Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	49D2117769	04/21/2021
Name of Provider or Supplier	**Street Address, City, State**	
Bon Secours Harbourview Outpatient Infusion Center	7185 Harbour Towne Parkway, Suite 107, Suffolk, 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 for BonSecours MMC-Harbourview Outpatient Infusion Center on April 21, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The survey also included an entrance interview and initial record review conducted remotely on 04/16 /21. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The laboratory was not in compliance with the following 42 CFR part 493 CLIA Regulations: D6063 - 42 C.F.R. 493.1421 Condition: Laboratory Testing Personnel. Specific deficiencies cited are as follows:
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records, policy and procedures, lack of documentation, and an interview, the laboratory failed to document evaluation taken for five (5) unacceptable hematology analyte results on American Proficiency Institute (API) 2020 Event 2. Findings include: 1. Review of the laboratory's API records (2019 Events 1-3, 2020 Events 1-3), a total of 6 events, revealed no evidence of remedial action for the following 5 unacceptable PT analytes scored on 2020 API Event 2: Hemoglobin sample #HSY 10 reported as 10.7 (expected result 11.3-13.2), MCH sample #HSY 10 reported as 24.9 (expected result 27.7-30.1), MCHC sample #HYS 10 reported as 31.3 (expected result 34.5-37.9), Platelet Count sample HYS #9 reported as 669 (expected result 381-636), MPV sample HYS #9 reported as 12.8 (expected result 9.7-10.5). 2. Review of the laboratory's procedures revealed an approved policy (Title: Evaluating Your Proficiency Testing Results) that stated: "If any PT result is not acceptable document the causes and the corrective action taken". 3. Review of the laboratory's PT corrective action forms revealed no evaluation or

	corrective action documentation for the unacceptable analyte scores listed above. 4. In an interview with the point of care coordinator, at approximately 2:30 PM, the above findings were confirmed.
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 tour, review of instrument maintenance logs, analyzer's user manual, and interview, the laboratory failed to perform and document preventative maintenance procedures for the Sysmex XP 300 hematology analyzer according to manufacturer's instructions during nine (9) of the twenty-six (26) months reviewed. Findings include: 1. During the tour of the laboratory on 4/21/21 at approximately 12:30 PM, the inspector noted the Sysmex XP 300 (Serial Number A9119) maintenance logs outlined the following preventative maintenance procedures listed to be checked and initialed once performed: DAILY: verify background, vacuum pressure, check trap pressure, perform daily QC, enter QC into Insight, verify QC, perform shutdown; WEEKLY: clean SRV/tray; MONTHLY: clean RBC/WBC transducers, clean waste chamber. 2. Review of the laboratory's Sysmex maintenance log documentation from 2 /1/19 to 4/20/21 revealed the laboratory failed to document: DAILY maintenance on 1 /30/20, 1/31/20, 12/16/20, 12/31/20; WEEKLY maintenance on two (2) of four (4) weeks in August 2019 (recorded on 8/13 and 8/26), 2 of 4 weeks in September 2019 (recorded on 9/9, 9/24), 2 of 4 weeks in October 2019 (recorded 10/16, 10/25), one (1) of 4 weeks in December 2019, (recorded 12/4, 12/10, 12/17); 1 of 4 weeks in June 2020 (recorded 6/8, 6/15, 6/24), 1 of 4 months in February 2021 (recorded 2/1, 2/12, 2 /19); MONTHLY maintenance in September 2019 and July 2020. The inspector requested additional documentation of the required daily, weekly, and monthly maintenance for the timeframes outlined above. No documentation was available for review. 3. Review of the Sysmex User Manual revealed manufacturer's maintenance instructions for the procedures outlined above. The user's guide stated: "Perform routine maintenance for daily, weekly, monthly, and quarterly as scheduled. The daily shutdown procedures are required to clean the transducer chambers and the diluted sample line and is important to perform at least once every 24 hours. Clean the sample rotator valve (SRV) and tray weekly and document on log. Clean the waste chamber monthly (takes approximately 15 minutes). Follow the instructions for preparing 5% from 6% Sodium Hypochlorite solution and document on the maintenance log. Clean the WBC and RBC transducers (takes approximately 7 minutes) once a month following the Instructions for Use and document on maintenance log". 4. In an interview with the point of care coordinator, at approximately 2:30 PM, the above findings were confirmed.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2)

	Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of policies and procedures, hematology service/calibration records, lack of documentation, and an interview, the laboratory failed to document hematology calibration procedures after two (2) major maintenance procedures were performed as outlined by facility policy during the twenty-six months reviewed (02/01/19 to 04/20/21). Findings include: 1. Review of the laboratory's procedures revealed a policy (Titled: Oncology Sysmex XP 300 Policy) that stated "calibration compensates for any bias inherent to the pneumatic, hydraulic, and electrical system that may affect the accuracy of results. Calibrators traceable to reference methods are used in the calibration of the analyzer. Calibration is performed every 6 months to ensure accuracy of the system. Calibration is also required if critical parts are replaced". 2. Review of the available Sysmex maintenance service reports and calibration documentation from February 2019 to the date of the inspection on 4/20/21 revealed the following: Field Service reports revealed that the Sysmex XP pneumatic unit compressor was replaced on 08/31/20 (Reference 3051216 due to low recovery/unable to recover and vacuum errors), and a Sysmex compressor rebuild was performed on 02/23/21 (Reference 3212848 due to faulty pneumatic compressor). The inspector requested to review calibration records for the Sysmex analyzer in August 2020 and February 2021 after the pneumatic parts replacements. The provided documentation revealed the following dates of calibration: 06/26/19, 11/19/19, 05/14/20, and 11/17/20. No additional calibration documentation was available for review. 3. In an interview with the point of care coordinator, at approximately 2:30 PM, the above findings were confirmed.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form, available testing personnel records, procedure/polices, lack of documentation, and interviews, the laboratory failed to retain documentation of personnel qualifications for one of sixteen testing personnel responsible for non waived Complete Blood Count patient testing in calendar year 2020. See D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a

chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:
Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), available testing personnel records, procedure /polices, lack of documentation, and an interview, the laboratory failed to retain documentation of personnel qualifications for one (1) of sixteen (16) testing personnel responsible for reporting Complete Blood Count (CBC) patient test results in calendar year 2020. Findings include: 1. Review of the laboratory's CMS 209 form revealed 16 testing personnel (TP) identified as performing non-waived CBC testing. 2. Review of the laboratory personnel documents revealed: TP A: General Nursing certificate from the country of Guyana and initial training verified/signed by TC on 10/23/20. (See Personnel Code Sheet) The inspector requested to review US equivalent education and /or transcript/diploma for the TP outlined above. The point of care coordinator stated on 4/21/21 at approximately 1:30 PM: "I notified our OPIC manager that the highest diploma/transcript was needed and they have not provided them. I told them that certifications are not accepted". 3. Review of the laboratory's procedures revealed a policy (Titled: Personnel Requirements) that stated: "All testing personnel must be meet one of the following two qualifications: A) MD/DO, PhD, MS, BS/BA, or associates degree in science or laboratory science/medical laboratory technology; B) high school graduate or equivalent with documented training for the actual testing performed by the laboratory". 4. In an interview with the point of care coordinator, at approximately 2:30 PM, the above findings were confirmed.