

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2138659	(X3) Date Survey Completed 01/15/2019
Name of Provider or Supplier Healthvisions Md	Street Address, City, State 1230 Alverser Drive, Midlothian, 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 Healthvisions MD was conducted on January 15, 2019 by a Medical Facilities Inspector with 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 an off-site desk review of the laboratory's 2017 and 2018 proficiency testing (PT) records, a total of six (6) events, and an email interview, the laboratory failed to attain a score of at least eighty (80) percent of acceptable responses for White Blood</p>

Cell Differential in two (2) of three (3) Hematology testing events resulting in unsuccessful PT performance. See 2130.

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 an off-site desk review of the laboratory's proficiency testing (PT) records and an email interview, the laboratory failed to attain a score of at least eighty (80) percent of acceptable responses for White Blood Cell (WBC) Differential in two (2) of three (3) Hematology testing events resulting in an unsuccessful PT performance. Findings include: 1. Desk review of the laboratory's 2017 and 2018 American Proficiency Institute (API) PT records, a total of six (6) events, revealed WBC Differential scores of less than eighty percent (80%) for the following Hematology events: 2018 2nd event - Differential score of 0%, 2018 3rd event - Differential score of 0%, resulting in an unsuccessful PT performance. 2. In an email from the lead medical assistant on January 15, 2019, the findings were confirmed for the PT testing events as outlined above.