

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D1043613	(X3) Date Survey Completed 01/10/2024
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
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the urinalysis quality control records and laboratory supervisor interview on January 10, 2024 at 11:10 AM, it was determined that the laboratory did not include or document a negative microscopic control material for manual microscopic urinalysis examinations, when 8,726 patients were processed and reported from January 1, 2022 to January 10, 2024. The findings include: 1. The urinalysis quality control records were reviewed on January 10, 2024 at 11:10 AM. 2. The laboratory did not include or document a negative control material for urinalysis microscopy test. 3. The laboratory supervisor confirmed on January 10, 2024 at 11:15 AM, that no negative microscopy control was implemented from January 1, 2022 to January 10, 2024, when 8,726 patients were processed and reported.</p>
D5479	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies</p>

and be responsible for results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on Mycoplasma pneumoniae IgM test manufacturer's instructions, worksheet records review and laboratory supervisor interview on January 10, 2024 at 12:45 PM, it was determined that the laboratory failed to follow manufacturer's instructions to document the internal control each day of patient and control testing, when 658 patients were processed and reported from December 20, 2022 to January 10, 2024. The findings include: 1. The laboratory uses the Immunocard reagent kit to perform patient Mycoplasma pneumoniae IgM test. 2. The manufacturer's instructions stated that the laboratory must monitor and document the internal control to ensure the validity of the Mycoplasma pneumoniae IgM test performed. 3. The Mycoplasma pneumoniae IgM test worksheet records showed on January 10, 2024 at 12:45 PM, that the laboratory did not document the observed results of the internal procedural control each day of patient and control testing. 4. The laboratory processed and reported 658 Mycoplasma pneumoniae IgM patient samples from December 20, 2022 to January 10, 2024. 5. The laboratory supervisor confirmed on January 10, 2024 at 12:50 PM, that the laboratory failed to monitor and document the internal control each day of Mycoplasma pneumoniae IgM patient and control testing.

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:

1. Based on review of the urinalysis quality control records and laboratory supervisor interview on January 10, 2024 at 11:10 AM, it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory quality control requirements of manual microscopic urinalysis examinations, when 8,726 patients were processed and reported from January 1, 2022 to January 10, 2024. Refer to D5445. 2. Based on Mycoplasma pneumoniae IgM test manufacturer's instructions, worksheet records review and laboratory supervisor interview on January 10, 2024 at 12:45 PM, it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the manufacturer's instructions and laboratory quality control requirements, when 658 patients were processed and reported from December 20, 2022 to January 10, 2024. Refer to D5479.