Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2194692	04/27/2021
Name of Provider or Supplier	**Street Address, City, State**	
Comprehensive Hematology Oncology Llc	6555 Cortez Road West, Bradenton, FL	

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	An announced CLIA initial survey was conducted at Comprehensive Hematology Oncology LLC on 04/27/2021. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
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 record review and staff interview, the laboratory failed to document corrective action when the room temperature and the refrigerator temperature was out of range for 8 days out of of 54 days reviewed (September 17, 2020 - April 27, 2021). Findings included: Record review of the procedure manual revealed an undated procedure titled "Instrument Maintenance." Review of the procedure revealed "Corrective action must be taken and documented when temperatures are outside of acceptable ranges." An additional undated procedure titled "Monthly Supervisory Review" stated "All department records shall be reviewed monthly by the Director /Designee to ensure that appropriate guidelines are being followed. This shall include the following criteria: Instrument maintenance and temperature checks are up to date. Discrepancies and actions taken are documented appropriately." Record review of the

	"Ambient Room Temperature and Humidity" logs initialed by the Technical Consultant revealed the acceptable room temperature range was 68-77 degrees Fahrenheit (F) and the "Refrigerator" logs indicated an acceptable range was 35.6-46.4 F. Review of the logs from September 17, 2020 - April 27, 2021 revealed the following out of range temperatures with no corrective action: Room Temperatures: 1. December 8, 2020: 66 F 2. January 18, 2021 : 66.6 F 3. February 2, 2021: 65 F 4. February 4, 2021: 66 F 5. March 25, 2021: 66 F Refrigerator temperatures: 1. November 12, 2020: 47 F 2. November 17, 2020 : 48 F 3. November 24, 2020: 48 F Phone Interview on 04/27/21 at 1:55 PM with the Technical Consultant revealed he had missed the out of range temperatures during his monthly supervisory review.