

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0671002	(X3) Date Survey Completed 09/04/2019
Name of Provider or Supplier Laboratorio Clinico Van Scoy	Street Address, City, State Ave Don Pelayo Aa-4 Hacienda Del Norte, Toa 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
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 OSOM Ultra Flu A&B manufacturer's instructions, Influenza A&B tests reports records review and general supervisor interview on September 4, 2019 at 10:10 AM, it was determined that the laboratory failed to follow manufacturer's instruction for report information when 83 out of 83 patients specimens were reported for Influenza A&B tests by OSOM Ultra Flu A&B from January 1,2019 to September 4, 2019. The findings include: 1 The laboratory uses the OSOM Ultra Flu A&B to detect the Influenza A&B antigen as Waived complexity. 2. OSOM Ultra Flu A&B manufacturer's instructions for the intended uses establish that the negative test results are presumptive and it is recommended this results be confirmed by viral culture and establish limitations for the negative test result (included in the insert). 3. On September 4, 2019 at 10:10 AM, the Influenza A&B tests reports records showed that the laboratory did not include the manufacturer required information. The laboratory reported the negative Influenza A or B as final results. 4. The general supervisor confirmed on September 4, 2019 at 10:10 AM, that the Influenza A&B tests reports did not include the required information. 5. The laboratory reported 83 out of 83 patients specimens for Influenza A&B tests by OSOM Ultra Flu A&B from January 1,2019 to September 4, 2019.</p>
D5449	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p>

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on Mycoplasma IGM quality control records (from April 2, 2019 to September 3, 2019) review and interview with the laboratory supervisor on September 4, 2019 at 9:35 AM, it was determined that the laboratory failed to include each day of testing a negative and a positive control materials when 22 out of 22 patients specimens were tested and reported for qualitative Mycoplasma IgM tests from April 2, 2019 to September 4, 2019 by the Immuno Card Mycoplasma method. The findings include :

1. On September 4, 2019 at 9:35 AM, the Mycoplasma IGM quality control records showed that the laboratory did not include each day of testing the negative nor the positive control materials from April 2, 2019 to September 4, 2019.
2. The laboratory includes the negative and the positive control materials when it placed in routine use the following lots numbers of the Immuno Card Mycoplasma reagents kit: a. lot 709030L004 on April 2, 2019. b. lot 709030L044 on August 1, 2019. c. lot 709030Lo49 on August 27, 2019.
3. The general supervisor confirmed on September 4, 2019 at 9:35 AM, that the laboratory did not include the negative and the positive control materials each day of testing, instead the laboratory includes a negative and a positive control materials when it places in routine use every new lot or new shipping of the Immuno Card Mycoplasma reagents Kit.
4. The laboratory tested and reported 22 out of 22 patients specimens for qualitative Mycoplasma IgM tests from April 2, 2019 to September 4, 2019 by the Immuno Card Mycoplasma method.

D6042

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(4)

(b) The technical consultant is responsible for-- (b)(4) 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 Mycoplasma IGM quality control records (from April 2, 2019 to September 3, 2019) review and interview with the laboratory supervisor on September 4, 2019 at 9:35 AM, it was determined that technical consultant failed to ensure compliance with the requirements for the analytic systems of the qualitative of Mycoplasma IgM tests. Refer to D 5449 (The laboratory did not include each day of testing a negative and a positive control materials when 22 out of 22 patients specimens were tested and reported for qualitative Mycoplasma IgM tests from April 2, 2019 to September 4, 2019 by the Immuno Card Mycoplasma method).

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 Mycoplasma IGM quality control records (from April 2, 2019 to September 3, 2019) review and interview with the laboratory supervisor on September 4, 2019 at 9:35 AM, it was determined that the laboratory director failed to ensure compliance with the requirements for qualitative Mycoplasma IgM tests . Refer to D 5449 (The laboratory failed did not include each day of testing a negative and a positive control materials when 22 out of 22 patients specimens were tested and reported for qualitative Mycoplasma IgM tests from April 2, 2019 to September 4, 2019 by the Immuno Card Mycoplasma method).