| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 40D0948077 | 12/13/2024 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Lares Medical Center Inc | Carr 111 Km 2 3, Lares, PR | |

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 the Laboratorio Clnico Lares Medical Center Inc. on December 13, 2024 by the Puerto Rico State Agency. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows: D5439 Calibration and Calibration Verification CFR (s): 493.1255 (b) |
| **D5439** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(b)<br><br>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (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.<br><br>This STANDARD is not met as evidenced by: |

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| | Based on routine chemistry calibration verification records review (years 2023-2024) and interview with the laboratory general supervisor on December 13, 2024 at 12:00 P. M., it was determined that the laboratory did not perform, at least every six months, the calibration verification procedures for sodium (Na+), potassium (K+), and chloride (Cl-) tests, when processed and reported 13,142 out of 13,142 electrolytes patient's test from January 1, 2023 to December 12, 2024. The findings include: 1. The laboratory used the Ortho Vitros 250 Chemistry Analyzer to perform Na+, K+, and Cl- tests. (Reviewed on December 13,2024 at 12:00 P.M.) 2. The laboratory performed Na+, K+, and Cl- calibration verification procedures in December 2022. (Reviewed on December 13, 2024 at 12:10 P.M.) 3. Review of routine chemistry calibration verification records showed that the laboratory did not perform Na+, K+, and Cl- calibration verification procedure in June 2023, December 2023, June 2024 and December 2024. (Reviewed on December 13,2024 at 12:20 P.M.) 4. The laboratory processed and reported 13,142 out of 13,142 Na+, K+, and Cl- patient's test from January 1, 2023 to December 12, 2024. (Reviewed on December 13, 2024 at 12: 30 P.M.) 5. The laboratory general supervisor confirmed on December 13, 2024 at 1: 00 P.M., that the laboratory failed to perform, at least every 6 months, the calibration verification procedures for Na+, K+, and Cl- tests. |
| **D6093** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5)<br><br>The laboratory director must ensure that the quality control 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 routine chemistry quality control records review (years 2023-2024 ) , and interview with the laboratory general supervisor on December 13, 2024 at 1:30 P.M., it was determined that the laboratory director failed to ensure that the laboratory general supervisor perform, at least every 6 months, the calibration verification procedure for Na+, K+, and Cl- tests. Refer to D6144. |
| **D6144** | GENERAL SUPERVISOR RESPONSIBILITIES<br>CFR(s): 493.1463<br><br>The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.<br><br>This STANDARD is not met as evidenced by:<br>Based on routine chemistry calibration verification records review (years 2023-2024) and laboratory general supervisor interview on December 13,2024, at 1:30 P.M., it was determined that the laboratory general supervisor failed to fullfill her responsability to ensure at least every 6 months, the calibration verification procedures for sodium (Na+), potassium (K+), and chloride (Cl-). Refer to 5439. |