

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D0228384	<b>(X3) Date Survey Completed</b> 05/15/2018
<b>Name of Provider or Supplier</b> Bon Secours Maryview Medical Center	<b>Street Address, City, State</b> 355 Crawford Street - Suite 300, Portsmouth, VA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced CLIA initial survey was conducted at the Bon Secours Maryview Medical Center (Portsmouth) 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:
<b>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on the review manufacturer instructions, maintenance records, procedures and interviews, the laboratory failed to maintain the Sysmex XP-300 analyzer maintenance records from June 1, 2016 through December 31, 2016. Findings include: 1. Review of the manufacturer instructions for the Sysmex XP-300 analyzer maintenance revealed the following: - Daily maintenance- perform shut down, verify background, verify vacuum pressure, check trap chamber, and perform quality control. - Weekly maintenance- clean sample rotator valve (SRV) tray. - Monthly or every 1500 samples- clean RBC and WBC transducer and clean waste chamber. - Quarterly or every 4500 samples- clean SRV. 2. Review of the maintenance records revealed that there was no documentation of the required maintenance from June 1, 2016 through December 31, 2016. 3. Review of the laboratory's procedure of moderate and high complexity testing revealed the following statement: "F. Maintain all QC records for at least two year. They need to be easily retrievable. QC records need to include: 1. calibrations 2. control results 3. required maintenance 4. remedial actions 5. Any relevant records that monitor test systems or testing personnel. 4. An</p>

interview with the office manager, point of care supervisors and primary testing personnel at approximately 12:30 PM confirmed that the laboratory failed to maintain the above-specified records from June 1, 2016 through December 31, 2016.

**D5781**

**CORRECTIVE ACTIONS**

CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on the review of the refrigerator temperatures, manufacturer's package insert (PI), policy and procedures and interviews, the laboratory failed to perform corrective action when the refrigerator temperatures failed to meet the laboratory's established range of 2-8 degree Celsius for fifty-one (51) of the three-hundred and sixty-five (365) days reviewed in 2017. Findings include: 1. Review of the refrigerator temperatures from January 1, 2017 up to December 31, 2017 and the PI for the Eightcheck 3-WP X-TRA hematology quality control materials revealed the following dates in 2017 in which the recorded refrigerator temperatures were above the established range of 2-8 degrees Celsius: January 7, 14, and 28, February 4, 11, 18 and 25, March 11, 18 and 25, April 1, 8, 15 and 22, May 11, 21, and 28, June 4, 10, 11, and 25, July 2, 9, 16, 23 and 30, August 6 and 13, September 3, 4, 14, 17 and 20, October 12, 15 and 22, November 5, 8, 9, 12, 13, 19, 26 and 27, December 3, 10, 14, 17, 21 and 23. On March 4, 2017 and June 24, 2017 the temperatures were below the established range. 2. Review of the laboratory's temperature chart policy revealed the following statement: "Procedure- B. Correct any deviation from the acceptable range by adjusting the thermostat. C. If any adjustment was necessary, monitor the temperature throughout the day to ensure that the proper temperature is achieved. D. If the temperature cannot be regulated, then the equipment may need to be serviced. Notify the laboratory manager or designee. F. If reagents, controls or specimens need to be moved to another appliance- please document under Corrective Actions." The review of the temperatures out of range revealed that the laboratory documented "over the weekend, normal by Monday. There was no other documentation of corrective actions. 3. An interview with the office manager, point of care supervisors and primary testing personnel at approximately 12:30 PM confirmed that the laboratory failed to perform corrective action when the refrigerator temperatures failed to meet the laboratory's established range for the above-specified dates.