Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D1093849	12/18/2018
Name of Provider or Supplier	**Street Address, City, State**	
Community Health Clinic	1957 Second Street, Richlands, 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 the Community Health Clinic (Richlands site) on December 18, 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:
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on the review of proficiency testing (PT) records and interview, the laboratory director failed to sign one (1) of six (6) attestation statements reviewed. PT record review included 2017 and 2018 testing events. Findings include: 1. Review of the Medical Laboratory Evaluation (MLE) PT records for all three events in 2017 and 2018 revealed that the laboratory director did not sign the 2017 MLE 3rd event (M3) attestation statement. 2. An interview with the laboratory director at approximately 2: 00 PM confirmed the above-listed findings.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on the review of proficiency testing (PT) records and interview, the laboratory

	director failed to review and sign one (1) of six (6) PT results reviewed. PT record review included 2017 and 2018 testing events. Findings include: 1. Review of the Medical Laboratory Evaluation (MLE) PT records for all three events in 2017 and 2018 revealed that the laboratory director did not review and sign the 2018 MLE 1st event (M1) PT results. 2. An interview with the laboratory director at approximately 2: 00 PM confirmed the above-listed findings.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on a tour of the laboratory, review of manufacturer's package insert (PI) and interviews, the laboratory failed to label thirteen (13) of the sixteen (16) hematology quality control (QC) materials with opened-vial expiration date according the manufacturer's PI on the date of survey on December 18, 2018. Findings include: 1. Tour of the laboratory revealed that the laboratory utilizes the Horiba Medical Mintrol hematology QC materials. The current box in the refrigerator contained 16 vials of QC material (4 low level, 4 normal level and 4 high level) lot number MX 414 expiration date January 5, 2019. Thirteen of the 16 vials did not have an open date nor a revised expiration date. (Cross Reference D5417) The inspector asked the primary testing personnel (TP) at approximately 1:15 PM, which vials was currently in use for QC procedures. She/he indicated that they would randomly pick one of each level and run daily QC. 2. Review of the Horiba Medical Mintrol PI revealed the following statement: "- 5. Stability and storage- Opened tubs are stable for 16 days provided they are handled properly, and provided the instructions in section "instructions for use" are followed." 3. An interview with the laboratory director at approximately 2:00 PM confirmed the above-listed findings.
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 a tour of the laboratory, review of the manufacturer's package insert (PI) and interviews, the laboratory failed to ensure that three (3) of the sixteen (16) hematology quality control (QC) materials were not used beyond the manufacturer's opened-vial expiration date from November 23, 2018 to the date of survey on December 18, 2018. Findings include: 1. Tour of the laboratory revealed that the laboratory utilizes the Horiba Medical Mintrol hematology QC materials. The current box in the refrigerator contained 16 vials of QC material (4 low level, 4 normal level and 4 high level) lot number MX 414 expiration date January 5, 2019. Three of the 16 vials had hand-written opened date of November 7, 2018. The primary testing personnel (TP)

	confirmed, in an interview at approximately 1:15 PM, that the 3 vials with the hand-written opened date of November 7, 2018 were still in use at the date of survey on December 18, 2018. 2. Review of the Horiba Medical Mintrol PI revealed the following statement: "- 5. Stability and storage- Opened tubs are stable for 16 days provided they are handled properly, and provided the instructions in section "instructions for use" are followed." 3. An interview with the laboratory director at approximately 2:00 PM confirmed the above-listed findings.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on the review of hematology records, policy and procedures, phone call with technical service, and interviews, the laboratory failed to follow the manufacturer's requirement and the established policy and procedures for performing calibration procedures at least once every six (6) months in the calendar year 2018. Findings include: 1. Review of the hematology records revealed that the laboratory performed the calibration procedures for the Horiba ABX Micros 60 hematology instrument on February 2, 2018. There was no other 2018 calibration documentation available for review at the date of survey on December 18, 2018. 2. Review of the policy and procedure manual revealed the following statement (signed by the laboratory director December 2016): "Calibration procedures- perform and document calibration procedures at least six (6) months and as recommended by the manufacturer." 3. A phone call with Horiba technical service at approximately 1:50 PM confirmed that the manufacturer requires calibration of the hematology instrument every 6 months. 4. An interview with the laboratory director at approximately 2:00 PM confirmed the above-listed findings.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

	This STANDARD is not met as evidenced by: Based on the review of two (2) patient test reports and an interview, the laboratory failed to ensure that the patient test results provided the name and address of the testing facility. Findings include: 1. The laboratory utilizes the Horiba ABX Micros 60 instrument print out as the final patient test result. The inspector reviewed 2 patient results. The reports did not have the laboratory's name and address on the reports. 2. An interview with the laboratory director at approximately 2:00 PM confirmed the above-listed findings.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on the review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records, policy and procedures, and interviews, the laboratory director failed to follow the established policy and ensure that one (1) of one (1) new TP had documented training and competency assessments prior to performing patient testing procedures for hematology on August 23, 2018. Findings include: 1. Review of CLIA CMS-209 form revealed that TP A was a new TP (See attached TP Code Sheet). 2. Review of TP records and an interview with TP A at approximately 12:00 PM revealed that there was no documentation of training and competency assessment for TP A. She/he stated that they began testing on August 23, 2018. 3. Review of the policy and procedure manual revealed the following statement (signed by the laboratory director December 2016): "Testing personnel: New testing personnel will be evaluated with forms from Appendix 1 prior to assignment in the lab." 3. Interview with the laboratory director at approximately 2:00 PM confirmed the above-listed findings.