

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  49D0229895	<b>(X3) Date Survey Completed</b>  01/07/2021
<b>Name of Provider or Supplier</b>  Bayview Medical Center	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An unannounced, off-site CLIA proficiency test desk review was conducted for Bayview Medical Center-Nowcare II on January 6-7, 2021 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:
<b>D2016</b>	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on an off-site desk review of the laboratory's American Proficiency Institute proficiency testing (PT) records and interviews, the laboratory failed to attain a score of at least eighty percent of acceptable responses for White Blood Cell Differential</p>

(Granulocytes, Lymphocytes, Monocytes) in two of three hematology testing events reviewed, resulting in an unsuccessful PT performance (reviewed: 2020 Events 1-3). See D2130.

**D2130**

**HEMATOLOGY**

CFR(s): 493.851(f)

Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on an off-site desk review of proficiency testing (PT) records (2020 Events 1-3) and interviews, the laboratory failed to attain a score of at least eighty percent (80%) of acceptable responses for White Blood Cell Differential Identification (WBC Diff) in the two (2) of three (3) hematology testing events reviewed, resulting in an unsuccessful PT performance. Findings include: 1. Review of the laboratory's American Proficiency Institute (API) PT records revealed WBC Diff scores of less than 80% for the following 2 events: API 2020 Hematology Event 1 - WBC Diff = 0%; Score for all five (5) challenges HEM #01- HEM -#05: Granulocytes = 0%, Lymphocytes = 0%, Monocytes = 0%; API report noted "results unsatisfactory performance"; API 2020 Hematology Event 3 - WBC Diff = 0 %; Score for all five (5) challenges HEM #11- HEM -#15: Granulocytes = 0%, Lymphocytes = 0%, Monocytes = 0%; API report noted "laboratory failed to participate"; resulting in an unsuccessful PT performance. 2. In an email correspondence interview with the facility's clinical coordinator on 1/6/21 at approximately 11:00 AM, and a telephone interview with the technical consultant on 1/7/21 at approximately 12:30 PM, the above findings were confirmed.