Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2145185	03/01/2019
Name of Provider or Supplier	**Street Address, City, State**	
Honorhealth Cancer Care	9250 N 3rd St Ste 3010, 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) 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: (1) Water quality. (2) Temperature. (3) Humidity. (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 temperature documentation for review and interview with the technical consultant, the laboratory failed to monitor and document the (A) humidity and (B) room temperature of the laboratory where patient testing is performed and the analyzer reagents are utilized and stored. Findings include: 1. The laboratory began Complete Blood Count (CBC) testing in March 2018 under the specialty of Hematology, with an approximate annual test volume of 3,050. 2. The laboratory performs patient testing on the Sysmex XN450 analyzer which has a humidity requirement of 30% - 85%, as stated in the manufacturer's operating manual. A3. No documentation was presented for review during the survey conducted on March 1, 2019 to indicate the laboratory monitored and documented the humidity of the laboratory where patient testing was performed from March 2018 through the date of the survey. A4. The technical consultant confirmed that the laboratory failed to monitor and document the humidity of the room where patient testing is performed. B3. No documentation was presented for review during the survey conducted on March 1, 2019 to indicate the laboratory monitored and documented the room temperature of the laboratory where patient testing is performed and analyzer reagents are utilized and stored from March 2018 through the date of the survey. B4. The manufacturer's acceptable temperature range listed on the Sysmex reagents used for

	the analyzer is 2 - 30 degrees Celsius. B5. The technical consultant confirmed that the laboratory failed to monitor and document the room temperature where patient testing is performed and the analyzer reagents are utilized and stored.