

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D0663285	(X3) Date Survey Completed 11/10/2020
Name of Provider or Supplier Medicine Multispecialty Center	Street Address, City, State 4921 Parkview Place Ste 5c, Saint Louis, 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
D5481	<p>CONTROL PROCEDURES CFR(s): 493.1256(f)(g)</p> <p>(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of activated clotting time (ACT) quality control (QC) records, manufacturer QC assay documentation, patient records and interview with the laboratory manager, the laboratory failed to ensure results of QC materials met manufacturer's test system criteria for acceptability before reporting patient test results. Two of two QC materials for lot number G0DLA005 performed in October 2020 failed to meet the manufacturer's stated "acceptable performance range." Findings: 1. Review of ACT QC records showed the laboratory obtained an unacceptable QC result of 193 on October 14, 2020 and an unacceptable QC result of 188 on October 28, 2020 for QC lot number G0DLA005. 2. Review of manufacturer's assay documentation showed an acceptable performance range of 215 to 344 for QC lot number G0DLA005. 3. Patient records retrieved by the laboratory manager showed the laboratory reported two patient test results in October 2020. 4. Interview with the laboratory manager on November 10, 2020 at 1:30 PM confirmed the laboratory failed to ensure QC results met the manufacturer's acceptable performance range before reporting patient results.</p>
D5783	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test</p>

results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:

Based on review of activated clotting time (ACT) quality control (QC) records for October 2020, lack of corrective action documentation and interview with the laboratory manager, the laboratory failed to take corrective action necessary to ensure reporting accurate and reliable patient test results. Findings: 1. Review of ACT QC records revealed results for QC lot number G0DLA005 failed to meet the manufacturer's acceptable performance range on October 14, 2020 and October 28, 2020. (Refer to # D5481) 2. The laboratory did not have documentation to show corrective action was taken for the failed QC results. 3. Interview with laboratory manager on November 10, 2020 confirmed the laboratory failed to take corrective action for QC results that failed to meet the manufacturer's acceptable performance range.