

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0895443	(X3) Date Survey Completed 02/26/2020
Name of Provider or Supplier Ah Wfb Hematology And Oncology - Elkin	Street Address, City, State 401 Eldon Parks Drive, Elkin, NC	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of 2018, 2019, and 2020 laboratory records and interview with the GS (general supervisor) and TP (testing personnel) 2/26/20, the laboratory failed to retain all analytic systems records for at least two years. Findings: 1. 2018 room and refrigerator temperature and room humidity records were not available for review at the time of the survey. 2. 2018 Coulter AcT diff 2 daily maintenance (startup /shutdown) records were not available for review at the time of the survey. 3. Records of a Coulter AcT diff 2 calibration performed 6/22/18 were not available for review at the time of the survey. 4. The assay sheet for 4C-ES Cell Control lot number 068600 /078600/088600 with expiration date 1/27/20 was not available for review at the time of the survey. During interview at approximately 12:50 p.m., the GS and TP #3 stated that the 2018 records must have been accidentally discarded when old records were purged.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of 2018, 2019, and 2020 hematology quality control records and interview with TP (testing personnel) 2/26/20, the laboratory failed to discard hematology quality control material that exceeded its expiration date. 72 patients were tested on 2 days using the expired control material. Review of 2018, 2019, and 2020 Coulter AcT diff 2 quality control records revealed the laboratory failed to discard Coulter 4C-ES quality control material (lot number 068000/078000/088000) that expired 11/4/19. The expired control material was used for patient testing on 11/5/19 and 11/6/19. 33 patients were tested 11/5/19 and 39 patients were tested 11/6/19. During interview at approximately 11:55 a.m., TP #3 confirmed that expired controls were used for patient testing. She stated the testing personnel who ran controls those days didn't recognize the icon on the analyzer which indicated the control material was expired.