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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 40D1016052 | (X3) Date Survey Completed 02/23/2023 |
| Name of Provider or Supplier Lab Cl Centro De Certificaciones Medicas Region | Street Address, City, State Calle Vallejo Esq Garcia Moreno, Rio Piedras, 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 | <p>The Centers for Medicare & Medicaid Services (CMS) New York (NY) Clinical Laboratory Improvement Amendments of 1988 (CLIA) Branch Location federal surveyor conducted an announced virtual CLIA recertification survey for LAB CL CENTRO DE CERTIFICACIONES MEDICAS REGION on February 23, 2023. Documents received were reviewed from February 17, 2023 to February 23, 2023. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. The following deficiency was found during the announced routine CLIA recertification survey performed on February 23, 2023.</p> |
| D6051 | <p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.</p> <p>This STANDARD is not met as evidenced by: Based on review the Puerto Rico (PR) Department of Health (DOH) Proficiency Testing (PT) Program records, and interview with the laboratory director (LD), technical consultant (TC) and administrative personnel, the laboratory failed to evaluate the assessment of 1 of 2 testing personnel (TP) for their performance of rapid plasma reagin (RPR) testing perform in 2021 and 2022. Finding Include: 1. On February 17, 2023, a virtual review of the PR DOH PT records from 2021 and 2022 revealed, 1 of 2 TP (TP#1) signed the attestations forms. 2. During there virtual survey (February 23, 2023 at 8:50 am), the laboratory could not provide TP#2's evaluations for their assessment of RPR test performance through testing previously analyzed specimens, internal blind testing samples or external PT in 2021 and 2022. 3. The LD and TC confirmed on February 13, 2023 around 8:55 am, that TP#2 was not evaluated for their performed of RPR testing in 2021 and 2022.</p> |