

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0229895	(X3) Date Survey Completed 06/21/2022
Name of Provider or Supplier Bayview Medical Center	Street Address, City, State 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 for Bayview Medical Center on June 21, 2022 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:
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of procedures, manufacturer's user guide/package inserts, daily temperature/environment logs, lack of documentation, and an interview, the laboratory failed to monitor daily relative humidity percent (%) and refrigerator temperatures to ensure manufacturer's operating and storage requirements were followed for the Abbott Emerald analyzer and hematology quality control (QC) materials utilized for Complete Blood Count (CBC) patient testing for twenty-eight (28) months reviewed (timeframe: February 2020 to the date of the inspection on June 21, 2022). Findings include: 1. Review of the laboratory's procedures revealed Quality Assurance protocols that outlined daily monitoring of environmental conditions that included laboratory room temperature/humidity and refrigerator/freezer temperatures. 2. Review of the Abbott manufacturer's guidelines revealed the following requirements: Emerald analyzer user guide - "Environmental Specifications: relative humidity range is 80% maximum"; Cell-Dyn QC package insert - "Stable through</p>

expiration date when stored 2-8 C, opened stability is eight consecutive days after open stored at 2-8 C". 3. Review of the available laboratory records for calendar year 2020, 2021, and year to date 2022 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 exit interview with the clinical consultant on 6/21/22 at approximately 4:00 PM confirmed the above findings.

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 a review of Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, lack of documentation, and an interview, the technical consultant (TC) failed to document hematology competency assessment for two (2) of 2 testing personnel (TP) in calendar years 2020 and 2021. Findings include: 1. Review of the CMS 209 personnel form revealed that the laboratory director (LD) identified TP A and TP B as responsible for performing hematology patient testing during calendar years 2020 and 2021. The LD also serves as TC. *See Personnel Code Sheet. 2. Review of personnel records revealed no Abbott Emerald hematology competency assessment for the 2 TP outlined above in calendar years 2020 and 2021. The inspector requested to review competency assessment documentation for both years. The clinical coordinator stated at approximately 3:30 PM: "We are having trouble finding the competency assessments to show you". No records were made available for review. 3. An exit interview with the clinical consultant on 6/21/22 at approximately 4:00 PM confirmed the above findings.