

<p>Statement of Deficiencies</p>	<p>(X1) Provider/Supplier/CLIA Identification Number</p> <p>40D0872956</p>	<p>(X3) Date Survey Completed</p> <p>02/04/2022</p>
<p>Name of Provider or Supplier</p> <p>Laboratorio Clinico Garnier</p>	<p>Street Address, City, State</p> <p>Barrio Guaraguao Abajo Carr 174, Km 5, Hm 7, Bayamon, PR</p>	
<p>For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.</p>		

<p>(X4) ID Prefix Tag</p>	<p>Summary Statement of Deficiencies</p>
<p>D2128</p>	<p>HEMATOLOGY CFR(s): 493.851(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 and laboratory director interview on February 4, 2022 at 8:54 AM, it was determined that the laboratory failed to take and document corrective actions when it obtained unsatisfactory results in hematology specialties. The findings include: 1. Puerto Rico Proficiency Testing Program records were reviewed from February 2020 to December 2021. 2. Review of Proficiency Testing results showed that the laboratory obtained unsatisfactory results of 60 percent in differential white blood cell for 5 parameters instrument in third testing event of 2020. No remedial actions were taken. 3. The laboratory director confirmed on February 4, 2022, that the laboratory failed to take remedial actions when obtained unsatisfactory results of 60 percent in differential white blood cell for 5 parameters instrument in the third testing event of 2020.</p>
<p>D5415</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and</p>

when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on revision of Covid-19 Ab IgG/IgM worksheet and interview with the laboratory director on February 4, 2022 at 9:50 A.M., it was determined that the laboratory did not document the reagent kit information. The findings include: 1. The laboratory perform a Covid-19 IgG/IgM antibody test (Healgen). 2. The laboratory did not document any information (name or manufacturer) about the manufacturer kit that was in used from December 29, 2021 to January 18, 2022. 3. The laboratory director confirm on February 4, 2022 at 9:50 AM that the laboratory fail to document the kit, lot and expiration date from the kit that was in used from December 29, 2021 to January 18, 2022.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on the revision of Covid-19 Ab IgG/IgM worksheet and interview with the laboratory director on february 4, 2022 at 9:50 AM it was determined that the laboratory used Covid-19 Ab IgG/IgM GreenSpring kit with exceeded expiration date. The findings include: 1. The laboratory used a Covid-19 Ab IgG/IgM Greenspring kit Lot # 20201101 expired 11/15/2021. 2. Review the worksheet of Covid-19 Ab IgG /IgM Greenspring kit, showed that the laboratory used the kit with exceeded expiration day from November 16, 2021 to December 28, 2021. 3. The laboratory director confirmed on february 4, 2022 at 9:50 AM that the laboratory used for 12 days a Greenspring kit for Covid-19 Ab IgG/IgM that exceeded the expiration date. The laboratory tested 14 patinet's samples with the expired reagent.

D5787

TEST RECORDS
CFR(s): 493.1283(a)

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 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 and worksheet of Covid-19 Ab IgG/IgM and interview with the laboratory director on February 4, 2022 at 9:45 AM it was determined that the laboratory failed to maintain and include the positive identification of the patients specimen tested for Covid-19 Ab IgG/IgM and the signature of the personnel authorized to perform the test. . The findings include: 1.

The worksheet included Kit name, lote, expiration date, date of testing, identificacion number of patient, name of the patient, test result, external control resut, internal control and the identification of the testing personnel. 2. Review (February 4, 2022 at 9:45 AM) of the Covid-19 Ab IgG patient worksheet from August 12, 2021 to January 28, 2022 showed that on the following dates the laboratory did not include the patient identification number: 8/25/2021, 8/31/2021, 9/2/2021, 9/7/2021, 9/28/2021, 9/29/2021, 10/6/2021, 10/13/2021, 10/21/2021, 10/22/2021, 12/21/2021, 12/28/2021, 12/29/2021, 1/11/2022, 1/17/2022, 1/18/2022. 3. Review of the Covid-19 Ab IgG/IgM patient worksheet showed that the laboratory did not include the identify of the personnel who performed the patient test from August 12,2021 to January 18, 2022. 4. 26 out of 26 patient teste results, recorded in the worksheet did not include the identity of the testing personnel. 5. The laboratory director confirmed on February 4, 2022 at 10:00 AM, that the laboratory did not include the patient identification nor the identity of the testing personnel.

D6018

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iii)

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)(iii) Ensure that 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 Proficiency testing records review and laboratory director interview on February 4, 2022 at 8:54 AM it was determined that the laboratory director did not ensure that remedial actions were taken when the laboratory obtained unsatisfactory results of 60 percent in differential white blood cell for 5 parameters instrument in the third testing event of 2020 event. Refer D 2128.

D6020

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

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.

This STANDARD is not met as evidenced by:
Based on quality control records review and laboratory director interview on February 4, 2022 at 11:30 AM, it was determined that laboratory director failed to ensure compliance with the requirements for analytic systems. Refer to D5417, D5415, D5787.