

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  25D2109619	<b>(X3) Date Survey Completed</b>  05/31/2018
<b>Name of Provider or Supplier</b>  Gamma Healthcare, Inc - Southaven	<b>Street Address, City, State</b>  3346 Goodman Rd East, Southaven, MS	
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>D5417</b>	<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: Based on observation of the Recomboplastin Prothrombin Time reagent in the refrigerator on the day of survey, 5/31/18, the Recomboplastin reagent on the ACL Elite analyzer, and interview with testing personnel at 10:30 am on 5/31/18, the laboratory was using Recomboplastin reagent (lot number N1259781 2G) which had exceeded the expiration date (12/2017) indicated by the manufacturer. Findings include: 2 expired (expiration date 12/2017) bottles of Recomboplastin reagent were found in the refrigerator on the day of survey. According to testing personnel and dates on the bottles, the reagent had been opened and used on 5/30/18 and 5/31/18 to test patients and quality control (QC). The Recomboplastin reagent currently programmed on the analyzer was lot number N0579856 2G expiration date 5/2019 with an ISI (International Sensitivity Index) of 1.02. 5/30/18 - Recomboplastin lot number N1259781 2G expiration date 12/2017 (ISI-1.04) was used to test QC and 39 patients for prothrombin time and INR. 5/31/18- Recomboplastin lot number N1259781 2G expiration date 12/2017 used to test QC and 17 patients for prothrombin time and INR</p>