

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  40D0673783	<b>(X3) Date Survey Completed</b>  03/06/2026
<b>Name of Provider or Supplier</b>  Sur -Med Medical Center, Corp	<b>Street Address, City, State</b>  8 Colon Pacheco, Salinas, PR	
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>	The Centers for Medicare & Medicaid Services (CMS) conducted an unannounced CLIA recertification survey at Sur -Med Medical Center on March 6, 2026. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. The following standard level deficiencies were found during the recertification CLIA survey ending on March 6, 2026.
<b>D5411</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on special chemistry instrument Access 2, maintenance quality control records review, manufacturer's instructions, and laboratory technical supervisor interview on March 6, 2026 at 1:55 PM, the laboratory failed to perform the following instrument weekly maintenance: clean instrument exterior, inspect liquid waste bottle, check waste filter bottle, inspect/clean primary probe, replace/clean aspirate probe, and run system check, when 13,227 patient specimens were processed and reported from January 8, 2025 to March 6, 2026 for special chemistry tests. The findings include: 1. The laboratory uses the Access 2 instrument to perform patient's special chemistry tests. 2. On March 6, 2026 at 1:50 PM, the Access 2 instrument manufacturer's instructions were reviewed, and showed that the instrument weekly maintenance includes the following: clean instrument exterior, inspect liquid waste bottle, check waste filter bottle, inspect/clean primary probe, replace/clean aspirate probe, and run system check. 3. On March 6, 2026 at 1:55 PM, the Access 2 instrument maintenance quality control records were reviewed, and showed that the laboratory failed to perform the instrument's weekly maintenance, when they processed and reported</p>

13,227 patient specimens from January 8, 2025 to March 6, 2026 for special chemistry tests. 4. The laboratory technical supervisor confirmed on March 6, 2026 at 2:15 PM, that the laboratory did not perform the weekly maintenance of the special chemistry instrument from January 8, 2025 to March 6, 2026 when they processed and reported 13,227 patient specimens for special chemistry tests.

**D5439**

**CALIBRATION AND CALIBRATION VERIFICATION**

CFR(s): 493.1255(b)

(b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on hematology calibration verification records, manufacturer's instructions, and laboratory technical supervisor interview on March 6, 2026 at 12:50 PM, the laboratory failed to perform the calibration verification procedures with at least the frequency recommended by the manufacturer's instructions (every six months) for the hematology tests performed by the XN-550 hematology system. The findings include: 1. The laboratory uses a XN-550 hematology system for CBC (Complete blood count) patient's tests. 2. Review of the manufacturer's instructions on March 6, 2026 at 12:45 PM showed that the laboratory must perform the calibration verification procedures every six months. 3. On March 6, 2026 at 12:50 PM, the calibration verification records of XN-550 hematology system showed that the laboratory did not perform at the scheduled calibration verification procedures for May 2025 and November 2025. 4. The laboratory processed and reported 24,951 CBC patient samples from November 23, 2024 to February 18, 2026. 5. The laboratory technical supervisor confirmed on March 6, 2026 at 12:55 PM, that the laboratory did not perform at least every 6 months the calibration verification procedures for the XN-550 hematology system.

**D5469**

**CONTROL PROCEDURES**

CFR(s): 493.1256(d)(10)(g)

(d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value

is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters.

This STANDARD is not met as evidenced by:

A. Based on chemistry quality control records review (years 2024 - 2026) and laboratory technical supervisor interview on March 6, 2026 at 1:32 PM, the laboratory failed to verify the stated value of the new lot of control materials, when the laboratory processed and reported the following tests: 4,419 Glycosylated hemoglobin (HbA1c), 3,291 Microalbumin, 686 Urine creatinine, and 1,443 Complete Metabolic Panel (CMP) patient samples from November 7, 2024 to March 6, 2026. The findings include: 1. The laboratory performs chemistry tests, which include HbA1c, Microalbumin, Urine creatinine, and CMP, with the Vitros 4600 analyzer. 2. On March 6, 2026 at 1:32 PM, the chemistry quality control records review (years 2024 - 2026), showed that there was no evaluation of the manufacturer's stated values for the following lot numbers: W2392 (HbA1c control level 1), X2393 (HbA1c control level 2), K2996 (Microalbumin control level 1), L2997 (Microalbumin control level 2), UC26081A (Urine creatinine control level 1), UC 26082A (Urine creatinine control level 2), E2828 (CMP control level 1), and P2830 (CMP control level 2), prior to placing them in routine. 3. The laboratory technical supervisor confirmed on March 6, 2026 at 1:38 PM, that no evaluations of the stated lots of control materials were performed prior to placing them in routine use. B. Based on special chemistry quality control records review (years 2024 - 2026) and laboratory technical supervisor interview on March 6, 2026 at 2:36 PM, the laboratory failed to verify the stated value of the new lot of control materials, when the laboratory processed and reported 2,572 Thyroid stimulating hormone (TSH), 489 Triiodothyronine uptake assay (T3U), 585 Thyroxine (T4), 804 Free thyroxine (FT4), 827 Carcinoembryonic Antigen (CEA), 793 Prostate specific antigen (PSA), 3,289 Vitamin D, 11 Creatinine Kinase- MB (CKMB), and 1,117 Troponin from September 30, 2024 to March 6, 2026. The findings include: 1. The laboratory performs special chemistry tests, which include TSH, T4, FT4, T3U, CEA, PSA, Vitamin D, CKMB, and Troponin, with the Access 2 analyzer. 2. On March 6, 2026 at 2:36 PM, the special chemistry quality control records review (years 2024 - 2026), showed that there was no evaluation of the manufacturer's stated values for the following lot numbers: 40461 (TSH, T4, FT4, T3U, CEA, PSA analytes control level 1), 40462 (TSH, T4, FT4, T3U, CEA, PSA analytes control level 2), 40463 (TSH, T4, FT4, T3U, CEA, PSA analytes control level 3), 1003711 (Vitamin D control level 1), 1003712 (Vitamin D control level 2), 27041 (CKMB control level 1), 27042 (CKMB control level 2), 27043 (CKMB control level 3), and 25041 (Troponin control level 1), 25042 (Troponin control level 2), and 25043 (Troponin control level 3), prior to placing them in routine. 3. The laboratory technical supervisor confirmed on March 6, 2026 at 2:45 PM, that no evaluations of the stated lots of control materials were performed prior to placing them in routine use.

**D6093**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(5)

(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;

	<p>This STANDARD is not met as evidenced by:  Based on hematology manufacturer's instructions and calibration verification records, chemistry, and special chemistry quality control records review (years 2024 - 2026), and interview with the laboratory supervisor on March 6, 2026 at 2:45 PM, the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the manufacturer's instructions and laboratory quality control requirements. Refer to D5411, D5439, and D5469.</p>
<p><b>D6117</b></p>	<p><b>TECHNICAL SUPERVISOR RESPONSIBILITIES</b>  CFR(s): 493.1451(b)(4)</p> <p>(b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;</p> <p>This STANDARD is not met as evidenced by:  Based on hematology manufacturer's instructions and calibration verification records, chemistry and special chemistry quality control records review (years 2024 - 2026), and interview with the laboratory technical supervisor on March 6, 2026, at 2:45 PM, the laboratory technical supervisor failed to fulfill her responsibilities to ensure compliance with the quality control requirements and manufacturer's instructions. Refer to D5411, D5439, D5469.</p>
<p><b>D6177</b></p>	<p><b>TESTING PERSONNEL RESPONSIBILITIES</b>  CFR(s): 493.1495(b)(3)</p> <p>(b)(3) Adhere to the laboratorys quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed;</p> <p>This STANDARD is not met as evidenced by:  Based on hematology manufacturer's instructions and calibration verification records, chemistry and special chemistry quality control records review (years 2024 - 2026), and interview with the laboratory technical supervisor on March 6, 2026, at 2:45 PM, the laboratory testing personnel failed to perform and document all quality control activities to ensure compliance with the chemistry, special chemistry, and hematology quality control requirements and manufacturer's instructions. Refer to D5411, D5439, D5469.</p>