

|  |  |   |
|--|--|---|
| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>11D2189810     | <b>(X3) Date Survey Completed</b><br><br>06/28/2022 |
| <b>Name of Provider or Supplier</b><br><br>Ras Medical Solution  | <b>Street Address, City, State</b><br><br>107 Highland Drive, Fayetteville, GA |   |
| 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 initial Clinical Laboratory Improvement Amendments (CLIA) survey was completed on June 28, 2022. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:  |
| <b>D3011</b>              | <p><b>FACILITIES</b><br/>CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on observation during the laboratory tour and staff interview, the laboratory failed to implement and establish proper safety procedures to ensure protection from physical, biochemical and biohazardous materials in the lab area. Findings include: 1. During the laboratory tour it was observed there was no hand wash sink with running water and a flush eyewash equipment (for emergency use) in the laboratory testing and processing area. 2. An interview with staff and facility manager, during the laboratory tour, on 06/28/2022, at approximately 10:30 A.M, confirmed the absence of a hand wash sink with running water or eyewash equipment.</p> |
| <b>D5293</b>              | <p><b>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT</b><br/>CFR(s): 493.1239(b)(c)</p> <p>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.</p>   |

This STANDARD is not met as evidenced by:  
Based on Quality Assessment (QA) document review and staff interview, the laboratory failed to document quality assessment activities on a monthly or quarterly basis that cover pre-analytic, analytic and post analytic phases of laboratory testing. The Findings include: 1. Daily maintenance logs including: Room Temperature, Humidity, Refrigerator and Freezer logs had incorrect normal ranges and location address on them. 2. No evidence that all maintenance logs were reviewed and signed by the General Supervisor (GS) or Laboratory Director in 2022. 3. An interview with staff and General Supervisor (GS), on 06/28/2022, at 12:30 PM, in the review room confirmed the lack of adequate QA checklist and standard maintenance logs for the laboratory in 2022.

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:  
Based on review of personnel records and interview with the Laboratory Director, the laboratory did not have a competency assessment policy that met the Clinical Laboratory Improvement Amendment (CLIA) six standards Criteria for testing personnel. Findings include: 1. Testing Personnel (TP #s 4 - 8 CMS 209) record review revealed six (6) month and annual competency assessments were performed in 2021 and 2022; however, the assessment did not contain the six CLIA standard criteria for personnel competency assessments. 2. An interview with staff and General Supervisor (GS) on 06/28/2022, at approximately 12:35 PM in the review room confirmed that the laboratory competency assessment policy does not contain the CLIA competency six standard criteria in 2021 or 2022.