

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D0229895	<b>(X3) Date Survey Completed</b> 07/08/2022
<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 July 7-8, 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, including Condition under 42 CFR part 493 CLIA Regulations - D2016 - 42 CFR. 493.803 Condition: Successful Participation).
<b>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> 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</p>

of at least eighty percent of acceptable responses for glucose and human chorionic gonadatropin (HCG) in two consecutive Chemistry testing events resulting in unsuccessful PT performance (reviewed: 2022 First and Second Event). See D2097.

**D2097**

**ROUTINE CHEMISTRY**

CFR(s): 493.841(g)

Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing 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) results and interviews, the laboratory failed to attain a score of at least eighty percent (80%) of acceptable analyte responses for Glucose (GLU) and human chorionic gonadatropin (HCG) on two (2) consecutive chemistry testing events reviewed for calendar year 2022 (Events 1-2). Findings include: 1. Review of the laboratory's American Proficiency Institute (API) Chemistry module results, revealed analyte scores of less than 80% for the following consecutive events: API Chemistry Endocrinology 2022 Event 1- HCG 0% (with API comment scored zero due to failure to participate); API Chemistry Endocrinology 2022 Event 2- HCG 0% (with API comment scored zero due to failure to participate); API Chemistry Routine 2022 Event 1- Hemocue Glu 0% (with API comment scored zero due to failure to participate); API Chemistry Routine 2022 Event 2- Hemocue Glu 0% (with API comment scored zero due to failure to participate). 2. Interviews with the laboratory's clinical coordinator by email on 07/07/22 at approximately 10:00 AM, and additional telephone interview on 07/08/22 at 4:30 PM, confirmed the above findings.