

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  26D0441688	<b>(X3) Date Survey Completed</b>  11/13/2019
<b>Name of Provider or Supplier</b>  Sullivan County Memorial Hospital Laboratory	<b>Street Address, City, State</b>  630 W 3rd St, Milan, MO	
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>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of the blood bank procedure manual, blood bank refrigerator alarm activation records for 2018 and to date 2019 and interview with the general supervisor, the laboratory failed to follow the procedure for performing quarterly blood bank refrigerator alarm activation. Findings: 1. The blood bank procedure manual states, "Low and high alarm activation: Done quarterly." 2. Review of blood bank refrigerator alarm records revealed the laboratory performed low and high alarm activation procedure less frequently than quarterly (three months). Records showed the laboratory performed the low and high activation procedure once every four months. 3. On interview November 13, 2019 at 11:30 AM, the general supervisor confirmed the laboratory performed the low and high activation procedure less frequently than quarterly as stated in the procedure manual.</p>
<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:</p>

Based on observation of coagulation reagent, patient records for November 2019 and interview with the general supervisor, the laboratory failed to ensure recombiplastin reagent in use for prothrombin time patient testing had not exceeded the expiration date. Findings: 1. Observation of coagulation reagent revealed one opened box with three vials of recombiplastin reagent, lot number N1072885, expired October 2019 and in use November 13, 2019. 2. Review of patient records from November 1, 2019 and to date November 13, 2019 revealed seven patient prothrombin time tests were performed using expired recombiplastin reagent. 3. Interview on November 13, 2019 at 11:30 AM the general supervisor confirmed the recombiplastin reagent expired and was in use for patient prothrombin time testing.