

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0862228	(X3) Date Survey Completed 08/01/2018
Name of Provider or Supplier Laboratorio Clefs Ponce	Street Address, City, State 1er Piso Antiguo Edificio Del Hospital Regional, Ponce, 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
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on observation and confirmation by the technical supervisor, the laboratory failed to ensure that one Acetone and one 100% Ethanol container were each labeled with the appropriate preparation and expiration dates.</p>
D5431	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and confirmation by the technical supervisor, the laboratory failed to perform the required annual centrifuge calibration for the Rotina 420 centrifuge. The last centrifuge calibration occurred May 19, 2016 and expired on</p>

May 19, 2017. The technical supervisor confirmed that during the period of May 20, 2017 to July 31, 2017, 114 patient specimens were processed using an uncalibrated centrifuge.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on reviewing patient test reports and confirmation by the technical supervisor, the laboratory failed to include the name and address of the laboratory location where the testing was performed. Eight of eight test reports identified the name and address of the Puerto Rico Department of Health laboratory located in Rio Piedras, Puerto Rico rather than Ponce, Puerto Rico.

D5809

TEST REPORT
CFR(s): 493.1291(e)

The laboratory must, upon request, make available to clients a list of test methods employed by the laboratory and, as applicable, the performance specifications established or verified as specified in 493.1253. In addition, information that may affect the interpretation of test results, for example test interferences, must be provided upon request. Pertinent updates on testing information must be provided to clients whenever changes occur that affect the test results or interpretation of test results.

This STANDARD is not met as evidenced by:
Based on reviewing two test reports and confirmation by the technical supervisor, the laboratory failed to provide information that may affect the interpretation of test results. VDRL test reports failed to indicate the method used for the testing. The technical supervisor confirmed that all VDRL test reports fail to indicate the testing method.