

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D1043613	(X3) Date Survey Completed 02/10/2022
Name of Provider or Supplier Laboratorio Clinico Ginara	Street Address, City, State 1253 Calle Juan Baez Urb San Martin, Rio Piedras, 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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on Hematology quality control records review and laboratory general supervisor interview it was determined that the laboratory failed to take a corrective action when a room humidity was out of range. The findings include: 1. On February 10, 2022 at 10:00 AM the Hematology room humidity records were review from January 2, 2020 to December 31, 2021. 2. The laboratory established in the temperature and humidity log that the room humidity range is between 40-70% . 3. From January 2, 2020 to December 31, 2021, the laboratory room humidity record showed that on 405 of 615 days, the laboratory documented the room humidity on the range of (30-39%). 4. The laboratory supervisor stated on February 10, 2022 at 10:11 AM that no corrective action were taken or documented.</p>
D5787	<p>TEST RECORDS CFR(s): 493.1283(a)</p> <p>The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of</p>

specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4)
The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:

Based on testing records review of Pregnancy worksheet and interview with the laboratory supervisor it was determined that the laboratory use whiteout on the pregnancy test worksheet. The findings include: 1. On February 10, 2022 at 9:10 AM, the pregnancy test worksheet review from January 4, 2021 to May 24, 2021 showed that whiteout was used on the fields designed to document the reagent lot number and expiration date. 2. On February 10, 2022 at 9:25 AM, the laboratory supervisor was interviewed about the use of whiteout on the pregnancy test worksheet. The supervisor did not give any explanation regarding the use of whiteout in the pregnancy records in the reagent lot number and expiration fields.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1299(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:

Based on Quality Assessment records review (QA) and laboratory supervisor interview, it was determined that the laboratory failed to evaluate the urinalysis (U/A) turn around time (TAT) as established. The findings include: 1. Review of the QA program on February 10, 2022 at 11:48 AM showed that the laboratory established on their program, that the U/A turn around time must be evaluated every year. The laboratory established that all U/A samples must be processed within two (2) hours after sample collection. 2. On February 10, 2022 at 11:53 AM, the TAT record showed that the evaluation performed on July 27, 2020 did not meet the criteria evaluation. None of the U/A TAT evaluated met the criteria, the laboratory processed the U/A samples after three (3) hours of sample collection. 3. The record did not include any corrective action, also the laboratory did not perform any evaluation of the U/A, turn around time during year 2021. 4. The laboratory supervisor stated on February 10, 2022 at 11:55 AM that she doesn't have time to perform the U/A TAT evaluation during year 2021.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES

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

The laboratory director must ensure that the quality assessment 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 Quality Assessment (QA) records review from July 27, 2020 to February 9, 2022 and laboratory supervisor interview on February 10, 2022 at 11:45 AM., it was determined that laboratory director failed to ensure compliance with turn around time (TAT) laboratory quality assessment (QA) requirements. Refer to D5891.