

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D2000974	(X3) Date Survey Completed 02/14/2020
Name of Provider or Supplier Laboratorio Clinico Figueroa	Street Address, City, State Carr Pr-155 Km 58 Hm 5 Barrio Pugnado Adentro, Vega Baja, 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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program (PRPTP) record (years 2018 to 2020), Rubella qualitative testing records (years 2019 to 2020) review and laboratory technical supervisor interview at 11:10 AM on February 14, 2020, it was determined that the laboratory failed to enroll in an HHS approved Proficiency Testing Program for Rubella qualitative tests when it processed and reported 14 out of 14 patient's Rubella qualitative specimens from January 11, 2019 to February 14, 2020. The findings include: 1. At 11:10 AM on February 14, 2020, the PRPTP records showed that the laboratory did not enroll in an HHS approved Proficiency Testing Program for Rubella qualitative tests from January 11, 2019 to February 14, 2020. 2. The technical supervisor confirmed at 11:10 AM on February 14, 2020, that the laboratory performed Rubella qualitative tests form January 11, 2019 to February 14, 2020. However, the PRPTP net showed that this tests was removed for the year 2019 and the laboratory did not enroll for this year. 3. The laboratory processed and reported 14 out of 14 patient's Rubella qualitative specimens from January 11, 2019 to February 14, 2020.</p>

<p>D5405</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(c)</p> <p>Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory.</p> <p>This STANDARD is not met as evidenced by: Based on Rubagen manufacturer's instructions, Rubella qualitative testing records (years 2019 to 2020) review and laboratory technical supervisor interview at 11:10 AM on February 14, 2020, it was determined that the laboratory failed to follow manufacturer's instruction for the quality control procedures when it processed and reported 14 out of 14 patient's Rubella qualitative specimens from January 11, 2019 to February 14, 2020. The findings include: 1. The laboratory performed the Rubella qualitative test using the undiluted patient's serum qualitative technique. 2. At 11:10 AM on February 14, 2020, the Rubagen manufacturer instructed the laboratory that when testing undiluted serum for the qualitative technique procedures specimens, the low positive and negative control should be used undiluted. 3. The technical supervisor confirmed at 11:10 AM on February 14, 2020, that the laboratory used each day of testing the high positive control besides the negative control instead low positive control besides the negative control form January 11, 2019 to February 14, 2020. 4. The laboratory processed and reported 14 out of 14 patient's Rubella qualitative specimens from January 11, 2019 to February 14, 2020.</p>
<p>D6076</p>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on PRPTP record (years 2018 to 2020), Rubagen manufacturer's instructions, Rubella qualitative testing records (years 2019 to 2020) review and laboratory technical supervisor interview at 11:10 AM on February 14, 2020, it was determined that the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the Proficiency Testing Program and the laboratory analytical system requirements. Refer to D 6079 (The laboratory director did not ensure that the laboratory is enrolled in an HHS approved Proficiency Testing Program for Rubella qualitative tests). Refer to D 6093 (The 4, 2020, it was determined that the laboratory director did not comply with the analytic system requirement for the Rubella qualitative test).</p>
<p>D6079</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b)</p> <p>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</p>

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 PRPTP record (years 2018 to 2020), Rubella qualitative testing records (years 2019 to 2020) review and laboratory technical supervisor interview at 11:10 AM on February 14, 2020, it was determined that the laboratory director failed to ensure that the laboratory is enrolled in an HHS approved Proficiency Testing Program for Rubella qualitative tests from January 11, 2019 to February 14, 2020. Refer to D 2000.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control 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 Rubagen manufacturer's instructions, Rubella qualitative testing records (years 2019 to 2020) review and laboratory technical supervisor interview at 11:10 AM on February 14, 2020, it was determined that the laboratory director failed to comply with the analytic system requirement for the Rubella qualitative tests from January 11, 2019 to February 14, 2020. Refer to D 5405.

D6117

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(4)

The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results.

This STANDARD is not met as evidenced by:
Based on Rubagen manufacturer's instructions, Rubella qualitative testing records (years 2019 to 2020) review and laboratory technical supervisor interview at 11:10 AM on February 14, 2020, it was determined that the technical supervisor failed to comply with the analytic system requirement for the Rubella qualitative tests from January 11, 2019 to February 14, 2020. Refer to D 5405.