

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  34D2188403	<b>(X3) Date Survey Completed</b>  11/01/2023
<b>Name of Provider or Supplier</b>  Cpn, Inc Db a Ah One Health Family Medicine And	<b>Street Address, City, State</b>  16645 Birkdale Commons Pkwy, Ste 100, Huntersville, NC	
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 surveyor observation, review of laboratory procedure and interview with testing personnel (TP) #1 11/1/23, the laboratory failed to label quality control reagents for the DxH 520 hematology analyzer with an open date and new expiration date when put in use. Findings: At approximately 9:15 a.m. surveyor observed three vials of quality control (QC) reagent, DxH 500 Series Control Lot #352315311, Lot #362315312 and Lot #372315313, in use and not labeled with an open date and new expiration date. Review of laboratory procedure, Beckman Coulter DxH 520 CBC and Automated Diff, revealed on page 9, "Procedure (External QC) 1. Remove control tubes from the refrigerator. Verify controls are within open stability. If opening a new set of controls, document open date and new open expiration date on vial. Allow to warm to room temperature 15-30C (59-86F) for 15 minutes before mixing.". During interview with TP #1 at approximately 9:15 a.m., TP #1 stated she writes the date in which the QC reagent expires on the maintenance log for the DxH 520 and the vials that are open are designated by marking the lid with a black marker. She also confirmed the QC vials in use were not labeled with an open date and new expiration date.</p>