

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D0442231	(X3) Date Survey Completed 06/19/2018
Name of Provider or Supplier Mercy Southeast Of Stoddard County	Street Address, City, State 1200 N One Mile Rd, Dexter, MO	
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
D5449	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, quality control (QC) logs and interview with the general supervisor, the laboratory failed to perform a positive and negative control each day of testing for moderately complex clostridium difficile(c-Diff) kit testing. Findings: 1. Review of the manufacturer's instructions for c-Diff kit testing showed the kit is classified as moderate complex. 2. Review of the quality control logs showed the laboratory failed to perform a positive and negative control each day of testing. 228 patients were tested from June 1, 2017 to May 31, 2018. 3. Interview with the general supervisor on June 19, 2018 at 1:00 PM confirmed, the laboratory did not test a positive and negative control each day of testing and did not complete an IQCP plan to reduce the frequency of testing external controls.</p>