

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  40D2002884	<b>(X3) Date Survey Completed</b>  05/04/2018
<b>Name of Provider or Supplier</b>  Laboratorio Clinico Genetic Science Laboratory	<b>Street Address, City, State</b>  Edif Caribbean Cinemas Suite 203 Centro Comercial, Guaynabo, PR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D1001</b>	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on manufacturer's instructions, tests reports records review and laboratory testing personnel interview on May 4, 2018 at 11:00 AM, it was determined that the laboratory failed to follow manufacturer's instruction when 3 out of 3 patients specimens were reported for Influenza A&amp;B Quick vue method by Quidel from April 1, 2018 to April 30, 2018. The findings include: 1 The Influenza A&amp;B Quick vue method by Quidel is a waived tests. 2. The Influenza A&amp;B Quick vue method by Quidel manufacturer instructions establish the following: the negative test is a presumptive results, the negative test results do not rule out possible other non-influenza viral infection and the positive test results do not rule out co-infections with other pathogens. 3. From April 1, 2018 to April 30, 2018, the laboratory reported 3 out of 3 patients specimens for Influenza A&amp;B Quick vue method by Quidel as following: a. Patient #036139-000: Influenza A...NEGATIVE; Influenza B...NEGATIVE b. Patient #031396-000: Influenza A...NEGATIVE, Influenza B...NEGATIVE c. Patient #036185-000: Influenza A..NEGATIVE, Influenza B...POSITIVE 4. From April 1, 2018 to April 30, 2018, the 3 out of 3 patients Influenza A&amp;B results reports (patient #036139-000, patient #031396-000 and patient #036185-000) included the tests method as "Sofia by Quidel" instead the method in use ( Quick vue method by Quidel). The patient #036139-000 results was reported on April 7, 2018, patient #031396-000 results was reported on April 5, 2018 and patient #036185-</p>

000 results was reported on April 14, 2018. 5. The testing personnel confirmed on May 4, 2018 at 11:05 AM, that those Influenza A/B results reports did not include the requiere information.

**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 manufacturer's instructions, tests reports records review and laboratory testing personnel interview on May 4, 2018 at 11:00 AM, it was determined that the laboratory director failed to ensure that the laboratory follow the manufacturer's instruction when 3 out of 3 patients specimens were reported for Influenza A&B Quick vue method by Quidel from April 1, 2018 to April 30, 2018. The findings include: 1 . The laboratory performed and reported the Influenza A & B tests by Quidel Quick vue method (waived tests). 2. The laboratory director failed to ensure that the laboratory follow the manufacturer's instruction when 3 out of 3 patients specimens were reported for Influenza A&B Quick vue method by Quidel from April 1, 2018 to April 30, 2018. 3. The Influenza A&B Quick vue method by Quidel manufacturer instructions establish the following: the negative test is a presumptive results, the negative test results do not rule out possible other non-influenza viral infection and the positive test results do not rule out co-infections with other pathogens. 3. From April 1, 2018 to April 30, 2018, the laboratory reported 3 out of 3 patients specimens were reported for Influenza A&B Quick vue method by Quidel as following: a. Patient #036139-000: Influenza A...NEGATIVE; Influenza B... NEGATIVE b. Patient #031396-000: Influenza A...NEGATIVE, Influenza B... NEGATIVE c. Patient #036185-000: Influenza A..NEGATIVE, Influenza B... POSITIVE 4. From April 1, 2018 to April 30, 2018, the 3 out of 3 patients Influenza A&B results reports (patient #036139-000, patient #031396-000 and patient #036185-000) included the tests method as "Sofia by Quidel" instead the method in use ( Quick vue method by Quidel). The patient #036139-000 results was reported on April 7, 2018, patient #031396-000 results was reported on April 5, 2018 and patient #036185-000 results was reported on April 14, 2018. 5. The testing personnel confirmed on May 4, 2018 at 11:05 AM, that those Influenza A/B results reports did not include the requiere information.