

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0933746	(X3) Date Survey Completed 05/16/2023
Name of Provider or Supplier Community Health Clinic Pc	Street Address, City, State 5705 Redbud Hwy, Honaker, 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 on 05/16/23 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**
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: **REPEAT DEFICIENCY** Based on the review of monthly maintenance logs, review of policy and procedures (P&P), manufacturer's operator quick guide, lack of documentation and interview, the laboratory failed to provide documentation of the weekly maintenance performed for 22 of 88 weeks from 09/01/21 up to the date of survey on 05/16/23 for the Sysmex XP-300 hematology analyzer. Refer to D5417.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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.</p>

This STANDARD is not met as evidenced by:
****REPEAT DEFICIENCY**** Based on the review of monthly maintenance logs, review of policy and procedures (P&P), manufacturer's operator quick guide, lack of documentation and interview, the laboratory failed to provide documentation of the weekly maintenance performed for 22 of 88 weeks from 09/01/21 up to the date of survey on 05/16/23 for the Sysmex XP-300 hematology analyzer. Findings include: 1. The laboratory utilizes the Sysmex XP-300 hematology analyzer to perform Complete Blood Counts (CBC). Review of monthly maintenance logs from 09/01/21 up to date of survey on 05/16/23 revealed lack of documentation for the following: Weekly Maintenance- 10/25-29/21; 11/22-26/21; 12/27-30/21; 01/24-28/22; 05/23-27/22; 05/31-06/03/22; 06/06-10/22; 06/13-17/22; 06/20-24/22; 06/27-07/01/22; 07/11-15/22; 07/25/-29/22; 08/15/-19/22; 08/22-26/22; 09/26-30/22; 10/24-29/22; 11/28- 12/02/22; 12/19/-23/22; 12/27-31/22; 01/16-20/23; 01/23-27/23; and 03/27-31/23. 2. Review of the P&P revealed the following statement (approved by lab director on 10/17/07): "CHC Clinic Laboratory Policy Sections; page 7" "Instrument function checks will be performed with frequency and procedure as directed by the manufacturer. They will be properly documented." 3. Review of the manufacturer's operator quick guide revealed the weekly maintenance procedures of cleaning SRV Tray. 4. An exit interview with the lab director on 05/16/23 at approximately 11:30 AM confirmed the 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 (P&P), and interview, the laboratory failed to follow the established P&P for performing calibration procedures at least once every six months from 02/22/22 up to 05/08/23 for the Sysmex XP-300 hematology analyzer. Findings include: 1. Review of the hematology records revealed that calibration procedures were performed on 02/22/22 and again on 05/08/23 for the Sysmex XP-300 hematology analyzer. There was no other calibration documentation available for review at the date of survey on 05/16/23 upon request. 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. An exit interview with the lab director on 05/16/23 at approximately 11:30 AM confirmed the findings.