Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0931373	04/23/2024
Name of Provider or Supplier	**Street Address, City, State**	
Oncology/Hematology Care, Inc	4350 Malsbary Road, Cincinnati, OH	

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
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the manufacturer's expiration date and an interview with the Technical Consultant (TC) #1, the laboratory failed to perform the Thermo Fisher Scientific brand thermometer maintenance as defined by the manufacturer. This deficient practice had the potential to affect 188,734 patients tested in the specialty of Hematology and the subspecialties of General Immunology, Routine Chemistry, and Endocrinology from 07/01/2022 through 04/23/2024. Findings Include: 1. Direct observation of a Thermo Fisher Scientific brand thermometer, serial number 1500080816, used to monitor the room temperature where the Sysmex instrument was utilized, revealed a calibration expiration date of 07/2022. 2. Further direct observation of a Thermo Fisher Scientific brand thermometer, serial number 150194986, used to monitor the room temperature where the Piccolo instrument was utilized, revealed a calibration expiration date of 07/2022. 3. TC#1 confirmed the laboratory did not perform instrument maintenance as required by the manufacturer and both Thermo Fisher Scientific brand thermometers were expired. The interview occurred on 04/23/2024 at 3:15 PM.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

	This STANDARD is not met as evidenced by: Based on record review and an interview with Technical Consultant (TC) #1, the laboratory failed to report the correct creatinine reference range values for six out of six patient test reports reviewed. This deficient practice had the potential to affect all patients tested in the subspecialty of Routine Chemistry for creatinine from 03/21 /2023 through 04/23/2024. Findings include: 1. Review of the laboratory's policy and procedure table 1.6 titled "Patient Testing Normal Ranges for Moderate Testing Performed in the Office", approved by the laboratory director on 10/2023 revealed the following creatinine ranges for male and female adults: Analyte Male Range Female Range Creatinine (mg/dL) 0.60-1.10 0.50-0.80 2. Review of six chemistry test reports found the following creatinine reference ranges listed: Date Accession # Reference Range 3/8/2024 2131723 (M) 0.73-1.18 mg/dL 3/8/2024 2131722 (M) 0.73-1.18 mg /dL 3/8/2024 2132007 (M) 0.73-1.18 mg/dL 3/1/2024 2129736 (F) 0.55-1.02 mg/dL 3 /1/2024 2130032 (F) 0.55-1.02 mg/dL 3/8/2024 2131932 (F) 0.55-1.02 mg/dL 3. An interview with TC #1, confirmed the creatinine reference ranges listed in the policy and procedure had not been updated. The interview occurred 04/23/2024 at 235 PM. M = male F = female mg/dL = milligrams per deciliter