

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D0661189	<b>(X3) Date Survey Completed</b> 11/02/2023
<b>Name of Provider or Supplier</b> Bayview Physicians Services Pc	<b>Street Address, City, State</b> 2000 Meade Pkwy, Suffolk, 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 announced CLIA validation survey was conducted at Bayview Physicians Services (doing business as Lakeview Medical Center) on November 1-2, 2023 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>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on a review of policies and procedures, tour, quality control (QC) records, lack of documentation, and an interview, the laboratory failed to follow their policy of weekly/monthly Chemistry QC evaluation for sixty-five (65) of ninety-six weeks and four of twenty-three months during the survey timeframe of January 2022 to November 2, 2023. Findings include: 1. Review of the laboratory policy and procedure manual revealed a policy (Quality Control Review) that outlined "QC will be reviewed weekly and followed by monthly lab director or designee review." 2. During the tour on 11/1/23 at 1 PM revealed the laboratory utilized an Abbott Architect C4000 (Serial Number SN- C461553) and Abbott i1000 (SN- I1SR60510) to analyze and report patient samples for the following chemistry analytes: Thyroid Stimulating Hormone, Thyroxine, Free Thyroxine, Triiodothyroxine, Free Triiodothyroxine, Quantitative Human Chorionic Gonadotropin, 25-Hydroxyl Vitamin D 25-OH-D, Estradiol, Follicle Stimulating Hormone, Luteinizing Hormone, Prolactin, Testosterone, Glycoslyated Hemoglobin A1C, Microalbumin, Total Iron Binding Capacity, Creatine Kinase, Creatinine, Urine Creatinine, Uric Acid, Urea</p>

Nitrogen, Triglyceride, Sodium, Total Protein, Potassium, Alkaline Phosphatase, Phosphorus, Iron, Cholesterol, HDL Cholesterol, LDL Cholesterol, Glucose, Chloride, Carbon Dioxide, Calcium, Direct Bilirubin, Total Bilirubin, Aspartate AminoTransferase, Albumin, Alanine Aminotransferase, Ferritin, Folic Acid, Magnesium, Prostate Specific Antigen, and Vitamin B12. 3. Review of the laboratory's Abbott analyzers' chemistry QC documentation for the forty-four analytes outlined above during timeframe of January 2022 - October 2023 revealed no weekly QC review was documented: Calendar Year 2022 - weeks of 1/3, 1/10, 1/24, 2/7, 2/14, 2/28, 3/7, 3/21, 3/28, 4/4, 4/11, 4/25, 5/2, 5/9, 5/16, 5/30, 6/6, 6/13, 6/27, 7/4, 7/11, 7/25, 8/1, 8/8, 8/15, 8/29, 9/5, 9/12, 9/19, 10/3, 10/17, 10/24, 10/31, 11/21, 11/28, 12/5, 12/19, 12/26; Calendar Year 2023 - weeks of 1/2, 1/16, 1/23, 1/30, 2/6, 2/20, 2/27, 3/6, 3/20, 3/27, 4/3, 4/17, 4/24, 5/1, 5/15, 5/22, 5/29, 6/26, 7/3, 7/17, 7/24, 7/31, 8/7, 8/14, 8/28, 9/4, 9/11, 9/25. No weekly QC evaluation was documented for the 65 weeks of ninety-six weeks outlined above. The inspector also noted that no monthly QC review was recorded as performed in March, April, and May of calendar year 2022 and in August 2023 (four of twenty-three months reviewed). 4. The inspector requested the QC review records for the weeks and months outlined above. No additional documentation was available for review. 5. An interview with the lab supervisor and quality manager on 11/2/23 at 1 PM confirmed the above findings.

**D6004**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(a)(b)

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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappropriates performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), personnel files, procedures, lack of documentation, and an interview, the laboratory director (LD) failed to ensure competency assessment duties were delegated to qualified technical consultant (TC) and technical supervisor (TS) in two of two years reviewed (survey review timeframe: January 2022 to November 1-2, 2023). Findings include: 1. Review of the CMS 209 form revealed the LD identified six testing personnel (TP) as qualified to perform moderate complexity patient hematology Completed Blood Counts by Abbott Emerald analyzer and moderate/high complexity chemistry analyte/panels by Abbott C4000 and i1000 analyzers. 2. Review of the personnel files revealed that the LD qualified to perform duties of TC and TS. Review of personnel files also revealed that the laboratory supervisor (TP A) and TP B signed as the TC performing hematology and TS for chemistry competency assessments for all TP in 2022 and 2023. The inspector noted that TP A had an Associates Degree in Education and TP B had a high school diploma on file. \*See Personnel Code Sheet. 3. Review of the laboratory procedures revealed a Standard Operating Procedure (title: Delegation by Laboratory Directory) that stated, "The laboratory director gives laboratory supervisor (identified TP A) authorization to perform orientation, all annual evaluations and documentation

of performance of competency assessments for all testing personnel." 4. The inspector requested to review a bachelor's degree in chemical, physical, or biological science or medical technology for TP A and TP B. No additional education documentation was available for review. 5. An interview with the laboratory supervisor and quality manager on 11/2/23 at 1 PM confirmed the above findings.