

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D2072977	(X3) Date Survey Completed 06/19/2018
Name of Provider or Supplier Laboratorio Clinico Ana Camila	Street Address, City, State Urb Minima La Carmen , Carr Pr-3 Km 158 Hm 5, Salinas, 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 BioSign Flu A+B manufacturer's instruction, Influenza A & B results reports records review and interview with the technical supervisor on June 19, 2018 at 9:34 AM, it was determined that the laboratory failed to follow manufacturer's instructions when 9 out of 9 patients specimens were tested and reported for Influenza A & B results from April 6, 2018 to June 11, 2018. The findings include: 1. The BioSign 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 June 19, 2018 at 9:34 AM, the Influenza A & B results reports records showed that 9 out of 9 patients specimens tested with the BioSign Flu A+B reagent kit were reported without the manufacturer required information . Also, those Influenza A & B reports include the information of the formed method (BinaxNow). 3. The technical supervisor confirmed on June 19, 2018 at 9:44 AM, that those reports did not include the manufacturer required information.</p>
D5291	<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</p>

identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:
Based on quality assurance program, clinical consultant competence records review and technical supervisor interview on June 19, 2018 at 10:40 AM, 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 the clinical consultant. 2. On June 19, 2018 at 10:40 AM, the clinical consultant competence records showed that the laboratory did not performed the annual competence since July 15, 2016. 3. The technical supervisor confirmed on June 19, 2018 at 10:50, that the last competence in records was performed on July 15, 2016.

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 Based on quality assurance program, clinical consultant competence records review and technical supervisor interview on June 19, 2018 at 10:40 AM, it was determined that the laboratory director failed to comply with the general laboratory system requirement. Refer to D 5791 (The laboratory failed to follow written protocol for the clinical consultant annual competence since July 15, 2016).