Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2136089	07/17/2024
Name of Provider or Supplier	**Street Address, City, State**	
Evms Hopes Free Clinic	830 Southampton Ave, Norfolk, 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 EVMS HOPES Free Clinic on July 16, 2024 by the Virginia Department of Health's Office of Licensure and Certification. The inspection also included follow up interviews with the office coordinator on 7/17/24. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows and includes the Condition under 42 CFR part 493 CLIA Regulation: D5400 -42 CFR. 493.1250 Analytic Systems.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on a laboratory tour, review of manufacturer's package instructions, and interview, the laboratory failed to ensure that nine (9) of 9 reagent boxes, two (2) of 2 quality control (QC) boxed reagents were stored following manufacturer's storage instructions and one (1) of 2 QC reagents were in-date as observed on the date of the initial inspection on July 16, 2024. Findings include: 1. During a tour on 7/16/24 at 1: 30 PM, the inspector noted the laboratory's refrigerator door was ajar. The inspector reviewed the contents and noted the following waived test reagents: 3 Piccolo Comprehensive Metabolic Panel (CMP) test cartridge packages (10 reagent disks per package, Lot 4111 expiration date 3/11/25), 5 Piccolo Lipid Panel test cartridge packages (5 reagent discs, Lot 3471 expiration date 11/13/24), 1 box Afinion HbA1c reagent cartridges (15 reagent cartridges, Lot 10226061 expiration date 12/4/25), 1 box of Abbott HbA1c QC (2 Vials, Lot 902953967 expiration 2/23/25), and 1 box of Bioresource Technology Inc. (BRT) Chemistry QC (6 Vials, Lot 1902013 expiration June 2020). 2. The inspector noted at the time of the inspection that the refrigerator's

	Wrenwane Traceable digital temperature reading was 22 C and 1 box of Bioresource Technology Inc. (BRT) Chemistry QC (6 Vials, Lot 1902013 expiration June 2020) was expired. 3. Review of the manufacturer's reagent and QC packages revealed storage temperature instructions as follows: Piccolo CMP Reagent Discs "Store 2-8 C", Piccolo Lipid Panel Reagent Discs "Store 2-8 C", Afinion HbA1c Test Cartridges "Store 2-8 C", Abbott Afinion HbA1c QC Vials "Store 2-8 C", BRT Piccolo Chemistry QC Vials "Keep Frozen, Store -15 C, can be stored 2-8 once thawed up to 14 days unopened". 4. The inspector inquired regarding the laboratory's temperature monitoring protocol for the refrigerator and protocols regarding observing reagent expiration dates. The office coordinator stated on 7/16/24 at 2:00 PM: "I am not sure how long the refrigerator door has been open. It could have been since our last free clinic day last week. We have not been recording temperatures. We had not noted that the Chemistry QC vials were expired and not stored frozen as required. I will reorder." 5. An interview with the office coordinator on 7/16/24 at 4 PM confirmed the above findings. .
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a tour, review of manufacturer's package insert instructions, procedures, analyzer performance verification records, lack of documentation, and interviews, the laboratory failed to: 1. ensure Complete Blood Count (CBC) quality control (QC) were in date and stored per manufacturer's requirements for three (3) of 3 QC kits as observed on the date of the initial inspection on July 16, 2024. See D5411; 2. monitor daily relative humidity percent and room/refrigerator temperatures to ensure manufacturer's operating and storage requirements were followed for the hematology analyzer and QC materials utilized for CBC testing from January 2024 to the date of the initial inspection on 7/16/24. See D5413; 3. evaluate and verify performance specifications for the Abbott Emerald hematology analyzer after it was relocated in September 2023 and up to the date of the survey on July 16, 2024. See D5421.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a tour, review of manufacturer's package insert instructions, and interviews, the laboratory failed to ensure Complete Blood Count (CBC) quality control (QC) materials were in date and stored per manufacturer's requirements for three (3) of 3

	QC kits as observed on the date of the initial inspection on July 16, 2024. Findings include: 1. During a tour on 7/16/24 at 1:30 PM the inspector noted the laboratory's refrigerator door was ajar. The inspector reviewed the contents and noted 3 Abbott Cell Dyn 18 Plus QC packages (lot 4064 with expiration date 6/21/24). The inspector noted that the QC packages were expired and felt warm to the touch. The inspector noted that the refrigerator's Wrenwane Traceable digital temperature reading was 22 C. 2. Review of the Abbott Cell Dyn QC package revealed storage temperature instructions - "Stable through expiration date when stored 2-10 C, opened stability is eight consecutive days after open stored at 2-10 C." 3. The inspector inquired regarding the laboratory's temperature monitoring protocol for the refrigerator and protocols regarding observing reagent expiration dates. The office coordinator stated on 7/16/24 at 2:00 PM: "I am not sure how long the refrigerator door has been open. It could have been since our last free clinic day last week. We have not been recording temperatures. We had not noted that the QC were expired. I will reorder." 4. An interview with the office coordinator on 7/16/24 at 4 PM confirmed the above findings.
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 a review of procedures, manufacturer's user guide/package inserts, lack of documentation, and an interview, the laboratory failed to monitor daily relative humidity percent (%), and room/refrigerator temperatures to ensure manufacturer's requirements were followed for the hematology analyzer and quality control (QC) materials utilized for Complete Blood Count (CBC) testing from January 2024 to the date of the initial inspection on July 16, 2024. Findings include: 1. Review of the laboratory's procedures revealed Abbott Emerald protocols that outlined daily monitoring of environmental conditions that included laboratory room temperature/ humidity ranges to be within the following guidelines: Temperature: 64-90 F (18-32 C). Humidity: Maximum 80%, 2. Review of the Abbott Cell-Dyn 18 Plus CBC QC package insert revealed instructions- "Stable through expiration date when stored 2-10 C, opened stability is eight consecutive days after open stored at 2-10 C". 3. Review of the available laboratory records from January 2024 to 7/16/24 revealed no record of laboratory room temperature/humidity or refrigerator temperature monitoring. The inspector requested to review documentation of the monitoring to manufacturer's specifications. No records were available for review. 4. An interview with the office coordinator on 7/16/24 at 4 PM confirmed the above findings
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 a review of the laboratory's Centers for Medicare and Medicaid Services (CMS) 116 form, hematology analyzer performance verification documentation, lack of documentation, and interviews, the laboratory failed to evaluate accuracy, precision, reportable range, and normal values (reference ranges) for Complete Blood Count (CBC) after the Hematology analyzer's installation in September 2023, and failed to verify performance specifications after instrument relocation as of the date of the initial survey on July 16, 2024. Findings include: 1. A pre-survey review of the laboratory's CMS 116 form revealed that the laboratory director identified the laboratory name and physical facility location as follows: EVMS HOPES Free Clinic 830 Southampton Ave Norfolk, Virginia 23507 2. During the onsite inspection review of the laboratory's Abbott Emerald (Serial Number 030722-010480) Integration Binder revealed that an Abbott field service technical specialist installed the hematology instrument on 9/7/23. The inspector noted that the installation was performed at: Eastern Virginia Medical School 714 Woods Avenue Norfolk, Virginia 23510 The inspector inquired regarding the specifics of the relocation of the hematology instrument from the medical school address to the current free clinic laboratory site. The office coordinator stated on 7/16/24 at 2:30 PM, "The analyzer was moved here to our free clinic laboratory after it was installed at the medical school." 3. Review of the hematology analyzer documents revealed no record of an evaluation/verification for CBC accuracy, precision, reportable range, and normal values (reference ranges) for the Abbott Emerald outlined above from the installation date of 9/7/23 to the date of the inspection on 7/16/24. The inspector noted that the field service tech included a hand written note on the installation notebook that stated, "Streck linearity results will be emailed to you. Please print them and review. The results may go to your spam mail so check the junk file". The inspector requested to review the Streck performance verification records. The office coordinator was able to locate an email with the Streck linearity report attached. The provided record (dated 9/8/23) had not been reviewed/evaluated nor was it approved by the laboratory director. The Streck report was addressed to Eastern Virginia Medical School and stated "Each laboratory must evaluate the data provided and use it as a guide in determining their level of instrument or testing accuracy, as well as evaluating acceptable reportable ranges." 4. The inspector inquired regarding what performance verification studies were completed once the analyzer was moved to the current free clinic laboratory. The office coordinator stated in a follow up interview on 7/17/24 at 1 PM, "A McKesson representative assisted with the relocation shortly after it was originally installed at the medical school.. I will need to reach out to ask if a second validation was completed. I do not have any records at this time. I will ask our lab director or clinical consultant to review and evaluate the performance studies." 5. The follow up interview with the office coordinator on 7/17/24 at 1 PM confirmed the above findings.