CBC testing (ID#s 377 and 599). 2. Review of the laboratory's procedure manual revealed that quality control must be performed and acceptable before performing any patient testing. 3. Review of randomly selected patient testing dates, quality control records and email communication revealed quality control was not performed and acceptable prior to patient testing as follows: 12 /14/2021---patient 205641 released at 8:45 am prior to acceptable QC at 9:27 am 04/13 /2022---patient 240503 released at 9:20 am prior to acceptable QC at 9:27 am Review of email received from the technical consultant on 06/21/2022 revealed a total of three patients were reported on the dates in question prior to acceptable QC. 4. Interview with the technical consultant on 06/15/2022 at 4 pm confirmed the laboratory failed to follow its' own procedure for ensuring QC was performed and acceptable prior to performing patient CBC testing on 12/14/2021 and 04/13/2022.