

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  03D2064240	<b>(X3) Date Survey Completed</b>  04/24/2018
<b>Name of Provider or Supplier</b>  Sierra Vista Pathology Pc	<b>Street Address, City, State</b>  5700 E Hwy 90, Sierra Vista, 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>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 direct inspection of histopathology stain reagents and interview with the facility personnel, the laboratory failed to properly label stain reagents used in conjunction with patient testing. Findings include: 1. The laboratory performs the Hematoxylin &amp; Eosin (H&amp;E) stain on histopathology specimens and performs approximately 17,817 patient tests annually. 2. Direct inspection of the stain reagents, Hema-Diff Solution 3: Thiazine Dye and Hema-Diff Solution 2: Xanthene Dye, revealed the containers were missing the lot number and expiration date for each reagent component. 3. The facility personnel confirmed that the reagent containers indicated above were not labeled with the current lot number and expiration date at the time of the survey.</p>