Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	18D0326926	03/15/2024
Name of Provider or Supplier	**Street Address, City, State**	
Elizabethtown Hematology Oncology	1107 Woodland Drive Suite 105, Elizabethtown, KY	

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
D0000	A recertification survey was conducted on 03/15/2024. The facility was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with deficiencies cited.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of laboratory policy, and confirmed in staff interview, the laboratory failed to establish a list of panic or alert values for 1 of 1 non-waived tests performed, Complete Blood Count (CBC), and failed to establish a procedure for the reporting of those values to medical providers. Findings included: Review of the laboratory's

	policy revealed no evidence of a written protocol/procedure that specified panic or alert values for a CBC or how these values were reported to medical providers. During an interview on 03/15/2024 at 10:30 AM, Testing Personnel #1 stated the laboratory did not have established panic or alert values and did not have a policy and procedure for reporting those values to medical providers. During an interview on 03 /15/2024 at 11:15 AM, the Laboratory Director confirmed the laboratory did not have established panic or alert values and did not have a policy and procedure for reporting those values to medical providers.