

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2138659	(X3) Date Survey Completed 02/16/2021
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 announced CLIA Recertification survey was conducted at Healthvisions MD in Midlothian, Virginia on February 16, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Initial entrance interview conducted on January 4, 2021. Specific deficiencies cited are as follows:
D6023	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's performance verification records, lack of documentation, and an interview, the laboratory director failed to review and approve the initial performance verification records for Complete Blood Cell counts (CBC) performed on the Abbott Emerald hematology analyzer prior to reporting patient results from August 13, 2020 until January 31, 2021. Findings include: 1. Review of the laboratory's Abbott Emerald (serial number 008105, installed 01/29/20) hematology analyzer's performance verification documentation revealed a lack of documentation of review and approval by the lab director for the accuracy, precision, and reportable range studies. In addition, the documents did not include verification of the reference (normal) ranges for CBCs after the instrument was installed. The instrument was taken out of use with the downgrade of the certificate on 03/12/20 and restarted with use on 08/13/20. 2. An interview with primary testing personnel on February 16, 2021 at approximately 1:30 PM confirmed that the instrument was taken</p>

out of use and later returned to use in the calendar year 2020. In addition, on February 17, 2021, an email with the primary testing personnel confirmed the lack of documentation by the lab director for review and approval of the initial performance verification documents on January 29, 2020.