

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D2138659	<b>(X3) Date Survey Completed</b> 11/02/2022
<b>Name of Provider or Supplier</b> Healthvisions Md	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced CLIA Recertification survey was conducted at Healthvisions MD on 11/02/22 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 is performing COVID-19 testing and is in compliance with the applicable COVID-19 reporting requirements.
<b>D2007</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records, Laboratory Personnel Report form (CLIA) (CMS-209 Form), and an interview, the laboratory failed to rotate PT among the nine testing personnel (TP) for five of five events reviewed. Dates of record review include all 3 events in 2021 and the first 2 events in 2022. Findings include: 1. The review of the American Proficiency Institute (API) PT records revealed that the testing personnel (TP) A performed all 3 events in 2021 and the 1st and 2nd events in 2022. (See attached personnel code list.) 2. Review of the CMS 209 laboratory personnel form revealed nine TP performing patient testing from 01/01/21 and up to the date of survey on 11/02/22. 3. An interview with the primary TP on 11/02/22 at approximately 1320 confirmed the findings.</p>
<b>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems</p>

activities specified in 493.1252 through 493.1289 for at least 2 years.

This STANDARD is not met as evidenced by:

Based on the review of the manufacturer's product correction notification, maintenance logs, lack of documentation, and interview, the laboratory failed to retain documentation of the performance of the weekly bleaching procedures for 19 of 43 weeks reviewed. Dates of record review include 01/03/22 up to the date of survey on 11/02/22. Findings include: 1. Review of the Abbott Product Correction notification (dated 02/21/19) revealed instructions to increase the bleach cleaning procedures from monthly to weekly. 2. Review of the Cell-Dyn Emerald instrument event logs indicating performance of maintenance procedures for 2021 and up to the date of survey on 11/02/22 revealed a lack of documentation of the performance of the weekly bleach cleaning procedures for the following weeks: January 3-7, 10-14, 17-21, 24-28, 2022, January 31, 2022 - February 4, 2022, February 7-11, 14-18, 21-25, 2022, February 28, 2022- March 4, 2022, March 7-11, 14-18, 21-25, March 28- April 1, 2022, April 4-8, 11-15, 18-22, 25-29, 2022, May 2-6, and 9-13, 2022. Total 19 weeks. 3. In an interview with the primary testing personnel on 11/02/22 at approximately 1200, they stated that they thought the event log for their Cell Dyn Emerald could be reprinted to show the performance of the required weekly maintenance. They attempted to retrieve the data from the instrument but was unable to provide the documents for review at the date of the survey on 11/02/22. 4. An exit interview with the primary testing personnel on 11/02/22 at 1320 confirmed the findings.