Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	49D2124964	01/25/2024
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 January 25, 2024 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 Condition.
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, lack of documentation, and interview, the laboratory failed to document performance of hematology analyzer preventative maintenance protocols according to manufacturer's instructions in two of the twenty-four months reviewed. See D5429 (*REPEAT DEFICIENCY).
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, lack of documentation, and interview, 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) monthly maintenance logs for the review timeframe of February 2022 to the date of the survey on 1/25/24, revealed the following lapse in preventative maintenance documentation for protocol "clean sample rotator valve (SRV) and tray": April 2023- weekly maintenance was not documented on the monthly log during timeframe of 4/3/23 - 4/7/23; June 2023 - weekly maintenance was not documented on the monthly log during timeframe of 6/19/23 - 6/30/23. The inspector requested to review documentation that the maintenance was performed during the three weeks on the 2 monthly logs as outlined above. Additional documentation was 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 Procedures) 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 technical consultant, on 1/25/24 at approximately 12:30 PM, confirmed the above findings.