| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 40D0676840 | 11/08/2022 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Laboratorio Clinico Toa Baja | Calle Bruno Cruz 77, Esquina Timoteo Salas, Toa Baja, 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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| **D2015** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(5)(6)<br><br>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT 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 testing personnel interview on November 8, 2022, it was determined that the laboratory failed to maintain a copy of the proficiency testing event records. The findings include: 1. The PRPTP records were reviewed from February 2021 to October 2022. 2. On November 8, 2022 at 9:00 AM, the laboratory proficiency records showed that the hematology results reported in the hematology first testing event performed in April 2022 did not concur with the print outs of the laboratory proficiency results found in the records. sample id analyte 2022-131 RBC ( red blood cell ) PT results Lab results print out 4.28 4.40 2022-132 RBC ( red blood cell ) PT results Lab results print out 5.52 5.57 2022-133 platelet PT results Lab results print out 60 64 2022-134 platelet PT results Lab results print out 63 51 2022-134 hematocrit PT results Lab results print out 18.1 17.1 3. The laboratory testing personnel confirmed on November 8, 2022 at 9:20 AM, that those proficiency testing results did not concur with the print outs of the laboratory proficiency results. |

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| **D5451** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(3)(iii)(g)<br><br>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on syphillis serology testing records review in year 2021-2022 and laboratory testing personnel interview on November 8, 2022 at 9:30 AM, it was determined that the laboratory failed to include a negative control material and a control material with tittered reactivity when patients specimens were tested for syphilis serology by rapid plasma reagin (RPR) quantitative tests. The findings include: 1. The laboratory perform syphilis serology by the Rapid plasma reagin (RPR) method. ( review on 11/8 /22 at 9:30 a.m.) 2. Review of records from January 2022 to November 8, 2022, the RPR testing records showed that the laboratory failed to include at least once a day, a negative control material and a control material with tittered reactivity when proficiency samples and two patients specimens were processed and reported for RPR quantitative test in the following days: ( review on 11/8/22 at 9:35 a.m.) Date Id patient Results 3/17/22 155319 R-1:1 4/28/22 2022-321 R 1:4 4/28/22 2022-322 R 1:4 4/28/22 2022-323 R 1:4 6/8/22 156607 R 1:1 9/16/22 2022-713 R 1:2 9/16/22 2022-714 R 1:4 9/16/22 2022-715 R 1:4 3. The laboratory processed and reported two (2) RPR patient test and six proficiency samples with tittered reactivity those days. ( review on 11/8/22 at 9:35 a.m.) 4. The laboratory testing personnel confirmed on November 8, 2022 at 9:40 AM, that the testing records showed that the laboratory did not perform nor document a control material with tittered reactivity those days. |
| **D6091** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(4)(iii)<br><br>The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.<br><br>This STANDARD is not met as evidenced by:<br>Based on Puerto Rico Proficiency Testing Program records review ( years 2021-2022 ) and laboratory testing personnel interview on November 8, 2022 at 10:30 A. M, it was determined that the laboratory director failed to evaluate any problems relate to PT performance. The finding includes: 1. The laboratory failed to maintain a copy of the proficiency testing event records. Refer to D2015. ( review on 11/8/22 at 9:00 a.m. ) |
| **D6093** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5)<br><br>The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. |

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| | This STANDARD is not met as evidenced by:<br>Based on syphilis serology testing quality control records review ( year 2021-2022 ) and laboratory testing personnel interview on November 9, 2022 at 10:30 A. M, it was determined that the laboratory director did not assure that the established quality control program for syphilis serology quantitative tests were followed. The finding includes: 1. Review of syphilis serology testing quality control records showed that the laboratory reported eight patients with tittered results and no tittered quality control material were included. Refer to D5451. ( reviewed on 11/8/22 at 9:30 a.m. ) |