

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D2047552	(X3) Date Survey Completed 05/04/2021
Name of Provider or Supplier Beltway Surgery Centers, Llc	Street Address, City, State 10601 N Meridian Street, Suite 100, Carmel, IN	
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
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on document review and interview, the laboratory failed to document maintenance for one of one analyzer (Abbott iStat) used for Chemistry and Hematology testing on eight of eight patients (PT#1-PT#8) reviewed in 2021. Findings include: 1) Policy titled, "Procedure: Various Measurements by Abbott iStat 1 Testing System," dated 01/2021, with the laboratory director's signature on 2/2021, read on page 2 of 26, "...F. CLEANING AND/OR DISINFECTING THE ANALYZER 1. Cleaning is required when the analyzer has visible organic material present. 2. Disinfecting is required after every use, if the analyzer is shared between patients..." 2) Medical record review indicated patients #1-8 had laboratory testing performed on the iStat in 2021: PT=patient mg/dL=milligram per deciliter mmol/L=millimole per liter Hct=hematocrit K+=potassium Glu=glucose PT#1 1/6/21 Glu=195 mg/dL PT#2 4/22/21 Glu=299 mg/dL PT#3 4/19/21 K+=5.2 mmol/L PT#4 1/29/21 Hct=33% PT#5 2/26/21 Hct=41% PT#6 3/26/21 Hct=38% PT#7 4/2/21 Hct=42% PT#8 1/27/21 Hct=40% 3) In interview on 5/4/21 at 12:21 pm, SP-2 confirmed there was no iStat maintenance documentation available for review. 4) Annual test volume=90.</p>