

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  49D1093849	<b>(X3) Date Survey Completed</b>  04/07/2022
<b>Name of Provider or Supplier</b>  Community Health Clinic	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An unannounced CLIA off-site proficiency testing desk review of Community Health Clinic (Richlands) was conducted on 04/05/22 and 4/06/22 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. D2017- 42 C.F.R 493.807 (a)(b) Condition- Reinstatement of Nonwaived Laboratories.
<b>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> 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:</p>

Based on off-site proficiency testing (PT) desk review, communication with the laboratory director on 04/05/22 and 4/06/22, the laboratory failed to achieve satisfactory performance of at least 80% for three consecutive events for the White Blood Cell Differential (WBC Diff) analyte for the second and third events in 2021 and the first event in 2022, resulting in a repeat unsuccessful performance. Refer to D2130.

**D2017**

**REINSTATEMENT OF NONWAIVED LABORATORIES**  
CFR(s): 493.807(a)(b)

(a) If a laboratory's certificate is suspended or limited or its Medicare or Medicaid approval is cancelled or its Medicare or Medicaid payments are suspended because it fails to participate successfully in proficiency testing for one or more specialties, subspecialties, analyte or test, or voluntarily withdraws its certification under CLIA for the failed specialty, subspecialty, or analyte, the laboratory must then demonstrate sustained satisfactory performance on two consecutive proficiency testing events, one of which may be on site, before CMS will consider it for reinstatement for certification and Medicare or Medicaid approval in that specialty, subspecialty, analyte or test. (b) The cancellation period for Medicare and Medicaid approval or period for suspension of Medicare or Medicaid payments or suspension or limitation of certification under CLIA for the failed specialty, subspecialty, or analyte or test is for a period of not less than six months from the date of cancellation, limitation or suspension of the CLIA certificate.

This CONDITION is not met as evidenced by:

Based on the off-site review of the Medical Laboratory Evaluation (MLE) Proficiency Testing (PT) scores, the CASPER 155D Individual Laboratory Profile report, and communication with the laboratory director, the laboratory has not participated in reinstatement testing for the White Blood Cell Differential (WBC Diff) analyte. Findings include: 1. As of the date of the desk review, the laboratory has not submitted evidence of satisfactory performance on two consecutive PT events for the analyte of WBC Diff. 2. A phone conference with the laboratory director on 04/05/22 at 9 AM revealed the laboratory director was unaware of the PT failure. They requested the day to review the results. The laboratory director acknowledged that the lab did not have evidence of two consecutive successful performance scores with the MLE for the analyte of WBC Diff. 3. An email communication with the laboratory director on 04/06/22 at 1518 revealed that the laboratory has voluntarily withdrawn its certification for the analyte of WBC Diff.

**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 off-site review of the proficiency testing (PT) scores for the second and third events in 2021 and the first event in 2022, the CASPER 0155D Individual Laboratory Profile report, and an interview with the laboratory director, the laboratory failed to achieve satisfactory performance of at least 80% for three consecutive events for the White Blood Cell Differential (WBC Diff) analyte. Findings include: 1.

Review of the Medical Laboratory Evaluation (MLE) hematology PT scores and the CASPER 0155D Individual Laboratory PT report revealed the following scores: 2021 2nd event WBC Diff- 0% 2021 3rd event WBC Diff- 0% 2022 1st event WBC Diff- 46% The laboratory received a repeat unsuccessful MLE PT score for the above listed analyte. 2. A phone conference with the laboratory director on 04/05/22 at 9 AM and an email communication on 04/06/22 at 1518 confirmed the findings.