

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D2113067	(X3) Date Survey Completed 07/25/2018
Name of Provider or Supplier Laboratorio Clinico Galiza	Street Address, City, State Pr-165, Calle 1, #A10, Villa Matilde, Toa Alta, 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
D1001	<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 Biosing Flu A & B manufacturer's instruction, Influenza A & B results reports records review and interview with the technical supervisor on July 25, 2018 at 10:30 AM, it was determined that the laboratory failed to follow manufacturer's instructions when 636 out of 636 patients specimens were tested and reported for Influenza A & B results from January 12, 2018 to July 23, 2018. The findings include: 1. The Biosing Flu A & B manufacture instructed the laboratory that the negative test results are presumptive and it is recommended these results be confirmed by viral culture; negative results do not preclude influenza virus infection and should not be used as sole basis for treatment or other management decision. 2. On July 25, 2018 at 10:30 AM, the Influenza A & B results reports records showed that 636 out of 636 patients specimens tested with the Biosing Flu A & B reagent kit were reported without the manufacturer required information . 3. The technical supervisor confirmed on July 25, 2018 at 10:35 AM, that those reports did not include the manufacturer required information.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p>

	<p>This STANDARD is not met as evidenced by: Based on quality assurance program, lack of technical supervisor/ technical consultant competence records(years 2017 and 2018) and laboratory director interview on July 25, 2018 at 12:10 PM, it was determined that the laboratory failed to follow written protocol to assess the general laboratory system requirements. The findings include: 1. The quality assurance program establishes to perform an annual competence for all laboratory's personnel. 2. On July 25, 2018 at 12:10 PM, the technical supervisor competence records showed that the laboratory did not evaluate annually her performance as technical supervisor and technical consultant since January 2017. The laboratory evaluated the technical supervisor (MT#1) as testing personnel and general supervisor. 3. The laboratory director confirmed on July 25, 2018 at 12:30 PM, that the last competence of the MT#1 in records, was not evaluated for the technical supervisor nor the technical consultant responsibility.</p>
<p>D5291</p>	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>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 general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on quality assurance program, lack of technical supervisor competence records (years 2017 and 2018) and laboratory director interview on July 25, 2018 at 12:10 PM, it was determined that the laboratory failed to follow written protocol to assess the general laboratory system requirements. Refer to D 5209 (The laboratory did not evaluate annually the performance of the technical supervisor / technical consultant since January 2017).</p>
<p>D5301</p>	<p>TEST REQUEST CFR(s): 493.1241(a)</p> <p>The laboratory must have a written or electronic request for patient testing from an authorized person.</p> <p>This STANDARD is not met as evidenced by: Based on test requisition records review, laboratory clerical staff, technical supervisor and laboratory director interview on July 25, 2018 at 12:45 PM, it was determined that the laboratory failed to have a written request for two out eight patient specimens results reported from July 18 2018 to July 20, 2018. The findings include: 1. On July 25, 2018 at 12:45 PM, the laboratory did not have a written request of two out of eight patient specimens results reported from July 18 2018 to July 20, 2018. 2. The laboratory clerical staff , technical supervisor and laboratory director confirmed on July 25, 2018 at 12:45 PM, that the laboratory did not have a written request for the two patients tests results.</p>
<p>D5791</p>	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p>

(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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on Quality Assessment (QA) program, analytic system assessment activities records (years 2017 and 2018) review and technical supervisor interview on July 25, 2018 at 10:00 AM, it was determined that the laboratory failed to follow QA written protocol to evaluated and document the patients tests results that appear inconsistent with the following criteria since January, 2017: patient age, sex, diagnosis, distribution of patients test results and relationship with other parameter. The findings include: 1. The QA program showed a written protocol to monitor and evaluate the tests results for inconsistency with patient information. 2. The laboratory did not document the patients results that appear inconsistent with the following criteria since January, 2017: patient age, sex, diagnosis, distribution of patients test results and relationship with other parameter. 3. The technical supervisor stated on July 25, 2018 at 10:00 AM, that the laboratory evaluated the test results for inconsistency with the patient information but not documented.

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 (QA) program, post-analytic system assessment activities records (years 2017 and 2018) review, technical supervisor and laboratory director interview on July 25, 2018 at 10:00 AM, it was determined that the laboratory failed to establish and follow a written protocol to evaluated and document the manually data entry of patients tests results for accuracy and reliably since January 2017. The findings include: 1. The QA program and the post-analytic system assessment activities records showed that the laboratory did not establish nor follow a written protocol to evaluated and document the manually data entry of patients tests results for accuracy and reliably since January 2017. 2. The technical supervisor and the laboratory director confirmed on July 25, 2018 at 10:00 AM, that the laboratory did not have the QA required written protocol but, they stated that all patients results reported were evaluated.

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 on QA program, lack of technical supervisor competence records, analytic

system and post analytic system assessment activities records (years 2017 and 2018) review , laboratory director and technical supervisor interview on July 25, 2018 at 12: 10 PM , it was determined that the laboratory director failed to comply with the QA program. Refer to D 5291 (The laboratory did not evaluated the technical supervisor/ technical consultant annual competence). Refer to D 5791 (The the laboratory failed to follow QA written protocol to evaluated and document the patients tests results that appear inconsistent with the following criteria since January, 2017: patient age, sex, diagnosis, distribution of patients test results and relationship with other parameter). Refer to D 5891 (The laboratory failed to establish and follow a written protocol to evaluated and document the manually data entry of patients tests results for accuracy and reliably since January 2017).