

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0232976	(X3) Date Survey Completed 04/10/2018
Name of Provider or Supplier Cvfp-Walk In-Candlers	Street Address, City, State 2832 Candlers Mountain Road, Lynchburg, 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 Physicians Treatment Center was conducted on April 10, 2018 by a Medical Facilities Inspector of the Virginia Department of Health's Office of Licensure and Certification. The laboratory was inspected under 42 CFR Part 493 CLIA regulations. Specific deficiencies cited are as follows:
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 proficiency testing (PT) desk review, the CASPER 0155D Unsuccessful PT report, and an interview, the laboratory failed to achieved satisfactory performance of at least 80% for two consecutive events for the Sodium (NA) analyte for the third</p>

event in 2017 and the first event in 2018, resulting in unsuccessful performance (Cross Reference D 2096).

D2096

ROUTINE CHEMISTRY

CFR(s): 493.841(f)

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

This STANDARD is not met as evidenced by:

Based on a proficiency testing (PT) desk review, the CASPER 0155D Unsuccessful PT report and an interview, the laboratory failed to achieved satisfactory performance of at least 80% for two consecutive events for the sodium (NA) analyte for the third event in 2017 and the first event in 2018, resulting in unsuccessful performance.

Findings include: 1. A PT desk review of the American Proficiency Institute (API) PT scores and review of the CASPER 0155D report revealed the following: API 2017 3rd event API 2018 1st event NA- 40% NA- 60% 2. An interview with the primary testing personnel at approximately 8:30 AM confirmed that the laboratory received unsatisfactory scores for two consecutive events for the analytes listed above, resulting in unsuccessful performance.