

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D1093849	(X3) Date Survey Completed 12/02/2021
Name of Provider or Supplier Community Health Clinic	Street Address, City, State 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 off-site proficiency testing desk review of Community Health Clinic (Richlands) was conducted on 12/02/21 by a Medical Facilities Inspector of the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The laboratory was not in compliance with the following Conditions under 42 CFR part 493 CLIA Regulations: D2016 - 42 C.F.R. 493.803 (a)(b)(c) Condition- Successful Participation.
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on review of the proficiency testing (PT) records for the third event in 2021, the CASPER 0153D Unsatisfactory and Unsuccessful PT Report and interview with the</p>

primary testing personnel, the laboratory failed to participate in the Medical Laboratory Evaluation (MLE) Hematology proficiency testing schedule for one of three testing events in 2021 (Refer to D2123). Based on the review of the proficiency testing (PT) scores for the second and third events in 2021, the CASPER 0153D Unsatisfactory and Unsuccessful PT Report, and an interview with the primary testing personnel, the laboratory failed to achieve satisfactory performance of at least 80% for two consecutive events for the White Blood Cell Differential (WBC Diff) parameter, in which the laboratory received scores of 0% for both events, resulting in unsuccessful performance (Refer to D2130).

D2123

HEMATOLOGY
CFR(s): 493.851(c)

Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:
Based on the review of proficiency testing (PT) records, the CASPER 0153D Unsatisfactory and Unsuccessful PT Report, and an interview with the primary testing personnel, the laboratory failed to participate in one of three Complete Blood Count (CBC) PT events in 2021. Findings include: 1. Review of the CASPER 0153D Unsatisfactory and Unsuccessful PT Report and the Medical Laboratory Evaluation (MLE) PT records for the third event in 2021 revealed the laboratory received a score of 0%: 2021 MLE-M3- 0%- for the CBC module (Notation by MLE-failure to participate). 2. An interview with the primary testing personnel on 12/02/21 at approximately 10:30 AM confirmed the findings.

D2130

HEMATOLOGY
CFR(s): 493.851(f)

Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:
Based on the review the proficiency testing (PT) scores for the second and third events in 2021, the CASPER 0153D Unsatisfactory and Unsuccessful PT report and interview with the primary testing personnel, the laboratory failed to achieve satisfactory performance of at least 80% for two consecutive events for the White Blood Cell Differential (WBC Diff) parameter, resulting in unsuccessful performance. Findings include: 1. Review of the Medical Laboratory Evaluation (MLE) hematology PT scores and the CASPER 0153D Unsuccessful PT report revealed the following scores: 2021 2nd event WBC Diff- 0% 2021 3rd event WBC Diff- 0% The laboratory

received an unsuccessful MLE PT score for the above listed analyte. 2. An interview with the primary testing personnel on 12/02/21 at approximately 10:30 AM confirmed the findings.