

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0707800	<b>(X3) Date Survey Completed</b>  05/12/2021
<b>Name of Provider or Supplier</b>  American Health S Llc DbA American Health	<b>Street Address, City, State</b>  15712 Sw 41 St Suite 16, Davie, FL	
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>D5415</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to label the quality control vials currently in use with the open and expiration dates. Findings Included: Examination of the Beckman Coulter 6C Cell Controls and 6C Retic Controls for the Beckman Coulter DxH 900 hematology analyzer on 05/04/2021 at 1:50 PM showed the quality control vials for level 1, 2 and 3 did not have the open date and the new expiration date for the vials currently being used. Review of the package insert for the controls noted the controls are good for 16 days once they have been opened. During an interview 05/04/2021 at 1:5430 AM, Testing Personnel H stated the open date and the new expiration date were not on the control vials.</p>