Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2124964	02/16/2022
Name of Provider or Supplier	**Street Address, City, State**	
Bon Secours Maryview Medical Outpatient Infusion	12720 Mcmanus Blvd Suite 311, Newport News, 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 Bon Secours Maryview Medical Center Outpatient Infusion Center on February 16, 2022 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 and include the Condition under 42 CFR part 493 CLIA Regulation:: D5400- 42 CFR. 493.1250 Analytic Systems.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a review of policies/procedures, monthly maintenance logs, instrument user manual, Centers for Medicare and Medicaid Services Statement of Deficiencies Plan of Correction (CMS-2567 POC), and interviews, the laboratory failed to: 1. follow their laboratory director's approved POC (dated 11/8/19) procedure outlining measures to maintain maintenance protocols per manufacturer's guidelines; 2. document performance of hematology analyzer weekly preventative maintenance protocols according to manufacturer's instructions in two of the twenty-four months reviewed. See D5401, D5429 (*REPEAT DEFICIENCY).
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a)

	A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures, 2019 Centers for Medicare and Medicaid Services Statement of Deficiencies Plan of Correction (CMS-2567 POC), maintenance logs, and interviews, the laboratory failed to follow an established procedure to ensure performance and documentation of required hematology analyzer preventative maintenance procedures in two (2) of the twenty-four (24) months reviewed. Findings include: 1. Review of the laboratory's records revealed the following procedures: a. Maintenance protocol (Title: XP-300 Procedure -Document 1049-LSS, Rev. 01) which stated "XP-300 Weekly Maintenance: Clean the sample rotor valve tray according to the Sysmex XP-300 Instructions for Use for details. Open the front cover of the instrument main unit. Slide the SRV tray to the front of the instrument to remove, clean the sample tray according to the user guide, replace, close the XP-300 front cover, document on the maintenance log." b. CMS-2567 POC (LD approved 11/8/19) which outlined a corrective action plan that stated "all required hematology maintenance will be documented per the manufacturer's guidelines and corrective action plan will be overseen by the technical consultant (TC) and nurse manager". 2. Review of the laboratory's Sysmex XP 300 hematology analyzer maintenance logs from January 2020 through January 2022 revealed no weekly maintenance was documented for one (1) of four (4) weeks in October 2020 and 2 of 4 weeks in January 2022. The inspector requested to review documentation of the required weekly maintenance for the weeks of 10/25/21, 1/10/22, and 1/16/22. The records were not available for review. 3. An interview with the TC, on 2/16/22 at approximately 12:30 PM, confirmed the above findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) 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. This STANDARD is not met as evidenced by: Based on a review of monthly maintenance logs, hematology instrument user manual, policies/procedures, and interviews, the laboratory failed to document performance of Sysmex XP 300 analyzer preventative maintenance procedures according to manufacturer's instructions in two (2) of the twenty-four (24) months reviewed. *REPEAT DEFICIENCY Findings include: 1. Review of the laboratory's Sysmex XP 300 (Serial Number A3611) maintenance logs revealed the following weekly preventative maintenance procedures listed to be checked and initialed once performed: Weekly Clean SRV/tray. The inspector reviewed the laboratory's Sysmex monthly maintenance logs from January 2020 through January 2022 and noted no weekly maintenance was documented for one (1) of four (4) weeks in October 2020 and 2 of 4 weeks in January 2022. The inspector requested to review documentation of the required weekly maintenance for the weeks of 10/25/21, 1/10/22, and 1/16/22. The records were not available for review. 2. Review of the Sysmex User Manual revealed manufacturer's maintenance instructions for the procedures outlined above.

	The user's guide stated: "Perform the following routine maintenance weekly as scheduled: Clean the sample rotator valve (SRV) and tray." 3. Review of the laboratory polices and procedures revealed a hematology policy (Title: XP-300 Procedure -Document 1049-LSS, Rev. 01) which stated "XP-300 Weekly Maintenance: Clean the sample rotor valve tray according to the Sysmex XP-300 Instructions for Use for details. Open the front cover of the instrument main unit. Slide the SRV tray to the front of the instrument to remove, clean the sample tray according to the user guide, replace, close the XP-300 front cover, document on the maintenance log." 4. An interview with the TC, on 2/16/22 at approximately 12:30 PM, confirmed the above findings.