

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D0315051	<b>(X3) Date Survey Completed</b>  04/11/2024
<b>Name of Provider or Supplier</b>  Raleigh Group, Pc	<b>Street Address, City, State</b>  2860 Covington Pike, Memphis, TN	
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 of the laboratory, review of the manufacturer quality control (QC) package insert, and staff interview, the laboratory failed to label two of two Bilirubin control vials with a corrected expiration date. The findings include: 1. Observation of the laboratory on 04/11/2024 at 9:45 am revealed the Reichert Unistat bilirubinometer instrument used for neonatal total bilirubin patient testing. The two Quantimetrix Bilirubin control vials were not labeled with a corrected expiration date. During the observation, testing person four stated that controls were used until the vial is empty before a new container is opened. 2. A review of the manufacturer package insert revealed the controls were stable for 21 days once opened. 3. An interview with the technical consultant on 04/11/2024 at 1:00 pm confirmed the laboratory failed to label two of two bilirubin controls with corrected expiration dates.</p>