Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2138659	12/10/2019
Name of Provider or Supplier	**Street Address, City, State**	
Healthvisions Md	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 the Healthvisions, MD on December 10, 2019 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:
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on the review of the Policy and Procedures (P&P), lack of documentation, and an interview with the primary testing personnel, the laboratory failed to establish a written P&P failed to include step-by-step instructions for collecting, performing and

	interpretations of results for microscopic vaginal Wet Preparation (Wet Mount) and 10% potassium hydroxide (KOH) microscopic examinations at the date of survey on December 10, 2019. Findings include: 1. Review of the P&P (signed review by lab director 11/2/18 and 11/4/19) revealed the lack of documentation of an established written P&P for for collecting, performing and interpretations of results for vaginal Wet Mount and 10% KOH microscopic examinations. The surveyor requested to review the above-specified document. The document was not available for review. 2. In an interview with the primary TP at approximately 3:00 PM, the TP stated that they really didn't do these tests, maybe a couple a year.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on the review of laboratory temperature records, quality control (QC) records, policy and procedure (P&P), lack of documentation, and an interview with the primary testing personnel, the laboratory failed to monitor and document room and refrigerator temperatures and relative humidity for twenty-four (24) of 260 dates of review in 2019. Dates of record review include January 1, 2019 through November 30, 2019. Findings include: 1. Review of the laboratory's "Daily Environmental Logs" and the Abbott Cell Dyn hematology QC records revealed the following dates QC procedures performed and lack of documentation of temperatures and relative humidity: February 2, 2019; April 6, 18, 22, and 29, 2019; May 2, 10, 11, 13, 14, 17, 18, 20, 21, 23, 24, 28 and 29, 2019; June 3 and 4, 2019; September 6, 2019; October 25 and 26, 2019 and November 2, 2019. Total of 24 dates. 2. Review of the laboratory's P&P (signed review by lab director 11/2/18 and 11/4/19) revealed the following statements: "Laboratory Refrigerator" "A thermometer is to be placed in the refrigerator and temperatures is to be checked each day and recorded on the temperature log." "Daily Environmental Log" "Take refrigerator and room temperatures readings along with relative humidity readings daily". 3. An interview with the primary testing personnel at approximately 3: 00 PM confirmed the findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of manufacturer's operations manual, hematology records, lack of documentation, and an interview with the primary testing personnel, the laboratory failed to perform and document Abbott Emerald hematology instrument semi-annual

	maintenance procedures at the date of survey on December 10, 2019. Dates of record review include December 1, 2018 and up to the date of survey. Findings include: 1. Review of the Abbott Emerald Operations Manual revealed the following statement: "Section 9. Semi-annual Maintenance-For optimal operation, the syringe pistons are to be lubricated every six months". 2. Review of the hematology records for the Abbott Emerald Cell Dyn (Serial Number 034509-001010) revealed the service representative performed the semi-annual lubricating of the syringe pistons on 12/28 /2018 and a lack of documentation of additional semi-annual procedures performed up to the date of survey was available for review upon surveyor's request. 3. An interview with the primary testing personnel at approximately 3:00 PM confirmed the findings.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on the review of hematology records, manufacturer's operation manual, policy and procedure (P&P), and an interview with the primary testing personnel, the laboratory failed to follow the manufacturer instructions for performing calibration procedures every six (6) months from January 1, 2019 up to the date of survey on December 10, 2019. Findings include: 1. Review of the hematology records for the Abbott Emerald Cell Dyn (Serial Number 034509-001010) revealed a calibration verification performed on 12/28/2018. No documentation of additional calibration procedures performed up to the date of survey was available for review upon surveyor's request. 2. Review of the manufacturer's operation manual and P&P revealed the following statements: "Abbott Emerald Operations Manual" "Section 6-When to Calibrate" "At least every six months." "Quality Assurance" (signed review by lab director 11/2/18 and 11/4/19) "Quality Control and Instrumentation- Follow manufacturer's directions in the operation of the instrument. Follow the manufacturer's recommendations for instrument maintenance." 3. An interview with the primary testing personnel at approximately 3:00 PM confirmed the findings.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

	This STANDARD is not met as evidenced by: Based on review of policy and procedures (P&P), Daily Environmental Logs, hematology instrument records, lack of documentation, and an interview with the primary testing personnel, the laboratory failed to follow the established Quality Assurance (QA) policy for the review of their analytic system for eleven (11) of 11 months from December 1, 2018 to November 30, 2019. Findings include: 1. Review of the laboratory's P&P (signed review by lab director 11/2/18 and 11/4/19) revealed the following statements: "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. The review of the laboratory's records revealed lack of documentation of the QA reviews from December 1, 2018 through November 30, 2019 (11 months). The surveyor requested to review QA documentation. The monthly Levey-Jennings printouts were provided to the surveyor. No other documentation was available for review. Review of the Daily Environmental Logs revealed dates in which the lab failed to document temperatures and relative humidity readings and lack of documentation of review by lab director and staff (Cross Reference D5413). Review of the hematology records revealed lack of documentation of performance of semi-annual maintenance procedures and lack of documentation of review by lab director and staff (Cross Reference D5429). Review of the hematology records revealed lack of documentation of performance of calibration verifications and lack of documentation of review by lab director and staff (Cross Reference D5439). 3. An interview with the primary testing personnel at approximately 3:00 PM confirmed the findings.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on the review of policy and procedures (P&P), Daily Environmental Logs, hematology instrument records, lack of documentation, and an interview with the primary testing personnel, the laboratory director failed to follow the established Quality Assurance (QA) policy for the review of their analytic system for eleven (11) of 11 months from December 1, 2018 to November 30, 2019. Cross Reference D5793.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)

	(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on the review of Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records, lack of documentation, and interview with the primary TP, the technical consultant failed to perform and document review of the annual competency assessments for three (3) of 3 TP in 2018. Findings include: 1. Review of the CMS-209 form revealed that the lab director also performs the duties of technical consultant and that there were 3 TP performing patient testing in 2018. See attached TP code sheet. 2. Review of the TP records revealed lack of documentation by the TC of performance and review of an annual competency assessments for: TP A for 2018- last date of competency assessment 11/1/17, TP B for 2018- initial training and competency 10/26/17, semi-annual 4/27/18, and TP C for 2018- initial training and competency 11/1/17 (left employment June 2019). 3. An interview with the primary TP at approximately 3:00 PM confirmed that the findings.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on the review of Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records, lack of documentation, and interview with the primary TP, the technical consultant failed to perform and document review of the semi-annual competency assessments for two (2) of 3 TP in 2018 and 2019. Findings include: 1. Review of the CMS-209 form revealed that the lab director also performs the duties of technical consultant and that there were 3 new TP. See attached TP code sheet. 2. Review of the TP records revealed lack of documentation by the TC of performance and review of a semi- annual competency assessments for: TP C for 2018- initial training and competency 11/1/17 (left employment June 2019), and TP D for 2019- initial training and competency 9/5/18 and annual competency 9/8/19. 3. An interview with the primary TP at approximately 3:00 PM confirmed the findings.