

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0669861	(X3) Date Survey Completed 11/29/2018
Name of Provider or Supplier Laboratorio Clinico Dr Agustin Stahl	Street Address, City, State Carr 174 Bloque 21 No 2o Sta Rosa, Bayamon, 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
D3009	<p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory's state license and certificate requirements records review and laboratory director interview on November 29, 2018 at 11:20 AM, it was determined that the laboratory failed to be in compliance with the laboratory's state requirements (Biomedical Generator Number). The findings include: 1. On November 29, 2018 at 11:20 AM, the laboratory's state license and certificate requirements records showed that the Biomedical Generator Number (DBR0C1192020003RN13) was due since May 16, 2013. 2. The laboratory director confirmed that the Biomedical Generator Number in records was due since May 16, 2013. She stated that the laboratory have the current Biomedical Generator Number, but it was not available.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on written procedures for preventive maintenance , laboratory test volume records and interview with the laboratory director on November 29, 2018 at 11:00 AM, it was determined that the laboratory failed to follow written instructions for the annual preventive maintenance of the following laboratory equipment and instrument</p>

from October 2017 to November 2018: thermometers, centrifuges, rotator, microscope and hygrometer. The findings include: 1. The laboratory written procedures for preventive maintenance establish to perform an annual preventive maintenance of the following equipment and instrument: thermometers, centrifuges, rotator, microscope and hygrometer. 2. On November 29, 2018 at 11:00 AM, the preventive maintenance record showed that those equipment and instrument showed that the annual preventive maintenance check was due in October 2017. 2. The laboratory director confirmed on November 29, 2018 at 11:00 AM , that the annual preventive maintenance of those equipment and instrument was due in October 2017. 3. The laboratory test volume records showed that the laboratory processed the following patients specimens from November 2017 to November 2018: a. urinalysis microscopic examination: 1910 patients specimens b. pregnancy tests: 28 patients specimens c. syphilis serology: 1584 patient specimens

D6005

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(c)

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. (c) The laboratory director must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed.

This STANDARD is not met as evidenced by:
Based on laboratory's state license and certificate requirements records review and laboratory director interview on November 29, 2018 at 11:20 AM, it was determined that the laboratory director failed to ensure that the laboratory be in compliance with the laboratory's state requirements (Biomedical Generator Number). Refer to D 3009 (The laboratory's state license and certificate requirements records showed that the Biomedical Generator Number (DBR0C1192020003RN13) was due since May 16, 2013).

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:
Based on written procedures for preventive maintenance , laboratory test volume records and interview with the laboratory director on November 29, 2018 at 11:00 AM, it was determined that the it was found that the laboratory director failed to ensure compliance with the analytic system requirements. Refer to D 5429 (The laboratory did not follow written instructions for the annual preventive maintenance of the following laboratory equipment and instrument from October 2017 to November 2018: thermometers, centrifuges, rotator, microscope and hygrometer).