

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0861654	(X3) Date Survey Completed 06/08/2022
Name of Provider or Supplier Laboratorio Clinico Pajuil	Street Address, City, State 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
D2094	<p>ROUTINE CHEMISTRY CFR(s): 493.841(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 (year 2020-2022) and laboratory general supervisor interview on June 8, 2022, it was determined that the laboratory failed to take and document corrective actions when it obtained unsatisfactory results in routine chemistry sub-specialties. The findings include: 1. On June 8, 2022 at 8:40 A.M. Puerto Rico Proficiency Testing Program records were reviewed from february 2020 to february 2022. 2. Review of Proficiency Testing results showed that the laboratory obtained unsatisfactory results of 60 percent in glucose test in the third testing event performed in october 2021. No remedial actions were taken. 3. The laboratory general supervisor confirmed on June 8, 2022 at 8:50 A. M. , that the laboratory failed to take remedial actions when obtained unsatisfactory results of 60 percent in glucose test in the third testing event performed in october 2021.</p>
D5469	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)</p> <p>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--</p>

Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on routine chemistry quality control records review (year 2021-2022) and laboratory general supervisor interview on June 8, 2022, it was determined that the laboratory failed to verify manufacturer's control values of control material used for tests performed by the Mindray BS-200 system. The findings include: 1. On June 8, 2022 at 9:30 AM., the laboratory quality control records were review from January 2021 to May 2022. 2. The laboratory uses the Mindray BS-200 system to perform routine chemistry patient's samples tests. 3. The laboratory did not verify the manufacturer's stated values for the following lot's numbers prior to place it in routine use on May 1, 2021: lot: 929001, exp date 9/30/2023 and lot: 920501, exp date: 3/31 /2023. 4. The laboratory general supervisor stated on June 8, 2022 at 9:40A.M., that the laboratory did not verify the manufacturer's stated values prior to place in routine use on May 1, 2021.

D6089

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(4)(i)

The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.

This STANDARD is not met as evidenced by:

Based on Puerto Rico Proficiency Program testing records review (2020-2022) and laboratory general supervisor interview on June 8, 2022 at 8:50 A.M., it was determined that the laboratory director failed to ensure that proficiency testing samples were tested as required under Subpart H requirements. Refer to D2094.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

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.

This STANDARD is not met as evidenced by:

Based on routine chemistry quality control records review (year 2021-2022) and interview with the laboratory general supervisor on June 8, 2022, it was determined that the laboratory director failed to ensure compliance with the requirements for routine chemistry tests. The finding includes: 1. On June 8, 2022 at 11:00 A.M. the laboratory general supervisor confirmed that the laboratory director failed to ensure

that the laboratory verified manufacturer's control values of control material used for tests performed by the Mindray BS-200 . Refer to D5469.

D6117

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(4)

The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results.

This STANDARD is not met as evidenced by:
Based on Puerto Rico Proficiency Testing Program records reviewed, routine chemistry quality control records review (year 2021-2022) and technical supervisor (general supervisor) interview on June 8, 2022 at 11:00 A.M, it was determined that technical supervisor failed to ensure compliance with the requirements for proficiency testing and analytic systems. Refer to D 2094 and D5469.