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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 40D2129287 | (X3) Date Survey Completed 05/05/2022 |
| Name of Provider or Supplier Laboratorio Clinico Juncal | Street Address, City, State Carr # 111, Km 27, Hm 6, Barrio Juncal, San Sebastian, 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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| D2128 | <p>HEMATOLOGY CFR(s): 493.851(e)</p> <p>(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program records reviewed and laboratory general supervisor interview , it was determined that the laboratory failed to take and document corrective actions when it obtained unsatisfactory results in hematology specialties. The findings include: 1. On May 5, 2022 at 10:45 A.M. , Puerto Rico Proficiency Testing Program records were reviewed from January 2021 to April 2022. 2. Review of Proficiency Testing results showed that the laboratory obtained unsatisfactory results of 60 percent in hematocrit and red blood cell in the third testing event performed on November 2021. No remedial actions were taken. 3. The laboratory general supervisor confirmed on May 5, 2022 at 10:55 A.M. , that the laboratory failed to take remedial actions when obtained unsatisfactory results in the third testing event of Hematology performed on November 2021.</p> |
| D6091 | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii)</p> <p>The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to</p> |

identify any problems that require corrective action.

This STANDARD is not met as evidenced by:

Based on review of Puerto Rico Proficiency Testing Program records, scores review and laboratory general supervisor interview ,it was determined that the laboratory director did not ensure that corrective actions were taken when the laboratory obtained unsatisfactory results. The findings include: 1. Puerto Rico Proficiency Testing Program records and results were reviewed since February 2021 to April 2022. 2. On May 5, 2022 at 10:45 A.M. the Proficiency Testing records review showed that the laboratory obtained unsatisfactory results of 60 percent in hematocrit and red blood cell tests in the third testing event performed in November 2021 . No remedial actions were taken. 3. The laboratory general supervisor confirmed on May 5, 2022 at 10:50A. M., that the laboratory did not take corrective actions in the third testing event. (November 2021) Refer to D 2128.