Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0232507	05/02/2018
Name of Provider or Supplier	**Street Address, City, State**	
Smyth County Community Hospital Laboratory	245 Medical Park Drive, Marion, 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 Smyth County Community Hospital on May 1 and May 2, 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:
D3041	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(6) Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. (i) In addition, retain immunohematology reports as specified in 21 CFR 606.160(d) (ii) and pathology test reports for at least 10 years after the date of reporting. This STANDARD is not met as evidenced by: Based on a laboratory tour, review of quality assurance (QA) documentation, patient test logs, and interviews, the laboratory failed to retain patient Complete Blood Count (CBC) manual differential reports for twenty-eight (28) of twenty-eight (28) months reviewed. Findings include: 1. During a laboratory tour and interview with the laboratory general supervisor at approximately 2 PM on 5/1/18, the inspector noted patient CBC manual differential slides were being counted using a Modulus counter (Serial Number SC2005) in the urinalysis and staining area adjacent to the core lab (the Modulus counter is not interfaced). The results were transcribed onto the Coulter DXH analyzer's patient result print out. The inspector requested to review result records of patient manual differential counts for calendar year 2017. No documentation of transcribed manual differential results from the Modulus counter was available for review. The technical supervisor and testing personnel stated "We write the differential results onto the instrument print out grid and throw the reports out after they are typed into the patient's file. We do not retain them". 2. Review of the laboratory's QA documentation from January 2016 through the date of the survey on 5/2/18 revealed no documentation of the Modulus CBC differential written results. 3.

	Review of the laboratory's patient test logs from January 2016 to the date of the survey, revealed the following number of manual differentials were resulted: 2016 - 145 manual differentials; 2017 - 63 manual differentials; 2018 - 14 manual differentials, through 5/2/18, a total of two hundred twenty-two (222). 4. In an interview on 5/2/18 at approximately 5:15 PM, the laboratory director, technical supervisor, general supervisors, and quality manager confirmed that the laboratory failed to retain two hundred twenty-two (222) patient CBC manual differential count reports in the twenty-eight (28) of twenty-eight (28) months reviewed.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on the tour of the laboratory, review of manufacturer 's package insert (PI), patient records and interviews, the laboratory failed to ensure that the Coulter Body Fluid Control materials were within the manufacturer ' s expiration dates prior to reporting two (2) patients on April 2 and 12, 2018 (Accession numbers: 220822 and 173185). Findings include: 1. The tour of the laboratory revealed that the Coulter Body Fluid Control materials, lot numbers 183232130, 193241380 and 203251380, had a hand-written open date on the vials of March 10, 2018. 2. Review of the manufacturer ' s PI revealed the control materials can be used a maximum of 18 times within 16 days. 3. Review of patient records for body fluid counts revealed that 2 patients were assayed on April 2, 2018 (Accession number 220822) and April 12, 2018 (Accession number 173185) which were beyond the manufacturer ' s defined expiration date. 4. An interview with the laboratory director, quality manager, general and technical supervisors, on May 2, 2018 at approximately 5:15 PM confirmed that the laboratory did not follow the manufacturer ' s PI for the Coulter Body Fluid Control materials.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the review of policies, manufacturer package inserts (PI), quality control (QC) records and interviews, the laboratory failed to follow the written policy for performing QC procedures every 30 days for the Alere Determine Human Immunodeficiency Virus (HIV) Ag/Ab Combo kit and the Cardinal Health Human chorionic gonadotropin (HCG) kit for two (2) of the twenty-four (24) months

	reviewed. 1. Review of the PI ' s for the HIV and HCG test systems revealed that use of serum samples elevated the test system to moderate complexity. In an interview with the general supervisor on May 2, 2018 at approximately 2:00PM, it was confirmed that the laboratory utilizes serum samples to perform patient testing for the HIV and HCG test systems. 2. Review of the Individualized Quality Control Plan (IQCP) policy (signed by the lab director on July 5, 2015) for the HIV, and HCG systems revealed the following statement: "QC protocol- QC is performed new shipment, new lot, with each new operator and 30 day QC." 3. Review of the QC records from January 1, 2016 to the date of the survey revealed the following: - HIV: Did not have documentation of the 30 day QC performed after June 26, 2016. Next date of QC performance was August 7, 2016. - HCG: Did not have documentation of 30 day QC performed after August 23, 2017. Next date of QC performance was October 15, 2017. 4. An interview with the laboratory director, general and technical supervisors on May 2, 2018 at approximately 5:15 PM confirmed that the laboratory did not follow the written IQCP policy for performing QC procedures every 30 days for the above-specified test systems.
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 the laboratory's 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 two (2) transfusion reactions reviewed. Findings include: 1. Review of the laboratory's Blood Bank policies revealed a procedure for Transfusion Reaction Workup that stated "the pathologist on call is to be notified of the results of the transfusion reaction screen and reported under pathologist interpretation" and "if a transfusion reaction is observed while the patient is in the hospital, this is to be noted by Nursing Services on the crossmatch/transfusion report by filling out the form Report of Transfusion Reactions". 2. Review of the laboratory's 2016 and 2017 transfusion reaction documentation, a total of two (2) reports, revealed that the transfusion reaction report was incomplete for: Order Number A73004272 on 3/30/18 at 17:05. The product transfused was two (2) units thawed fresh frozen plasma (FFP), Units W043217056609 and W043218000412, for Patient M148294. The inspector noted that the Transfusion Reaction Workup Report for Order Number A73004272 was incomplete for the required field of Pathologist Interpretation Notification and that the Report of Transfusion Reactions was incomplete for the required field of Nurse Completion of Suspected Transfusion Reaction for one (1) of the two (2) units of FFP. The inspector requested to review the missing documentation. No documentation was available for review. The general supervisor stated; "our laboratory tech could not

	reach the pathologist on this event and was unable to complete the form. It was not noticed that the nursing staff only completed one of the two nurse reports." 3. In an interview with the laboratory director, technical supervisor, general supervisors, and quality manager on 5/2/18 at approximately 5:15 PM, it was confirmed that the laboratory failed to follow the established policy for transfusion reaction work up protocols on 3/30/18 as outlined above for Blood Bank Order Number A73004272.
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: Based on a laboratory tour, review of the laboratory's policies and procedures, Quality Assurance (QA) documentation, patient test logs, and an interview, the laboratory failed to follow their written policy to perform function checks of the manual Complete Blood Count (CBC) differential test results every six months for two (2) of two (2) years reviewed. Findings include: 1. During a laboratory tour and interview with the laboratory general supervisor at approximately 2 PM on 5/1/18, the inspector noted patient CBC manual differential samples were being counted using a Modulus counter (Serial Number SC2005) in the urinalysis and staining area adjacent to the core lab. 2. Review of the laboratory's policies and procedures revealed a QA policy "Correlation of Tests Performed on Different Instruments or Methods" which stated: "Automated and Manual Cell Differentials will be correlated at least once every six months. The comparison is necessary to assure that there is a compatibility between the data generated on the different devices. The department supervisor is to initiate the testing and the data will be retained with proficiency and quality control data." 3. Review of the laboratory's Quality Assurance (QA) documentation from January 2016 through the date of the survey on 5/2/18 revealed no documentation of the Modulus CBC differential correlation function checks. The inspector requested to review the Modulus counter manual cell differentials correlation documentation. The general supervisor stated "We did not perform the checks in 2016 or 2017". 4. In an interview with the laboratory director, technical supervisor, general supervisors, and quality manager at approximately 5:15 PM on 5/2/18, it was confirmed that the laboratory failed to follow their written policy to perform correlation function checks of the manual CBC differential every six months in calendar years 2016 and 2017.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on the review of temperature records, patient records, procedures, and interviews, the laboratory director failed to ensure that the Leica CM1950 Cryostat

	temperature was within the laboratory ' s established range on the dates of performing patient testing for three (3) of the three (3) patients reviewed (Accession numbers: 22615, 3076 and 6034). Findings include: 1. Review of the Leica CM1950 Cryostat temperature and patient records for histology frozen section tissue processing revealed the following dates in which patient samples were processed when the Cryostat temperature was outside acceptable range: September 6, 2017- Accession number 22615; temperature recorded as -16 degrees Celsius, February 8, 2018- Accession number 3076; temperature recorded as -10 degrees Celsius, March 19, 2018- Accession number 6034; temperature recorded as -17 degrees Celsius. 2. Review of the procedure for "Performance of Frozen Section Analysis and Use of Leica CM1950 Cryostat" (signed October 13, 205) revealed the following statement: "Calibration and Quality Control Daily the temperature of the cryostat is recorded. Acceptable range: -18 to -25 degrees Celsius." 3. In an interview on May 1, 2018 at approximately 3:30 PM, the laboratory director confirmed that on the dates of patient testing listed above the Cryostat temperature was not within the acceptable range.