| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 05D0856340 | 06/12/2025 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Corazon C Medina, Md Inc | 1751 W Romneya Dr, Ste H, Anaheim, CA | |

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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| **D2087** | ROUTINE CHEMISTRY<br>CFR(s): 493.841(a)<br><br>(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.<br><br>This STANDARD is not met as evidenced by:<br>Based on the surveyor's review of the laboratory's policy and procedure, American Association of Bioanalysts - Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) records, and interviews with the technical consultant (TC) and testing personnel (TP), it was determined that the laboratory failed to attain at least 80 percent of the acceptable score in Routine Chemistry for the Magnesium (Mg), Aspartate Aminotransferase (AST), and Albumin analytes. The findings include: 1. The surveyor reviewed the PT records wherein AAB-MLE reported unsatisfactory scores for Mg, AST and Albumin analytes. The results were as follows: a. Mg PT analyte in third event of 2023 (Q3-2023), Overall score: 60% Specimen Reported Expected 11 4.1 3.1 - 5.2 12 *3.4 1.5 - 2.5 13 *34.7 2.6 - 4.4 14 3.2 2.4 - 4.0 12 2.9 2.1 - 3.5 b. AST PT analyte in the first event of 2024 (Q1-2024), Overall score: 20% Specimen Reported Expected 01 15 10.0 - 15.0 02 *261 162.0 - 244.0 03 *197 122.0 - 182.0 04 *40 26.0 - 39.0 05 *375 223.0 - 335.0 c. Albumin PT analyte in the second event of 2024 (Q2-2024), Overall score: 60% Specimen Reported Expected 06 4.5 4.0 - 4.9 07 3.2 2.9 - 3.5 08 *1.6 1.7 - 2.1 09 *3.5 2.6 - 3.2 10 2.3 2.0 - 2.5 Legend: * = unsatisfactory score reported 2. The TC and TP affirmed by interviews on June 12, 2025, at approximately 9:50 a.m. that the laboratory obtained the PT unsatisfactory scores mentioned in statement #1. 3. According to the laboratory's testing declaration submitted on the day of the survey, the laboratory performed approximately 8,000 patient test samples for Routine Chemistry including Mg, AST, and Albumin analytes during the time the laboratory received an unsatisfactory proficiency testing scores. Thus, the accuracy and reliability of patient test reported cannot be determined. |

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| **D2099** | ENDOCRINOLOGY<br>CFR(s): 493.843(b)<br><br>(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.<br><br>This STANDARD is not met as evidenced by:<br>Based on the surveyor's review of the American Association of Bioanalysts - Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) reports and interviews with the technical consultant (TC) and testing personnel (TP), it was determined that the laboratory failed to attain a score of at least 80 percent in Endocrinology for Thyroid-Stimulating Hormone (TSH) for the first event of 2025 (Q1-2025). The findings include: 1. The laboratory obtained a score of 60% for the TSH analyte as reported by AAB-MLE PT for the Q1-2025 event. 2. The TC and TP affirmed on June 12, 2025, at approximately 10:30 a. m. that the laboratory obtained the unsatisfactory proficiency score as mentioned on statement#1 for the TSH analyte. 3. Based on the laboratory's annual test volume declaration signed by the laboratory director on 6/11 /2025, the laboratory analyzed and reported approximately 1,000 Endocrinology patient tests which included the TSH analyte. The realiability and quality of patient tests reported cannot be assured. |
| **D2122** | HEMATOLOGY<br>CFR(s): 493.851(b)<br><br>(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.<br><br>This STANDARD is not met as evidenced by:<br>Based on the surveyor's review of the laboratory's American Association of Bioanalysts - Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) records and interviews with the technical consultant (TC) and testing personnel (TP); it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for Hematology on the first event of 2024 (Q1-2024). The findings include: 1. The AAB-MLE proficiency program reported an unsatisfactory score of 60% for the Hematocrit analyte for Q1-2024 event. 2. The TC and TP affirmed by interview on June 12, 2025, at approximately 10:30 a.m. that the laboratory received the unsatisfactory score as mentioned in statement #1. 3. The reliability and quality of Hematology results reported could not be assured when the laboratory failed to attain overall scores of at least 80% in the PT event. 4. According to the testing declaration form submitted at the time of survey, the laboratory performed and reported 2,500 patient tests in Hematology annually including the time when the unsatisfactory PT scores were obtained. |
| **D6036** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413<br><br>The technical consultant is responsible for the technical and scientific oversight of the laboratory. The technical consultant is not required to be onsite at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide consultation, as specified in paragraph (a) of this section. |

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| | This STANDARD is not met as evidenced by:<br>Based on the surveyor's review of the proficiency testing results from the American Association of Bioanalysts - Medical Laboratory Evaluation, and interviews with the technical consultant (TC) and testing personnel on June 12, 2025; this deficient practice is cited due to failure of the TC to provide technical and scientific oversight of the laboratory. The findings include: 1. Unsatisfactory proficiency testing score for Routine Chemistry. See D2087. 2. Unsatisfactory proficiency testing score for Endocrinology. See D2099. 3. Unsatisfactory proficiency testing score for Hematology. See D2122. |