

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0890532	(X3) Date Survey Completed 10/04/2021
Name of Provider or Supplier Crozer Chester Med Ctr Operating Room	Street Address, City, State 1 Medical Center Blvd, 4th Floor Or, Upland, PA	
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
D5545	<p>HEMATOLOGY CFR(s): 493.1269(b)(d)</p> <p>(b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on quality control record review and interview of the Laboratory Director and Point of Care Coordinator, on the date of the the survey (10/04/2021), the laboratory failed to run two levels of control materials each 8 hours of operation when performing Activated Clotting Time testing using the Hemochron Signature Elite analyzer. Findings: 1. Each month or change of reagents, 2 levels of external controls are run on the Hemochron Signature Elite analyzer.for Activated Clotting Time. 2. The laboratory did not have a complete Individualized Quality Control Program. 3. During the survey, the Laboratory Director confirmed the above findings.</p>