Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2104158	05/15/2018
Name of Provider or Supplier	**Street Address, City, State**	
Bon Secours Maryview Medical Center	155 Kingsley Lane - Suite 150, Norfolk, 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 Bon Secours Maryview Medical Center (Norfolk) on May 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:
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) 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 quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the review of the hematology policy and procedures, quality control (QC) records, patient testing data, and interviews, the laboratory failed to perform at least two levels of QC materials on August 29, 2017 prior to reporting three (3) patients (Accession numbers: 6139810, 6139593 and 6143669). Findings include: 1. Review of the Sysmex XP 300 hematology policy revealed the following procedure: "VI. Quality Control- B. Frequency of Control Use and QC Data Review- EightCheck 3 WP X-TRA levels: 1, 2, and 3 will be run daily- Patient samples can be run only after three levels of QC are within range." 2. Review of the QC records and the Sunquest Laboratory Information System (LIS) patient testing data revealed that on August 29, 2017 the laboratory did not have documentation of performing the QC procedures prior to reporting 3 patients (Accession numbers: 6139810, 6139593 and 6143669). 3. An interview with the office manager, point of care supervisors and primary testing personnel at approximately 3:20 PM confirmed that the laboratory failed to perform the daily QC procedures for the above-specified date prior to reporting patients.