

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  03D2026564	<b>(X3) Date Survey Completed</b>  03/03/2020
<b>Name of Provider or Supplier</b>  Honorhealth Cancer Care	<b>Street Address, City, State</b>  10320 W Mcdowell Rd, Bldg H, Ste 8025, Avondale, AZ	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the manufacturer's criteria for the relative humidity requirement for the environment where the Sysmex hematology analyzer is operated, the humidity range indicated on the laboratory's log sheets and interview with the facility personnel, the laboratory failed to follow the manufacturer's instructions for the humidity levels where the Sysmex hematology analyzer is operated. Findings include: 1. The laboratory performs patient testing on the Sysmex XN450 hematology analyzer, with an approximate annual test volume of 21,600. 2. The manufacturer's specifications for the relative humidity (RH) are between 20% and 85% with no condensation. 3. The laboratory's temperature logs indicated an acceptable humidity range of 0% - 80%. 4. The facility personnel acknowledged that the laboratory's established humidity range was not consistent with the manufacturer's requirements.</p>