Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0016172	02/15/2019
Name of Provider or Supplier	**Street Address, City, State**	
Southern Virginia Regional Medical Center	727 North Main Street, Emporia, 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 Southern Virginia Regional Medical Center on February 13 and 14, 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:
D2020	BACTERIOLOGY CFR(s): 493.823(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on a review of the laboratory's 2018 proficiency testing (PT) records and an interview, the laboratory failed to attain a score of at least eighty (80) percent (%) of acceptable responses for blood cultures in one (1) out of three (3) bacteriology testing events reviewed. Findings include: 1. Review of the laboratory's 2018 PT records, a total of 3 events, revealed that the laboratory participated with College of American Pathologists (CAP) for microbiology testing and that they received blood culture scores of less than 80% for the following bacteriology event: 2018 2nd event - Challenge sample BC5-03 performance reported as unacceptable, resulting in a score of 50%. 2. In an exit interview with the Chief Executive Officer, Senior Director of Clinical Operations - Facility Compliance Officer, Quality Manager, and Laboratory Manager at approximately 5:00 PM on 2/14/19, the above findings were confirmed.
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

	This STANDARD is not met as evidenced by: Based on a review of the laboratory's 2018 proficiency testing (PT) records and an interview, the laboratory failed to attain a score of at least eighty (80) percent of acceptable responses for Sodium in one (1) out of three (3) general chemistry testing events reviewed. Findings include: 1. Review of the laboratory's 2018 American Proficiency Institute (API) PT records, a total of 3 events, revealed Sodium (Na) scores of less than eighty (80) percent for the following general chemistry events: 2018 2nd event - Na challenge samples CH-06 and CH-08 performances reported as unacceptable, resulting in a score of 60%. 2. In an exit interview with the Chief Executive Officer, Senior Director of Clinical Operations - Facility Compliance Officer, Quality Manager, and Laboratory Manager at approximately 5:00 PM on 2/14 /19, the above findings were confirmed.
D2153	ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(a) Failure to attain a score of at least 100 percent of acceptable responses for each analyte or test in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on a review of the laboratory's proficiency testing (PT) records and an interview, the laboratory failed to attain a score of at least one hundred (100) percent (%) of acceptable responses for D(Rho) typing in one (1) out of three (3) 2018 blood bank testing events reviewed. Findings include: 1. Review of the laboratory's 2018 American Proficiency Institute (API) PT records, a total of 3 events, revealed D(Rho) scores of less than 100 % for the following blood bank event: 2018 2nd event - Challenge sample RED-09 performance reported as unacceptable, resulting in a D (Rho) score of 80%. 2. In an exit interview with the Chief Executive Officer, Senior Director of Clinical Operations - Facility Compliance Officer, Quality Manager, and Laboratory Manager at approximately 5:00 PM on 2/14/19, the above findings were confirmed.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) 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 establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on a laboratory tour, review of policy and procedure manuals, equipment maintenance records, quality assurance (QA) plan, and an interview, the laboratory failed to follow the established monthly maintenance protocol for one (1) Sorvall Cellwasher 2 for twenty-four (24) of 24 months reviewed. Findings include: 1. During a blood bank tour on 2/13/19 at approximately 11:00 AM, the inspector noted a

	Sorvall Cellwasher 2 on the work bench. 2. Review of the blood bank procedure manual revealed a Daily Routine procedure that stated: "all maintenance procedures for equipment maintenance should be recorded on the Blood Bank Maintenance Log". 3. Review of the 2017 and 2018 Blood Bank Maintenance Logs revealed a preventative maintenance procedure for "Clean and Decontaminate Cell Washer". The cleaning procedures were listed as "perform on a monthly basis". Review of the maintenance logs from January 2017 to the date of the survey revealed that the cleaning was not documented for 24 of 24 months reviewed. The inspector requested documentation of the monthly maintenance. No record was available for review. 4. Review of the blood bank QA plan revealed a statement: "automatic cell washer maintenance is performed and recorded according to the designated schedule log". 5. In an exit interview with the Chief Executive Officer, Senior Director of Clinical Operations - Facility Compliance Officer, Quality Manager, and Laboratory Manager at approximately 5:00 PM on 2/14/19, 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: A. 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) blood banking centrifuge and one (1) core lab urinalysis centrifuge during twenty-four (24) of the 24 months reviewed. Findings include: 1. During a blood bank tour on 2/13/19 at approximately 11:00 AM, the inspector noted a Clay Adams Serofuge, serial number (SN) A535046 with a clinical engineering tag 573203 in use for Anti-D testing. During a core laboratory tour on 2/14/19 at approximately 9:00 AM, the inspector noted a Fisher Scientific Medifuge (SN 42264842, clinical engineering tag 573305) in the urinalysis and specimen processing area with a pre-set speed of 2,000 RPM. The inspector inquired if the centrifuge was used for both blood and urine sediment sample processing. The primary hematology testing personnel stated, "we use that centrifuge primarily for urine sediment exams." 2. Review of the blood bank and hematology procedure manuals revealed: Anti-D procedure that stated: "centrifuge test tube at 900-1000g for 15 to 20 seconds"; Urinalysis procedure that stated: "spin 12 ml of urine (in urinalysis centrifuge tube) at 2000 rpm (400 RCF) for 5 minutes". 3. Review of the 2017 and 2018 centrifuge maintenance documentation revealed no records of RPM verifications for: Clay Adams Serofuge (SN A535046, clinical engineering tag 573203) for the stated requirement of 900-1000g.; Fisher Scientific Medifuge (SN 42264842, clinical engineering tag 573305) for the stated requirement of 2,000 RPM. The inspector requested to review the 2017 and 2018 centrifuge RPM documentation. No documentation was available for review. 4. In an exit interview with the Chief Executive Officer, Senior Director of Clinical Operations - Facility Compliance Officer, Quality Manager, and Laboratory Manager at approximately 5:00 PM on 2/14

	/19, the above findings were confirmed. B. Based on a tour, review of maintenance logs, user guide, and interviews, the laboratory failed to document alarm function checks for the BacT Alert blood culture system during twenty-four (24) of the 24 months reviewed. Findings include: 1. During a tour of the microbiology lab room on 2/13/19 at approximately 1:00 PM, the inspector noted a Biomerieux BacT Alert and Vitek 2 analyzers in use for patient blood culture, microbial identifying, and antibiotic susceptibility testing. The inspector noted that the microbiology testing area was separated from the core lab and located in an adjacent room. The microbiology lab area was not monitored by staff members at the time of the survey tour or record review. 2. Review of the 2017 and 2018 microbiology maintenance log sheets revealed documentation of weekly alarm checks for the Vitek 2. The inspector requested to review alarm checks for the BacT Alert. No records were available for review. The inspector inquired how the laboratory ensured that the blood culture audible alarms were in working order for those times that the room was not monitored by testing personnel. The laboratory manager stated: "we do perform maintenance checks on the alarm for the Vitek and should add the BacT Alert. We are able to hear it from the core lab'. 3. Review of the Biomerieux user guide, with the laboratory manager, revealed that the BacT Alert instrument's audible alarm could be switched off by an operator. The user guide stated: "audible alarms and control screen should be left on at all times, checked and tested periodically'. 4. In an exit interview with the Chief Executive Officer, Senior Director of Clinical Operations - Facility Compliance Officer, Quality Manager, and Laboratory Manager at approximately 5:00 PM on 2/14 /19, the above findings were confirmed.
D5559	IMMUNOHEMATOLOGY CFR(s): 493.1271(e)(f) (e) Investigation of transfusion reactions. (e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. (e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of policies and procedures, transfusion reaction documentation, and interviews, it was determined that the laboratory failed to follow the established policy for transfusion reaction work up protocols for one (1) of five (5) reactions reviewed. Findings include: 1. Review of the laboratory's Blood Bank policies revealed a procedure for Evaluation of Suspected Transfusion Reaction Workup that stated (under subtitle Instructions for the Laboratory): "instructions for the laboratory on the Blood Reaction Report Form must be followed. Steps 1-4 must be completed for all transfusion reactions immediately". 2. Review of the laboratory's 2016 and 2017 transfusion reaction documentation, a total of five (5) reports, revealed that the transfusion reaction report was incomplete for: Patient Chart 285070 on 9/7/17. The product transfused was two (2) units thawed fresh frozen plasma (FFP). The inspector noted that the Blood Reaction Report Form was incomplete for the required fields of Steps 1, 3, and 4. There were no entries by the laboratory. The inspector requested to

	review the missing documentation. No documentation was available for review. 3. In an exit interview with the Chief Executive Officer, Senior Director of Clinical Operations - Facility Compliance Officer, Quality Manager, and Laboratory Manager at approximately 5:00 PM on 2/14/19, the above findings were confirmed.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: A. Based on a tour, review of policies and procedures, Quality Assurance (QA) documentation, and an interview, the laboratory failed to establish and follow a policy for a comparison of hematology test results performed on two (2) Beckman Coulter instruments utilized for patient Complete Blood Count (CBC) testing in calendar years 2017 and 2018. Findings include: 1. During a tour of the core laboratory room on 2/14/19 at approximately 9:00 AM, the inspector noted the following hematology instruments in use for CBC testing: Beckman Coulter AcTdiff, serial number (SN) 5322050, Beckman Coulter DXH 800, SN 5303548. 2. Review of the laboratory's hematology policies and procedures revealed no QA plan to evaluate a method to method comparison of CBC test results resulted on the Beckman Coulter AcTdiff, serial number (SN) 5322050 and Beckman Coulter DXH 800, SN 5303548. 3. The inspector requested to review documentation of twice a year evaluation of the two instruments' CBC testing. No QA documentation of acceptability of instrument to instrument review was available. The primary hematology testing personnel stated: "we have testing personnel competency assessments on both analyzers and can develop a method to method comparison policy to combine those tasks". 4. In an exit interview with the Chief Executive Officer, Senior Director of Clinical Operations - Facility Compliance Officer, Quality Manager, and Laboratory Manager at approximately 5:00 PM on 2/14/19, the above findings were confirmed. B. Based on a laboratory tour, review of policies and procedures, patient test logs, and an interview, the laboratory failed to follow their policy to perform twice a year correlations of manual Complete Blood Count (CBC) differential test results with automated hematology cell counts for two (2) of the 2 years reviewed. Findings include: 1. During a tour of the core laboratory room on 2/14/19 at approximately 9:00 AM, the inspector noted 2 hematology instruments in use for CBC patient testing (Beckman Coulter AcTdiff, serial number SN 5322050 and Beckman Coulter DXH 800, SN 5303548) and a Hematek 2000 Slide Stainer in use for patient manual differential slide preparation. 2. Review of the laboratory's policies and procedures revealed a Manual Differential Count policy that stated: "the tech will write the manual differential on the instrument printed results and manually enter into LIS, correlations (tech to tech and tech to instrument)will be done every 6 months for r value comparisons (should be >or equal to 0.99)". 3. Review of the patient data log documentation from January 2017 through the date of the survey review on 2/14/19, revealed one (1) documentation of the CBC differential correlation function checks performed in 2017. The inspector requested to review additional the manual cell differential method correlation documentation. The primary hematology testing personnel stated: "We did not perform two checks in 2018. We performed it twice in

	2017, but the record is misfiled at this time". 4. In an exit interview with the Chief Executive Officer, Senior Director of Clinical Operations - Facility Compliance Officer, Quality Manager, and Laboratory Manager at approximately 5:00 PM on 2/14 /19, the above findings were confirmed. C. Based on a tour, review of policies and procedures, Quality Assurance (QA) documentation, and an interview, the laboratory failed to follow a policy for a comparison of chemistry test results performed on two (2) Siemens Dimension EXL 200 instruments utilized for chemistry and endocrinology patient testing in calendar year 2017 and 2018. Findings include: 1. During a core laboratory tour on 2/14/19 at approximately 9:00 AM, the inspector noted the following chemistry instruments: Siemens Dimension EXL 200, serial number (SN) DE270882, Siemens Dimension EXL 200, serial number (SN) DE270886. 2. Review of the laboratory's chemistry policy and procedure manual revealed a procedure to evaluate, twice annually, a comparison of test results on the two analyzers listed above. The policy stated: "twice annually the chemistry analyzer's testing will be compared against each other and the two methods are considered equivalent if the bias is clinically insignificant". The inspector inquired regarding a specific criteria for bias acceptability for the method comparisons. The lab manager stated: "I look at the comparisons of the analytes' results and decide if the two instruments were reporting close enough based on my experience." 3. The inspector requested to review 2017 and 2018 documentation of twice a year evaluations of the instrument to instrument comparison studies for the two EXL 200 analyzers. The review revealed no evaluation of comparison acceptability of the instrument to instrument study was recorded for the four (4) reports. 4. In an exit interview with the Chief Executive Officer, Senior Director of Clinical Operations - Facility Compliance Officer, Quality Manager, and Laboratory Manager at approximately 5:00 PM on 2/14 /19, the above findings were confirmed.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on the review of policy and procedure manuals, and interviews, the laboratory did not have a written quality assurance (QA) policy for quality measures to ensure monitoring, assessing, and corrective action for analytic problems in the core laboratory for the twenty-four (24) months reviewed. Findings include: 1. Review of the core laboratory's chemistry and hematology policy and procedure manuals revealed no documentation of a QA policy for monitoring, assessing, and corrective action for patient test results utilizing the Beckman Coulter AcTdiff, Beckman Coulter Unicell DXH 800, Sysmex CA 500, Hematek 2000, two (2) Siemens EXL 200 analyzers, and two (2) Fisher Scientific Medifuges centrifuges. The inspector requested to review a QA policy. The laboratory manager was able to print a QA policy in use at a company affiliated hospital and stated: "this plan is not specific for our instruments and work patterns but I will use it as a template to help with developing our QA plan". 2. In an exit interview with the Chief Executive Officer, Senior Director of Clinical Operations - Facility Compliance Officer, Quality Manager, and Laboratory Manager at approximately 5:00 PM on 2/14/19, the above findings were confirmed.