Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0227776	03/19/2019
Name of Provider or Supplier	**Street Address, City, State**	
Bon Secours Mercy Health Laburnum Medical Center	4620 S Laburnum Ave, Richmond, 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 validation survey was conducted at Bon Secours Mercy Health Laburnum Medical Center on March 19, 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	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) 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 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 seven (7) of 7 PT events among personnel performing Complete Blood Count (CBC) patient testing during the twenty-four (24) months reviewed. Findings include: 1. Review of the CMS Form 209 revealed eleven (11) testing personnel. The laboratory director (LD) confirmed in an entrance interview that five (5) of the 11 testing personnel (TP) performed patient CBC testing on the Abbott Emerald hematology analyzer in calendar years 2017 and 2018. 2. Review of the laboratory's Medical Laboratory Evaluation (MLE) PT documentation, a total of seven (7) events, revealed that TP A performed 7 of the 7 hematology events reviewed. TP A signed PT attestation and Emerald instrument print outs for: 2017 MLE Event M1, 2017 MLE Event M2, 2017 MLE Event M3, 2018 MLE Event M1, 2018 MLE Event M2, 2018 MLE Event M3, 2019 MLE Event M1. (See Personnel Code Sheet.) 3. In an exit interview with the LD and hospital quality manager at approximately 2:00 PM, the above findings were confirmed.

D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a laboratory tour, review of procedures, review of maintenance logs, and interviews, the laboratory failed to define and document function checks for centrifuge revolutions per minute (RPM) for one (1) urinalysis centrifuge during twenty-four (24) of the 24 months reviewed. Findings include: 1. During a laboratory tour at approximately 10:00 AM, the inspector noted a Van Guard V6 500 centrifuge in the urinalysis specimen processing area. The inspector inquired if the centrifuge was used for both blood and urine sediment sample processing. The laboratory director (LD) stated: "we only use that centrifuge for urine sediment exams." 2. Review of the procedure manual revealed a Microscopic Urinalysis Procedure that stated: "Centrifuge urine aliquot for 5 minutes at 1,500 to 2,000 RPM's". 3. Review of the 2017 and 2018 equipment maintenance documentation revealed no records of RPM verifications for the Van Guard V6 500 (SN 88343, clinical engineering tag 525074) for the procedure's stated requirement of 1,500 to 2,000 RPM. The inspector requested to review 2017 and 2018 urinalysis centrifuge RPM calibration documentation. No documentation was available for review. 4. In an exit interview with the LD and hospital quality manager at approximately 2:00 PM, the above findings were confirmed.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records and an interview, the laboratory director (LD) failed to document evaluation of and corrective action for unacceptable or unscored analyte results on three (3) of six (6) scored PT events in the twenty-four (24) months reviewed. Findings include: 1. Review of the laboratory's Medical Laboratory Evaluation (MLE) hematology and chemistry PT documentation, a total of 6 scored events, revealed no evidence of corrective action or self grading for the following unacceptable analyte scores: 2017 MLE Event 3: HD-11 Red Blood Cell Count (RBC) scored as unacceptable, HD 15 Platelet (PLT) scored as unacceptable;

	2018 MLE Event 2: LED-6 Blood Lead -no score; 2018 MLE Event 3: HD-15 Platelet (PLT) scored as unacceptable. The inspector requested to review documentation that the laboratory evaluated corrective action for the unacceptable RBC and PLT scores outlined above. The inspector requested to review documentation of self grade for the unscored Lead challenge failure outlined above. Documentation was not available for review. 2. In an exit interview with the LD and hospital quality manager at approximately 2:00 PM, the above findings were confirmed.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, and interviews, the technical consultant (TC) failed to perform annual Potassium Hydroxide (KOH) Wet Prep Microscopic Examination competency evaluations for six (6) of seven (7) testing personnel in calendar years 2017 and 2018. Findings include: 1. Review of the CMS Form 209: Laboratory Personnel Report revealed that the laboratory director (LD) also performed the duties of TC and eleven (11) testing personnel (TP). The LD, in an entrance interview, confirmed the following 7 TP performed patient KOH Wet Prep tests in calendar years 2017 and 2018: TP A, TP B, TP C, TP D, TP E, TP F and TP G. 2. Review of the laboratory personnel files revealed that TP B, TP C, TP D, TP E, TP F, and TP G lacked an annual KOH Wet Prep competency evaluation in calendar years 2017 and 2018 (See Personnel Code Sheet). 3. In an exit interview with the LD and hospital quality manager at approximately 2:00 PM, the above findings were confirmed.