Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D1093849	10/07/2021
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 unannounced CLIA complaint investigation was conducted at the Community Health Clinic (Richlands) on 10/05/21 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: The laboratory was not in compliance with the following 42 CFR part 493 CLIA Regulations: D5400 - 42 C.F. R. 493-1250 Condition: Analytic Systems ***REPEAT DEFICIENCY*** D6000 - 42 C.F.R. 493-1403 Condition: Moderate Complexity Laboratory Director ***REPEAT DEFICIENCY***
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: ***REPEAT DEFICIENCY*** Based on the review of policy and procedures (P&P), plan of correction (POC) submitted on 06/21/21, record review, lack of documentation, and interviews, the laboratory failed to: 1. follow the established P&P and POC ensuring that at least two levels of the hematology quality control (QC) materials were within manufacturer's established ranges prior to reporting patients (Refer to D5447 part A) and 2. follow the established P&P and POC ensuring that at least two levels of the hematology quality control (QC) materials were assayed prior to reporting patients (Refer to D5447 part B).
D5447	CONTROL PROCEDURES

CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
REPEAT DEFICIENCY A. Based on the review of policy and procedures (P&P), record review, plan of correction (POC) submitted on 06/27/21, and interviews, the laboratory failed to follow the established P&P and the POC ensuring that at least two levels of the hematology quality control (QC) materials were within manufacturer's established ranges prior to reporting patients for three (3) of 24 dates reviewed from 09/01/21 up to 10/05/21 while reporting 35 patients. Findings include: 1. The laboratory utilizes the Horiba ABX Micros 60 analyzer (serial number 604CS95933) to perform Complete Blood Counts (CBC). Review of the laboratory's P&P (approved by the LD on 10/17/2007) revealed the following statements: "CHC Clinic Laboratory Policy Sections; page 6" "Control Procedures: Perform and document control procedures using two levels of control materials. For each, analyze each day for chemistry and each 8 hr for hematology so that test are run and also recommended by the manufacturer. No patient test results will be reported unless the control results are adequate." 2. Record review from 09/01/21 up to 10/05/21 (to include daily QC printouts, patient testing logs, maintenance records and patient results) revealed the following: Hematology QC materials in use- Mintrol Mx 431 expiration date 11/05/21. 09/28/21- Hemoglobin and Hematocrit QC failed for the normal and high level acceptable ranges- eight patients reported. 09/29/21- Hemoglobin and Hematocrit QC failed for the normal and high level acceptable ranges- 14 patients reported. 10/04/21- Hemoglobin QC failed for the normal and high level acceptable ranges- 13 patients reported. During an interview with the primary testing personnel (TP) at approximately 11:00 AM, they stated that the instrument had issues on 09/30/21 and that they sent the lab samples to the affiliated site. During the review of the QC results for 09/28/21, 9/29/21 and 10/04/21 with the inspector, they realized the QC parameters for the above-specified analytes and levels failed. The inspector requested to review corrective actions taken or logged for the dates. The primary TP stated that they had not logged any issues for the failed QC parameters at the date of the survey on 10/05/21. 3. Review of the POC submitted on 06/21/21 revealed the following statements: "QC must be performed every 8 hours of patient testing. Keep all copies for technical consultant to review on a monthly basis. Document in action log if you have a problem and what you did to resolve the issue." 4. An exit interview with the lab director on 10/05/21 at approximately 12:20 PM confirmed the findings. B. Based on the review of policy and procedures (P&P), record review, plan of correction (POC) submitted on 06/21/21, lack of documentation and interviews, the laboratory failed to follow the established P&P and the POC ensuring that at least two levels of the hematology quality control (QC) materials were assayed prior to reporting patients for one (1) of 24 dates reviewed from 09/01/21 up to 10/05/21 while reporting 11 patients. Findings include: 1. See D5447 part A, finding #1 for detail of P&P. 2. Record review from 09/01/21 up to 10 /05/21 (to include daily QC printouts, patient testing logs, maintenance records and patient results) revealed lack of documentation of performance of QC materials for 10 /01/21 and 11 patients reported. The inspector requested to review documentation of the performance of the hematology QC materials or corrective actions for 10/01/21.

	During an interview with the primary testing personnel on 10/05/21 at approximately 11:00 AM, they stated that there were no logged corrective actions for that day and that the QC documentation was not available for review. 3. See D5447 part A, finding #3 for detail of POC. 4. An exit interview with the lab director on 10/05/21 at approximately 12:20 PM confirmed the findings.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: ***REPEAT DEFICIENCY*** Based on the review of policy and procedures (P&P), plan of correction (POC) submitted on 06/21/21, record review, lack of documentation, and interview, the laboratory director failed to follow the established P&P and the POC. Refer to D6022
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: ***REPEAT DEFICIENCY*** Based on the review of policy and procedures (P&P), plan of correction (POC) submitted on 06/21/21, record review, lack of documentation, and interview, the laboratory director failed to follow the established P&P and the POC for four of 24 dates reviewed from 09/01/21 up to 10/05/21 and reporting 46 patients. Findings include: 1. Refer to D5447 part A, finding #1 for statement of P&P. 2. Review of the POC submitted by the lab director on 06/21/21 revealed the following statements: "Lab director is responsible to review and sign all QC and QA reports for each month. Re-hiring lab consultant to assist in review and submitting to the lab director monthly. Lab director is responsible for the overall testing systems. A technical consultant has been hired as of June 7, 2021 and will be responsible for reviewing the testing systems and provide corrective actions as applicable. The lab director will review and sign." 3. Record review 09/01/21 up to 10 /05/21 (to include daily QC printouts, patient testing logs, maintenance records, corrective action log and patient results) revealed the following: 09/28/21- Hemoglobin and Hematocrit failed for the normal and high levels acceptable ranges- eight patients reported. 09/29/21- Hemoglobin and Hematocrit failed for the normal and high levels acceptable ranges- 14 patients reported. 10/01/21- Lack of documentation of performance of hematology QC materials and 11 patients reported. 10/04/21- Hemoglobin failed for the normal and high levels acceptable ranges- 13 patients reported. Refer to D5447 part A and B. No corrective actions or issues documented on the "Horibia Corrective Action" log sheets reviewed at the date of

	survey on 10/05/21. An interview with the primary testing personnel on 10/05/21 at approximately 11:00 AM confirmed the lack of documentation of instrument issues and corrective actions for the above-specified dates. 4. An exit interview with the lab director on 10/05/21 at approximately 12:20 PM confirmed the above findings. They stated that they were aware of instrument issues on 09/30/21 and brought specimens to the affiliated site but unaware of the additional issues. They stated that they were scheduled to review records in the PM on 10/05/21 and that as to date; there was no signed contract with the intended lab consultant. In addition, they confirmed that at the date and time of the survey, there was no quaility assurance documents for review.