| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 40D0861654 | 09/05/2024 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Laboratorio Clinico Pajuil | Carretera 490 Km 4 Hm 5, Hatillo, 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** | The Centers for Medicare & Medicaid Services (CMS) conducted an unannounced CLIA recertification survey at Laboratorio Clnico Pajuil on September 5, 2024. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. The following standard level deficiencies were found during the unannounced routine CLIA recertification survey ending on September 5, 2024. |
| **D2093** | ROUTINE CHEMISTRY<br>CFR(s): 493.841(d)<br><br>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.<br><br>This STANDARD is not met as evidenced by:<br>Based on Puerto Rico Proficiency Testing Program records reviewed ( 2023-2024) and laboratory director interview on September 5, 2024 at 11:44 A.M., it was determined that the laboratory failed to participate in the routine chemistry first testing event performed in February 2023. The findings include: 1. Proficiency testing records were reviewed from February 2023-August 2024. 2. The laboratory did not participate in the first testing event of routine chemistry ( routine chemistry, urinalysis, urine sediment) performed in February 2023, a testing score of 0 % was obtained . (review on September 5, 2024 at 11:45 A.M.) 3. The deadline of the first testing event report of routine chemistry was February 24, 2023. 4. The laboratory director confirmed on September 5, 2024 at 11:55 A.M. , that the laboratory failed to participate in the first testing event of routine chemistry specialty in February 2023. |
| **D2094** | ROUTINE CHEMISTRY<br>CFR(s): 493.841(e)<br><br>(1) For any unsatisfactory analyte or test performance or testing event for reasons |

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| | 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 (PRPT) records review ( year 2023-2024 ) and laboratory director interview on September 5, 2024 at 9:40 A.M. , it was determined that the laboratory failed to take and document corrective actions when it obtained an unsatisfactory results in routine chemistry test. The findings include: 1. Proficiency testing records review from February 2023 to August 2024. (review at 9: 40 a.m.) 2. The PRPT review on September 5, 2024 at 9:45 a.m. , showed that the laboratory did not take and document corrective actions when it obtained an unsatisfactory results in the second testing event performed in May 2024 . Tests with unsatisfactory results: 20 % for: albumin,aspartate aminotransferase (AST),total bilirubin, hDL ( high density lipoprotein ) , glucose. 0 % for: calcium. chloride, cholesterol, potassium, sodium and total protein 3. The laboratory director confirmed on September 5, 2024 at 10:00 A.M., that the laboratory failed to take and document corrective actions when it obtained an unsatisfactory results for the above mentioned tests. |
| **D2104** | ENDOCRINOLOGY<br>CFR(s): 493.843(d)<br><br>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.<br><br>This STANDARD is not met as evidenced by:<br>Based on Puerto Rico Proficiency Testing Program records reviewed ( 2023-2024) and laboratory director interview on September 5, 2024 at 11:44 A.M., it was determined that the laboratory failed to participate in the first testing event of human chorionic gonadotropin ( hCG) performed in February 2023. The findings include: 1. Proficiency testing records were reviewed from February 2023-August 2024. 2. The laboratory did not participate in the first testing event of hCG test performed in February 2023, a testing score of 0 % was obtained . ( review on September 5, 2024 at 11:45 A.M. ) 3. The deadline of the first testing event report of hCG test was February 24, 2023. 4. The laboratory director confirmed on September 5, 2024 at 11:55 A.M. , that the laboratory failed to participate in the first testing event of hCG test in February 2023. |
| **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 |

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| | 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 records review ( 2023-2024 ) and laboratory director interview on September 5, 2024 at 9:50 A.M., it was determined that the laboratory failed to take and document corrective actions when it obtained an unsatisfactory results for platelet analyte in the first testing event of year 2024. The findings include: 1. Puerto Rico Proficiency Testing Program records and results were reviewed since February 2023 to August 2024. 2. Review of Proficiency Testing records on September 5, 2024 at 9:50 A.M, showed that the laboratory obtained an unsatisfactory testing result in the first proficiency testing event of year 2024 of 60% in platelet analyte. No remedial actions were taken nor documented for this analyte. 3. The laboratory director confirmed on September 5, 2024 at 10:10 A.M.that the laboratory failed to take or document the corrective action when an unsatisfactory score was obtained in the platelet analyte. |
| **D5421** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(1)<br><br>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of routine chemistry performance specifications records and laboratory director interview on September 5, 2024 at 10:35 A.M., it was determined that the laboratory failed to complete the evaluation of the performance specifications of the new routine chemistry system. The findings include: 1. The laboratory acquired on May 2023 a new system to perform routine chemistry tests ( Inmola). 2. The performance specifications records showed that the laboratory did not verify that the manufacturer's reference intervals (normal values) were appropriate for the laboratory's patient population. 3. The laboratory director confirmed on September 5, 2024 at 10:35 A.M. , that the laboratory did not verify if the manufacturer's reference intervals (normal values) were appropriate for the laboratory's patient population prior to begin to test patient's samples. 4. The laboratory processed and reported approximately 7,412 routine chemistry tests performed by Inmola system since May 2023. |
| **D5439** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(b)<br><br>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as |

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| | acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.<br><br>This STANDARD is not met as evidenced by:<br>Based on routine chemistry calibration verification records, manufacturer's instructions, and laboratory director interview on September 5, 2024 at 10:40 AM, it was determined that the laboratory failed to perform the calibration verification procedures with at least the frequency recommended by the manufacturer's instructions (every six months) for the routine chemistry tests performed by the Inmola -Daytona system. The findings include: 1. The laboratory begin to use a new routine chemistry system ( Inmola) in May 2023. 2. Review of the manufacturer's instructions on September 5, 2024 at 10:45 A.M. showed that the laboratory must perform the calibration verification procedures every six months. 3. The calibration verification records of Inmola system showed that the laboratory did not perform at least every 6 months the calibration verification procedures. The calibration verification procedures were perform on May 2023 when the laboratory performed the validation procedures . 4. The laboratory processed and reported 6,256 patient samples since November 2023. 5. The laboratory director confirmed on September 5, 2024 at 10: 50 AM, that the laboratory did not perform at least every 6 months the calibration verification procedures for the routine chemistry system. |
| **D5445** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on the urinalysis quality control records review (years 2023-2024) and laboratory director interview on September 5, 2024 at 12:00 P.M., it was determined that the laboratory did not include or document a negative microscopic control material for manual microscopic urinalysis examinations, when 1,434 out of 1,434 patients were processed and reported since January 2023. The findings include: 1. The |

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| | urinalysis quality control records were reviewed on September 5, 2024 at 12:00 P.M. 2. The records showed that the laboratory did not include or document a negative control material for urinalysis microscopy test. ( Reviewed on September 5, 2024 at 12:10P.M.) 3. The laboratory director confirmed on September 5, 2024 at 12:40 P.M.) July 10, 2024 at 10:00 AM, that no negative microscopy control was implemented from January 2, 2023 to September 5, 2024 when when 1,434 patients urine samples were processed and reported. |
| **D6016** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(4)(i)<br><br>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;<br><br>This STANDARD is not met as evidenced by:<br>1. Based on Puerto Rico proficiency testing records review( 2023-2024 ) and laboratory director interview on September 5, 2024 at 12:15 P.M., it was determined that the laboratory failed to ensure that proficiency testing samples were tested as required under Subpart H requirements. Refer to D2093, D2094, D2104 and D2128. |
| **D6020** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<br><br>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.<br><br>This STANDARD is not met as evidenced by:<br>Based on urinalysis , routine chemistry quality control records review from January 2023 to September 5, 2024 and interview with the laboratory director on September 5, 2024 at 12:30 P.M., it was determined that the laboratory director (sole personnel) did not ensure that quality control procedures for the urinalysis nor routine chemistry were being followed. Refer to D5421, D5439 and D5445. |