Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0229895	03/20/2018
Name of Provider or Supplier	**Street Address, City, State**	
Bayview Medical Center	7924 Chesapeake Blvd, 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 Recertification survey was conducted at the Bayview Medical Center on March 20, 2018 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:
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on the review of the Laboratory Personnel Report (CLIA) (Form CMS-209), procedure manual, and interviews, the laboratory failed to establish written procedures for competency assessment of the Potassium Hydroxide (KOH) and Vaginal Wet Preparations (Wet Prep) microscopic examinations. Findings include: 1. Review of the Form CMS-209 revealed that there are two (2) testing personnel (TP) performing KOH and Wet Prep microscopic examinations. See attached list. 2. Review of the laboratory's procedure manual revealed no written competency assessment procedure for those individuals performing the above-mentioned testing. 3. An interview with the office manager and primary TP at approximately 1:00 PM confirmed that the laboratory did not have competency assessment procedures for the KOH and Wet Prep microscopic examinations.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

	This STANDARD is not met as evidenced by: Based on the review of the policy and procedure manual, proficiency testing records and an interview with the primary testing personnel (TP), the laboratory failed to verify the accuracy of the vaginal wet preparations (Wet Prep) microscopic examinations twice a year in 2017. Findings include: 1. Review of the policy and procedure manual revealed that the laboratory performs Wet Prep microscopic examinations. 2. Review of the American Proficiency Institute (API) 2017 records for Wet Prep revealed the following scores: 2017 Event 1- 0%, 2017 Event 3- 0%. An interview with the primary TP at approximately 10:35 AM revealed that the laboratory utilizes API proficiency testing to verify the accuracy of the Wet Prep examinations twice a year. The inspector requested to review additional accuracy checks for Wet Prep due to the failures received from API. There was no additional documentation available for review. 3. An interview with the office manager and primary TP at approximately 1:00 PM confirmed that the laboratory failed to verify the accuracy of the Wet Prep microscopic examinations twice a year in 2017.
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 package insert (PI), temperature logs and interviews, the laboratory failed to follow the manufacturer's storage requirements for Hematology quality control materials for seventy-seven (77) of two-hundred and seventy-three (273) days reviewed from June 1, 2016 through June 30, 2017. Findings include: 1. Review of the Cell Dyn 18 Plus Control PI for storage requirements revealed that the quality control materials are to be stored at 2-10 degrees Celsius. 2. Review of the refrigerator temperature logs revealed the temperatures colder than 2 degrees Celsius for the following number of days: October 2016- 9 days, November 2016- 7 days, December 2016- 21 days, January 2017- 8 days, February 2017- 9 days, March 2017- 9 days, April 2017- 5 days, May 2017- 4 days, June 2017- 5 days, A total of 77 days. 3. An interview with the office manager and primary testing personnel at approximately 1:00 PM confirmed that the laboratory failed to follow the manufacturer's storage requirements for the Hematology quality control materials for the months and number of days listed above.
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 tour of the laboratory, manufacturer's package insert (PI), maintenance records, an interviews, the laboratory failed to follow the manufacturer maintenance protocols for one (1) of one (1) thermometer used to monitor the refrigerator temperatures from October 1, 2016 and up to the date of survey on March 20, 2018. Findings include: 1. The tour of the laboratory revealed that the refrigerator in the laboratory contained quality control materials for the hematology analyzer. The laboratory utilizes the Fisher Scientific Min-Max Time Setup Thermometer, serial number 140632893 with calibration expiration date of 09/22/2016, to monitor the refrigerator temperatures. 2. Review of the PI for the thermometer revealed the following statement: "Calibration and Preventative Maintenance: Each digital thermometer should be sent back to the manufacturer for recalibration or replacement (whichever option is more cost effective) nearing the recalibration date printed on the recalibration sticker located on the back of the thermometer." 3. Review of the laboratory's equipment maintenance records from October 1, 2016 and up to the date of survey on March 20, 2018 revealed no calibration documentation for the thermometer (140632893) prior to 09/22/2016 or the purchase of a new thermometer with a current calibration date. The inspector also requested to review documentation of a written maintenance protocol for verifying the accuracy of the expired thermometer. The documentation was not available for review. 4. An interview with the office manager and primary testing personnel at approximately 1:00 PM confirmed that the laboratory did not follow the manufacturer maintenance protocols for 1 thermometer used to monitor the refrigerator temperatures from October 1, 2016 and up to the date of survey on March 20, 2018.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the package insert (PI), patient data report, and interviews, the laboratory failed to perform external quality control materials for the serum Human Chorionic Gonadotropin (HCG) tests each day of patient testing in 2017 for six (6) of the six (6) patients reported. Findings include: 1. Review of the Consult HCG serum /urine combo test kit PI revealed that the use of serum samples for this test kit is categorized moderate complexity testing. The review of the PI also revealed that the manufacturer recommends that external quality control materials be run with each new kit lot number and follow local, state, and/or federal regulations. 2. The inspector requested to review the documentation of performing the external quality control materials each day of patient testing using serum samples. The documentation was not available for review. Review of the SRS Electronic Medical Record patient data report for serum HCG tests reported in 2017 revealed the following 6 patients: Patient A- reported 01/12/2017, Patient B- reported 01/23/2017, Patient C- reported 02/03 /2017, Patient D- reported 03/22/2017, Patient E- reported 04/24/2017, Patient F- reported 05/11/2017. 3. An interview with the office manager and primary testing personnel at approximately 1:00 PM confirmed that the laboratory failed to perform

	external quality control materials for the serum HCG tests each day of patient testing in 2017.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on the review of package insert (PI), temperature logs and interviews, the laboratory failed to document corrective actions taken when the refrigerator temperatures were not within the manufacturer's acceptable storage requirements for seventy-seven (77) of two-hundred and seventy-three (273) days reviewed from June 1, 2016 through June 30, 2017. Cross Reference D5413. Findings include: 1. Review of the Cell Dyn 18 Plus Control PI for storage requirements reveals that the quality control materials are to be stored at 2-10 degrees Celsius. 2. Review of the refrigerator temperature logs revealed the temperatures were colder than 2 degrees Celsius for 77 of the 273 days reviewed. The inspector requested to review corrective actions taken for days in which the recorded refrigerator temperatures that were not within the manufacturer's storage requirements. There was no documentation available for review. 3. An interview with the office manager and primary testing personnel at approximately 1:00 PM confirmed that the laboratory failed to perform and document corrective actions for the days in which the refrigerator temperatures were not within the manufacturer's storage requirements.
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 the quality assurance (QA) policy and records, and interviews, the laboratory director failed to ensure that the QA checklists were documented and reviewed for fourteen (14) of the twenty-six (26) months reviewed. Findings include: 1. Review of the QA policy, signed by the laboratory director (no date provided), revealed the following statements: "the laboratory director is responsible for the overall QA Plan for the laboratory to include the identification and correction of the any detected problems. Problems identified by the plan will be documented along with the corrective action taken by the laboratory personnel and the director to correct them." The laboratory utilizes a monthly QA checklist to document the review of the testing system to include personnel, procedure manual, quality control, patient test management, proficiency testing, communications and QA reviews. 2. The inspector requested to review the QA checklists reviewed and signed by the laboratory director for the twelve (12) months in 2017 and for January and February 2018. The

	documents were not available for review. 3. An interview with the office manager and primary testing personnel at approximately 1:00 PM confirmed that the laboratory director did not ensure that the QA check lists were maintained for the calendar year 2017 and in January and February 2018.