

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2124964	(X3) Date Survey Completed 10/24/2019
Name of Provider or Supplier Bon Secours Maryview Medical Outpatient Infusion	Street Address, City, State 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-MIH on October 24, 2019 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:
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), proficiency testing (PT) records, and interviews, the laboratory failed to rotate PT among the thirteen (13) personnel who performed Complete Blood Count (CBC) patient testing in calendar year 2018 and up to the date of the inspection, on October 24, 2019. Findings include: 1. Review of the CMS 209 form revealed 13 testing personnel (TP) listed as having performed/reported patient CBC testing during the seventeen (17) months reviewed. 2. Review of the laboratory's American Proficiency Institute (API) PT documentation (2017 Event 3, 2018 Events 1-3, 2019 Events 1-2) revealed that TP A signed as testing personnel on the following attestation statements: 2017 3rd Event; 2018 2nd Event; 2018 3rd Event; 2019 1st Event. TP A performed four (4) of the six (6) events reviewed. (See Personnel Code Sheet.) 3. In an interview with the nurse manger and point of care coordinator, at approximately 2:30 PM, the above findings were confirmed.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p>

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 instrument maintenance logs, analyzer's user manual, and interviews, the laboratory failed to perform and document preventative maintenance procedures for the Sysmex XP 300 Hematology analyzer according to manufacturer's instructions during three (3) of the seventeen (17) months reviewed. Findings include: 1. Review of the laboratory's Sysmex XP 300 (Serial Number A3611) maintenance logs revealed the following preventative maintenance procedures listed to be checked and initialed once performed: Daily: verify background, vacuum pressure, check trap pressure, verify daily QC, perform shutdown; Weekly: clean SRV/tray; Monthly: clean RBC/WBC transducers, clean waste chamber. The inspector reviewed the laboratory's Sysmex maintenance logs from 5/1/18 to 10/24/19 and noted: No daily maintenance was documented as performed April 1-16, 2019; No weekly maintenance was documented 3 of four (4) weeks in April 2019 (one week recorded on 4/19/19), and two (2) of 4 weeks in August 2019 (2 weeks recorded on 8/5/19, 8/20/19); No monthly maintenance documentation in March 2019. The inspector requested additional documentation of the required maintenance for the timeframes outlined above. No documentation was 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 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". 3. In an interview with the nurse manger and 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 (CMS 209), testing personnel records, and interviews, the laboratory failed to retain documentation of education qualifications for two (2) of thirteen (13) testing personnel (TP) responsible for reporting moderate complexity Complete Blood Count (CBC) hematology patient test results during the seventeen (17) months reviewed. 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), personnel records, and interviews, the laboratory director (LD) failed to maintain documentation of education qualifications for two (2) of thirteen (13) testing personnel (TP) from May 2018 to the date of the survey on October 24, 2019. Findings include: 1. Review of the CMS 209 Laboratory Personnel Report revealed 13 TP listed as qualified to perform moderate complexity Complete Blood Count (CBC) hematology testing. 2. Review of the available laboratory personnel records revealed no documentation of education for TP B and TP C. The inspector requested to review the documentation. The records were not available for review. (See Personnel Code Sheet.) 3. In an interview with the nurse manger and point of care coordinator, at approximately 2:30 PM, the above findings were confirmed.