Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 49D2122950	**(X3) Date Survey Completed** 11/15/2018
Name of Provider or Supplier Wellmont Medical Associates, Inc	**Street Address, City, State** 743 Island Road, Bristol, VA	
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**
D0000	An announced CLIA Recertification survey was conducted at the Wellmont Medical Associates on November 15, 2018 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on a review of quality control (QC) records, and interviews, the laboratory failed to retain the Beckman Coulter "6C Cell control " manufacturer's assay information inserts documenting Complete Blood Cell (CBC) count QC acceptable ranges for ten (10) of ten (10) QC lot numbers utilized from May 2017 until October 2018. Findings include: 1. Review of the laboratory's Intralaboratory Quality Assurance Program (IQAP) documents for the Beckman Coulter AcT diff 2 from May 2017 until October 2018 revealed 10 lot numbers of "6C Cell control" QC material were utilized to document and evaluate patient testing on the DxH 600 analyzer. The following QC lot numbers had no acceptable ranges or manufacturer's package inserts : 123171640/133181640/143191649 exp May 27, 2017, 123171860/133181860 /143191860 exp December 8, 2017, 123171920/133181920/143191920 exp January, 22, 2018, 123172000/133182000/143192000 exp March 16, 2018, 123172030 /133182030/143192030 exp April 6, 2018, 123172060/133182060/143192060 exp Aril 27, 2018, 123172110/133182110/143192110 exp June 8 2018, 123172140 /133182140/143192140 exp July 6 2018, 123172180/133182180/143192180 exp August 3 2018, 12317220/133182220/143192220 exp Sept 7 2018. A total of 10 "6C Cell control" QC lot numbers with no acceptable ranges or manufacturer's package

	inserts. 2. The surveyor requested to review the package inserts for the 10 lot numbers of QC listed above. No documentation was provided at the date of survey. 3. An interview with the laboratory manager and technical supervisor at approximately 2:45 PM confirmed the findings.