

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2138659	(X3) Date Survey Completed 07/10/2018
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 initial survey was conducted at Healthvisions MD on July 10, 2018 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirement. Specific deficiencies cited are as follows:
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on review of the laboratory's proficiency testing records and an interview, the laboratory failed to enroll in a Center for Medicare and Medicaid Services (CMS) approved Proficiency Testing (PT) program for one (1) of three (3) PT events reviewed from December 2017 until July 2018. Findings include: 1. Review of the laboratory's PT records revealed the laboratory participated in the following: American Proficiency Institute (API) for 2017 Hematology Third Event, American Proficiency Institute for 2018 Hematology Second Event. The inspector requested documentation for the American Proficiency Institute for 2018 Hematology First Event. No documentation was available for review. 2. An interview with Testing Personnel A at approximately 9:20 AM, confirmed that the laboratory did not participate in a CMS approved PT program for the Hematology First Event of 2018. TP-A stated that she/he realized that the facility did not receive API Hematology</p>

Event 1. She/he immediately contacted API, enrolled and participated in the 2018 Hematology Second Event.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's performance verification records, and an interview, the laboratory failed to verify the reportable and reference (normal) ranges for Complete Blood Cell counts (CBC) performed on the Abbott Emerald hematology analyzer prior to reporting patient results from December 1, 2017 until July 10, 2018. Findings include: 1. Review of the laboratory's Abbott Emerald (serial number 034509, installed 10/25/17) hematology analyzer's performance verification documentation revealed the documentation did not include verification of the reportable and reference (normal) ranges for CBCs after the instrument was installed. The surveyor requested to review documentation that the laboratory evaluated and verified the reportable and reference (normal) ranges for the Abbott Emerald prior to patient testing. The laboratory provided no documentation for review. 2. An interview with Testing Personnel A at approximately 10:30 AM, confirmed that the laboratory failed to document the verification of the reportable and normal ranges for CBCs performed on the Abbott Emerald analyzer prior to patient testing that began in December 2017.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

A. Based on review of the laboratory's policy and procedure manual, quality assurance (QA) records and interview, the laboratory failed to follow their written QA policy for the review of their analytic system for seven (7) of seven (7) months from December 2017 to July 2018. Findings include: 1. Review of the laboratory's policy and procedure manual revealed a policy, "Quality Assurance Guidelines", which states "Quality Assurance Review - Our laboratory uses this quality assurance program to improve the laboratory services we provide to our physicians and patients. We will perform a quality review at least monthly and review the results with the laboratory director approval. Changes in our policy or procedures resulting from this quality review will be made known to the entire laboratory staff. The laboratory director or supervisor will initial and date our written reviews and actions. Quality

Assurance Records - The record of our quality assurance reviews are filed with this plan. They are available for review by the director, consultant, staff, and laboratory surveyors. All records are dated and initialed by the staff performing the reviews and the laboratory director." 2. Review of the laboratory's quality assurance records revealed no documentation of the quality assurance review for the seven (7) months from December 2017 until July 2018. The surveyor requested to review documentation that the laboratory performed a quality assurance review December 2017 to July 2018. The laboratory provided no documentation for review. 3. An interview with Testing Personnel A at approximately 2:00 PM confirmed the laboratory did not perform monthly quality assurance reviews as described within the policy from December 2017 to July 2018. B. Based on review of the laboratory's policy and procedure manual, quality control records and interviews, the laboratory failed to follow their written QA policy for the evaluation of their Abbott Emerald quality control program for seven (7) of seven (7) months from December 2017 to July 2018. Findings include: 1. Review of the laboratory's policy and procedure manual revealed a policy, "Quality Assurance Guidelines", which states "Quality Control and Instrumentation-We will evaluate our quality control program for calibration and control data for each test method used in the lab and determine: If calibrators and controls are run according to written policies and procedures. If personnel have taken appropriate corrective action when calibration or control values are out the acceptable range. This information will be recorded and kept with our Quality Assurance Records.... Quality Assurance Review- Our laboratory uses this quality assurance program to improve the laboratory services we provide to our physicians and patients. We will perform a quality review at least monthly and review the results with the laboratory director approval. Changes in our policy or procedures resulting from this quality review will be made known to the entire laboratory staff. The laboratory director or supervisor will initial and date our written reviews and actions." 2. Review of the laboratory's Abbott Emerald Hematology analyzer's quality control records revealed no documentation of the evaluation of the control data for the Emerald for seven (7) of seven (7) months from December 2017 until July 2018. The surveyor requested to review documentation that the laboratory evaluated the control data of the Emerald analyzer from December 2017 to July 2018. The laboratory provided no documentation for review. 3. An interview with Testing Personnel A at approximately 2:00 PM confirmed the laboratory did not perform monthly evaluations of the control data for the Emerald analyzer as described within the policy from December 2017 to July 2018.