| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 40D2046807 | 10/20/2022 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Laboratorio Clinico Cubuy, Inc | Centro De Servicios Multiples Plaza Taina,, Canovanas, 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** | HEMATOLOGY<br>CFR(s): 493.851(e)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on Puerto Rico Proficiency Testing Program (PRPTP) records review from February 2021 to October 2022 and laboratory general supervisor interview on October 20, 2022, it was determined that the laboratory failed to take and document corrective actions when it obtained an unsatisfactory results in hematology specialties. The findings include: 1. The PRPTP records and results were reviewed from February 2021 to June 2022 on October 20, 2022 at 9:14 AM. 2. Review of proficiency testing (PRPTP) records on October 20, 2022 at 9:14 AM, showed that the laboratory obtained unsatisfactory results of 60 percent in Hematocrit (HCT) tests in April 2022 (PRPTP first testing event) and 80 percent in Hematology Cell Identification tests in June 2022 (PRPTP second testing event). No remedial actions were taken. 3. The general supervisor confirmed on October 20, 2022 at 11:44 AM, that the laboratory did not take corrective actions in April 2022 and June 2022 testing events. |
| **D5775** | COMPARISON OF TEST RESULTS<br>CFR(s): 493.1281(a)(c)<br><br>(a) If a laboratory performs the same test using different methodologies or |

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| | instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.<br><br>This STANDARD is not met as evidenced by:<br>Based on hematology quality control records review and test result comparison records (2021 and 2022) and laboratory general supervisor interview on October 20, 2022 at 9:37 AM, it was determined that the laboratory failed to evaluates twice a year the relationship of the WBC differential results between the manual method and the Cell Dyn 3200 system since April 21, 2021. The findings include: 1. The laboratory performed automatic cell differential by Cell Dyn 3200 hematology system. 2. Review of the hematology quality control and test result comparison records on October 20, 2022 at :37 AM, showed that the laboratory did not performed the relationship between the manual cell differential and automatic cell differential since April 21, 2021. 3. The laboratory general supervisor confirmed on October 20, 2022 at 11:50 AM, that the laboratory failed to evaluate twice a year a relationship between the maul cell differential and automatic cell differential by hematology system since April 21, 2021. |
| **D5801** | TEST REPORT<br>CFR(s): 493.1291(a)<br><br>The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.<br><br>This STANDARD is not met as evidenced by:<br>Based on hematology quality controls records review from January 2021 to October 20, 2022, laboratory written policies review and laboratory general supervisor interview on October 20, 2022, it was determined that the laboratory failed to verify the accuracy of transmitted calculated results. The finding includes: 1. The laboratory uses Cell Dyn 3200 system to perform Complete Blood Count (CBC) samples tests. 2. The hematology quality control records were reviewed on October 20, 2022 at 9:37 AM, from January 2021 to October 20, 2022. 3. The laboratory written policies establishes on October 202, 2022 at 9:37 AM, that the laboratory verify each six months the transmitted results of the hematology media (MCV, MCH and MCHC). 4. The laboratory general supervisor confirmed on October 20, 2022 at 11:50 AM, showed that the laboratory did not verify the hematology results reported from calculated data since April 21, 2021. |
| **D6092** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(4)(iv)<br><br>The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. |

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| | This STANDARD is not met as evidenced by:<br>Based on Puerto Rico Proficiency Testing Program (PRPTP) records review from February 2021 to October 2022 and laboratory general supervisor interview on October 20, 2022, it was determined that the laboratory director failed to establish and follow a corrective action plan when the laboratory obtained unsatisfactory results. The findings include: 1. Puerto Rico Proficiency Testing Program (PRPTP) records and results were reviewed since February 2021 to December 2016 on October 20, 2022 at 9:14 AM. 2. Review of Proficiency Testing records on October 20, 2022 at 9: 14 AM, showed that the laboratory obtained unsatisfactory results of 60 percent in Hematocrit (HCT) tests in April 2022 (PRPTP first testing event) and 80 percent in Hematology Cell Identification tests in June 2022 (PRPTP second testing event). No remedial actions were taken. 3. The general supervisor confirmed on October 20, 2022 at 11:44 AM, that the laboratory did not take corrective actions in April 2022 and June 2022 testing events. Refer to D2128. |
| **D6103** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(13)<br><br>The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.<br><br>This STANDARD is not met as evidenced by:<br>Based on personnel records review and laboratory general supervisor interview on October 20, 2022 at 9:10 AM, it was determined that the laboratory failed to follow the written procedures to monitor and ensure the competency evaluations of the Clinical Consultant. The finding includes: 1. Review of the personnel records on October 20, 2022 at 9:10 AM, showed that the laboratory director did not evaluated annually the competence of the Clinical Consultant. The last competence in records was performed on April 4, 2021. |
| **D6120** | TECHNICAL SUPERVISOR RESPONSIBILITIES<br>CFR(s): 493.1451(b)(7)(8)<br><br>(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (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.<br><br>This STANDARD is not met as evidenced by:<br>Based on personnel records review and laboratory general supervisor interview on October 20, 2022 at 9:16 AM, it was determined that the laboratory failed to follow the established schedule for testing personnel competence evaluation. The findings include: 1. Review of the laboratory schedule for testing personnel competence |

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| | evaluation on October 20, 2022 at 9:16 AM, showed that it must be performed every year. 2. The laboratory did not perform the testing personnel (MT # 1) competence evaluation since February 19, 2022. 3. The general supervisor confirmed on October 20, 2022 at 11:52 AM, that the competence evaluation were not performed as established. |