

| | | |
|--|---|---|
| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 40D2263629 | (X3) Date Survey Completed 07/11/2024 |
| Name of Provider or Supplier Clinica Todo Salud - Laboratorio Clinico | Street Address, City, State Parque Industrial L-238-0-61, Carretera Pr-725., Aibonito, 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 |
|---------------------------|---|
| D0000 | The Centers for Medicare & Medicaid Services (CMS) conducted an unannounced CLIA recertification survey at CLINICA TODO SALUD-LABORATORIO CLINICO on July 11, 2024. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. The following condition level deficiencies were found during the unannounced routine CLIA recertification survey ending on July 11, 2024. |
| 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 events review, proficiency testing written manual and laboratory general supervisor interview on July 11, 2024 at 9:15 A.M., it was determined that the laboratory failed to take and document corrective actions when it obtained an unsatisfactory results in routine chemistry specialties. The findings include: 1. Puerto Rico Proficiency Testing (PRPT) events and scores were reviewed from November 2022 to April 2024, on July 11, 2024 at 9:00 AM. 2. Review of Proficiency Testing scores showed that the laboratory obtained unsatisfactory result of 20 percent in sodium analyte on the second event of PRPT on May 2023. No remedial actions were taken. 3. The laboratory proficiency written manual has established that the laboratory will complete a failure report, record the steps of the investigation and will contact the instrument technical service. 4. On July</p> |

11, 2024 at 9:15 AM, the laboratory supervisor confirmed that the laboratory fail to take corrective action when the laboratory obtained unsatisfactory results in routine chemistry specialties.

D2128

HEMATOLOGY
CFR(s): 493.851(e)

(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.

This STANDARD is not met as evidenced by:

Based on Puerto Rico Proficiency Testing events record review and laboratory supervisor interview on July 11, 2024 at 9:30 AM, it was determined that the laboratory failed to take and document corrective actions when it obtained an unsatisfactory results for cell identification analyte in the first testing event of year 2024. The findings include: 1. Puerto Rico Proficiency Testing event records were reviewed since November 2022 to April 2024. 2. Review of Proficiency Testing events on July 11, 2024 at 9:20 AM, showed that the laboratory obtained unsatisfactory score of the 60% in the first testing event of year 2024 for cell identification. No remedial actions were taken. 3. The laboratory supervisor confirmed on July 11, 2024 at 9:30 AM that the laboratory failed to take the corrective action when an unsatisfactory score was obtained in the cell identification analyte.

D5449

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(ii)(g)

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-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on Mycoplasma pneumoniae IgM test quality control and patient test worksheet records review on July 11, 2024 at 11:22 A.M., and laboratory supervisor interview, it was determined that the laboratory did not include an external positive and negative control material, each day of Mycoplasma pneumoniae IgM patient testing in 7 out of 7 months of year 2024 (January 2024 to July 2024). The findings include: 1. The laboratory uses the Immunocard reagent kit to perform patient Mycoplasma pneumoniae IgM test. 2. Review of Mycoplasma pneumoniae IgM quality control and patient test worksheet records on July 11, 2024 at 11:18 A.M., showed that the laboratory did not include any control material each day of patient testing from January 2, 2024 to July 10, 2024, when 231 out of 231 patients were processed and reported. 3. The laboratory supervisor confirmed on July 11, 2024 at 11:22 A.M., that the laboratory failed to include a negative and positive control material each day of patient testing.

D6079

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(a)(b)

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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on personnel records review and interview with the laboratory general supervisor on July 11, 2024 at 8:30 A.M., it was determined that the laboratory director did not fully file his responsibility when did not hire or delegates the technical supervisor duties and responsibility to any qualified personnel. Refer to D6108.

D6091

LABORATORY DIRECTOR RESPONSIBILITIES

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

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.

This STANDARD is not met as evidenced by:

Based on Puerto Rico Proficiency Testing Program records, laboratory proficiency results review and laboratory supervisor interview on July 11, 2024 at 9:30 A. M, 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. The laboratory obtained a 20 % testing score for sodium and no remedial action was taken . Refer to D2094. 2. The laboratory obtained a 60 % testing score for cell identification and no remedial action was taken . Refer to D2128.

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 Mycoplasma pneumoniae IgM test quality control and patient test worksheet records review and laboratory supervisor interview on July 11, 2024 at 11:22 A.M., it was determined that the laboratory director did not make sure that the laboratory follow the quality control requirements for Mycoplasma pneumonia tests. Refer to D5449.

D6108

LABORATORY TECHNICAL SUPERVISOR

CFR(s): 493.1447

The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart.

This CONDITION is not met as evidenced by:

Based on personnel records review and laboratory general supervisor interview on July 11, 2024 at 8:30 A.M., it was determined that the laboratory failed to fill the technical supervisor position. The findings include: 1. On July 11, 2024 at 8:25 AM, the personal records was review to identify new hirings and showed that the technical supervisor position was not filled. 2. On July 11, 2024 at 8:30 AM, the laboratory general supervisor confirmed that the technical supervisor position was not filled and the duties and responsibilities were not delegated to any staff.