Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2145146	04/22/2025
Name of Provider or Supplier	**Street Address, City, State**	
Honorhealth Cancer Care	19646 N 27th Ave Ste 301, Phoenix, AZ	

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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on lack of humidity records for review from January-May 2024, review of the manufacturer's environmental specifications for the Sysmex XN 450 hematology analyzer and interview with the Technical Consultant (TC-1), the laboratory failed to monitor and document the ambient humidity of the room where the instrument is utilized for patient testing on 54 out of 101 testing dates. Findings include: 1. The laboratory utilizes the Sysmex XN 450 analyzer to conduct patient testing in the specialty of Hematology with a reported annual test volume of 70,548. 2. The manufacturer's environmental specifications for the Sysmex XN 450 analyzer list an operating relative humidity range of 20%-85%. 3. The laboratory failed to provide documentation demonstrating the ambient humidity of the room where the analyzer is utilized was monitored and recorded on each day of patient testing for 54 out of 101 testing dates during the timeframe of January 2, 2024 through May 8, 2024. 4. The TC-1 interviewed on 4/22/25 at 10:46 AM confirmed the laboratory failed to monitor and document the ambient humidity on each day of patient testing as indicated above.
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 review of the laboratory's temperature logs, lack of corrective action documentation and interview with the Technical Consultant (TC-1), the laboratory failed to document corrective action taken for humidity measurements that were outside the laboratory's established range for 11 out of 57 testing dates in May 2024, December 2024 and January 2025. Findings include: 1. The laboratory utilizes the Sysmex XN 450 analyzer to conduct patient testing in the specialty of Hematology with a reported annual test volume of 70,548. The manufacturer's environmental specifications for the Sysmex XN 450 analyzer list an operating relative humidity range of 20%-85%. 2. Review of the monthly temperature logs from May 2024, December 2024 and January 2025 revealed the documented humidity measurement was not within the laboratory's established humidity range for 11 out of 57 testing dates. 3. The laboratory failed to document corrective action taken for the humidity measurements that were outside the laboratory's established humidity range on the 11 testing dates indicated above. 4. The TC-1 interviewed on 4/22/25 at 10:45 AM confirmed the laboratory failed to document corrective action for the humidity measurements that were outside the laboratory's established humidity range for the 11 testing dates indicated above.