Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0229895	01/08/2020
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 Bayview Medical Center-Nowcare II on January 8, 2020 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:
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on a review of 2018 and 2019 proficiency testing (PT) records, lack of documentation, and an interview, the laboratory failed to document remedial /corrective action for one (1) event, 2018 Event 3 unsatisfactory hematology analyte performance scores for Red Blood Count (RBC) and Hematocrit (HCT), out of six (6) events reviewed. Findings include: 1. Review of the laboratory's American Proficiency Institute (API) PT documentation for 2018 (Events 1-3) and 2019 (Events 1-3), a total of 6 events, revealed no corrective action documented for the following unsatisfactory performance: 2018 Event 3- RBC scored at zero percent (0%) and HCT scored at forty percent (40%). The inspector requested to review corrective/remedial action for the unsatisfactory PT performance outlined above. No documentation was available for review. 2. In an exit interview with the primary testing personnel at approximately 1:30 PM, the above findings were confirmed.

D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on a review of 2018 and 2019 proficiency testing (PT) records, lack of documentation, and an interview, the laboratory failed to evaluate seventy (70) non-graded PT results reported on four (4) of six (6) events reviewed. Findings include: 1. Review of the laboratory's American Proficiency Institute (API) PT documentation for 2018 (Events 1-3) and 2019 (Events 1-3), a total of 6 events, revealed no evaluation or verification of accuracy for the non-graded challenge responses for: 2018 Event 1 UA-02 Urobilinogen; 2018 Event 3 UA-05 Urobilinogen; 2019 Event 1 UA-01 Urobilinogen; HEM-02 Platelet; 2109 Event 2 UA-04 Urobilinogen; 2019 Event 2 HEM 06 to HEM 10 for each of the thirteen (13) analytes included in the Complete Blood Count (CBC) Hematology Module (Hematocrit, Hemoglobin, MCH, MCHC, MCV, MPV, Red Cell Count, RDW, Platelet, White Blood Count, Granulocytes, Lymphocytes, Monocytes); a total of 70 non-graded responses. The inspector requested to review evaluation documentation for the events outlined above. No additional documentation was available for review. 2. In an exit interview with the primary testing personnel at approximately 1:30 PM, the above findings were confirmed.
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 a review of proficiency testing (PT) records, lack of documentation, and an interview, the laboratory failed to verify the accuracy of their White Blood Cell (WBC) Differential Monocyte counts twice annually in calendar year 2019. Findings include: 1. Review of the laboratory's American Proficiency Institute (API) hematology PT documentation for 2018 (Events 1-3) and 2019 (Events 1-3), a total of 6 events, revealed the following Monocyte count performance: 2019 Event 1- score of 60%; 2019 Event 2 -non-graded responses, no self grade or corrective action noted for HEM 06 through HEM-10. The inspector requested to review twice annual accuracy verification for the Monocyte component of the WBC differential for calendar year 2019. No addition documentation was available for review. 2. In an exit interview with the primary testing personnel at approximately 1:30 PM, the above findings were confirmed.
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 facility tour, review of policies and procedures, manufacturer's operations manual, hematology instrument maintenance and calibration records, and lack of documentation, the laboratory failed to: 1. document the date of discontinuance of a microscopy procedure during the twenty-one (21) months reviewed (see D5409); 2. document performance of required hematology analyzer semiannual maintenance in calendar years 2018 and 2019 (see D5429); 3. document calibration procedures for patient Complete Blood Count testing on the Abbott Emerald analyzer every six months, per policy and the manufacturer's instructions, during the twenty-one (21) months reviewed (see D5437).
D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). This STANDARD is not met as evidenced by: Based on a facility tour, review of policies and procedures, lack of documentation, and interviews, the laboratory director (LD) failed to document the date of discontinuance of the Wet Prep microscopy procedure during the twenty-one (21) months reviewed. Findings include: 1. During a tour of the laboratory, at approximately 10:30 AM, the inspector noted one bottle of expired Health Link KOH 10% reagent stored in the urinalysis testing storage area (expiration date 09/21/18, Lot 1726808). The inspector inquired of the policy for expired reagents. The primary testing personnel stated: "We no longer use that reagent. It should be thrown out. We try to not keep or use expired reagents". 2. Review of the laboratory's policy and procedure manual (reviewed/approved by the LD on 09/20/2019) revealed a procedure for Wet Prep microscopy and outlined use of 10% KOH for the slide preparation. The inspector inquired of the laboratory's policy for documenting initial use and date of discontinued (retired) policies. The primary testing personnel stated, at approximately 1:00 PM: "We do still have the reagent and the procedure is still in our manual, but the lab has decided to discontinue Wet Prep testing". 3. The inspector requested to review documentation of the date of discontinuance of Wet Prep testing during the review timeframe of April 2018 to the date of the survey on 01/08/20. No record was available for review. 4. In an exit interview with the primary testing personnel at approximately 1:30 PM, the above findings were confirmed.
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 the policy and procedure manual, manufacturer's operations manual, instrument maintenance records, lack of documentation, and an interview, the laboratory failed to document performance of required maintenance (twice annually) for the Abbott Emerald Cell-Dyn Hematology analyzer in calendar years 2018 and 2019. Findings include: 1. Review of the laboratory's procedure manual revealed a maintenance policy (title: Emerald Cell-Dyn Maintenance) that stated: "Every 6 months grease pistons". 2. Review of the Abbott Emerald Operations Manual revealed manufacturer's instructions to "perform Lubricating Syringe Pistons maintenance procedure twice annually". 3. Review of the laboratory's Emerald hematology maintenance logs, from April 2018 through January 2020, revealed that the semiannual piston syringe lubrication maintenance was recorded as performed once (on 08/21/19). The inspector requested to review additional documentation of the piston syringe maintenance in 2018 and 2019. No other records were available. 4. In an exit interview with the primary testing personnel at approximately 1:30 PM, the above findings were confirmed.
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 review of policies and procedures, calibration records, lack of documentation, and interviews, the laboratory failed to document calibration procedures for patient Complete Blood Count (CBC) testing on the Abbott Emerald Cell-Dyn Hematology Analyzer every six (6) months, according to policy and the manufacturer's instructions, during the twenty-one (21) months reviewed. Findings include: 1. Review of the laboratory's policy and procedure manual revealed: The laboratory utilized a copy of the Abbott Emerald manufacturer's guide in their hematology procedure. The manufacturer guide outlined a CBC calibration frequency of every 6 months. An approved maintenance policy (title: Emerald Cell-Dyn Maintenance) stated: "Every 6 months calibrate using the pre-cal checklist from the appendix of the operator manual". 2. Review of the laboratory's Emerald hematology calibration records from April 2018 to 01/08/20 revealed one calibration recorded as performed on 08/21/19. The lab inspector requested to review additional calibration records during the 21 month review timeframe. No additional calibration documentation was available. The primary testing personnel stated at approximately 12:45 PM: "In the past, our office had a lab tech from another office take care of the Emerald calibrations. I was not aware that the frequency was twice per year until recently". 3. In an exit interview with the primary testing personnel at approximately 1:30 PM, the above findings were confirmed.

D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on a review of 2018 and 2019 hematology proficiency testing (PT) records, lack of documentation, and an interview, the laboratory director failed to document evaluation of and corrective action for twenty-five (25) unacceptable analyte scores received for Platelet (PLT), Lymphocyte (LY), Red Blood Cell (RBC), Hematocrit (HCT), Mean Corpuscular Hemoglobin (MCH), Mean Corpuscular Hemoglobin Concentration (MCHC) and Monocyte (MONO) counts noted on three (3) of six (6) PT events reviewed. Findings include: 1. Review of the laboratory's American Proficiency Institute (API) PT documentation for 2018 (Events 1-3) and 2019 (Events 1-3), a total of 6 events, revealed no evidence of evaluation for the following unacceptable hematology analyte scores: PLT: HEM 08 resulted 108 (acceptable range of 52-89) on 2018 Event 2; LY: HEM 09 resulted 14.2 (acceptable range of 10.6-13.9) on 2018 Event 2 and HEM 14 resulted 21.7 (acceptable 22.4-27.5) on 2018 Event 3; RBC: HEM 11 resulted 3.29 (acceptable 3.39-3.83), HEM 12 resulted 4.67 (acceptable 4.77-5.39), HEM 13 resulted 4.79 (acceptable 4.84-5.47), HEM 14 resulted 3.74 (acceptable 3.82-4.32), HEM 15 resulted 1.93 (acceptable 2.00-2.27) on 2018 Event 3; HCT: HEM 11 resulted 27 (acceptable 28-33), HEM 12 resulted 41 (acceptable 42-49), HEM 13 resulted 44 (acceptable 45-52) on 2018 Event 3; MCH: HEM 11 resulted 29.5 (acceptable 24.7-29.4), HEM 12 resulted 30.8 (acceptable 26.4-30.3), HEM 13 resulted 33.0 (acceptable 28.4-32.9), HEM 14 resulted 30.2 (acceptable 25.9-29.9), HEM 15 resulted 28.0 (acceptable 23.4-27.8) on 2018 Event 3; MCHC: HEM 11 resulted 35.4 (acceptable 29.1-34.5), HEM 12 resulted 35.1 (acceptable 29.4-34.0), HEM 13 resulted 35.8 (acceptable 30.3-35.1), HEM 14 resulted 34.7 (acceptable 29.1-33.9), and HEM 15 resulted 33.8 (acceptable 27.8-33.0) on 2018 Event 3; MONO: HEM-14 resulted 6.5 (acceptable 2.3-6.0), HEM-15 resulted 7.2 (acceptable 1.4-6.7) on 2018 Event 3, and HEM-01 resulted 7.9 (acceptable 3.7-7.6), HEM-02 resulted 11.0 (acceptable 2.6-9.5) on 2019 Event 1; a total of 25 unacceptable analyte scores. The inspector requested to review documentation that the laboratory evaluated the unacceptable results outlined above. Documentation was not available for review. 2. In an exit interview with the primary testing personnel at approximately 1:30 PM, the above findings were confirmed.