| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 10D0994171 | 09/16/2025 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Baycare Medical Group, Inc | 620 10th St N Ste 3a, Saint Petersburg, FL | |

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 |
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| **D0000** | An announced CLIA recertification survey was conducted at Baycare Medical Group Inc. on 09/16/2025. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiencies cited are as follows: |
| **D5435** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(b)(2)<br><br>(b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview, the laboratory reported patient test results when an instrument temperature was outside the laboratory's established range for one (08/2025) of three months reviewed (08/2025, 07/2024, 11/2023). Findings included: 1. Daily Quality Assurance/Quality Control Checklist(s) for 08/2025, 07/2024, and 11/2023 were reviewed. The checklist indicated the required temperature range for the cryostats were -21 degrees to -30 degrees Celsius. The temperature was documented out of range 15 days of 15 days for 08/2025 for cyrostat #2. The temperatures were documented as follows: (A) -32 on the 8th, 11th, 12th, and 13th, (B) -35 on the 15th and 18th, and (C) -34 on the 19th through the 22nd and the 25th through the 29th. 2. Interview with Testing Person A on 09/16/2025 at 12:30 p.m. confirmed the temperatures were out of range and patient testing was reported. |
| **D6093** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5) |

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| | (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and staff interview, the Laboratory Director failed to establish a quality assessment program (QAP) to monitor all phases or components of the laboratory. Findings included: 1. The laboratory policies and procedures were reviewed. No policy could be found that reflected a QAP was established to review or monitor ongoing compliance for all aspects of laboratory testing; General Laboratory, Preanalytic, Analytic, Postanalytic, and Personnel. 2. Interview with the Laboratory Director on 09/16/2025 at 12:30 p.m. confirmed the above. |