

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0658114	(X3) Date Survey Completed 08/16/2019
Name of Provider or Supplier Laboratorio Clinico-Patologico Sevilla	Street Address, City, State Munoz Marin #100 Ave Esquina Casillas, Humacao, 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
D5405	<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 Microscan manufacturer's instructions, bacteriology procedures manual, bacteriology quality control records (years 2018 -2019) review and technical superviosr interview on August 16, 2019 at 12:35 PM, it was determined that the laboratory failed to follow the Microscan manufacturer's instruction when 129 out of 129 patients culture specimens were processed and reported for the microorganisms identification and susceptibility panels by the Microscan method from January 2, 2019 to August 16, 2019. The findings include: 1. The Microscan's manufacturer instructed the laboratory to incubate the microorganisms identification and susceptibility panels at temperature of 35 C. 2. The bacteriology procedures manual establishes to incubate the microorganisms identification and susceptibility panels at temperature of 35 C for 16 hours. 3. On August 16, 2019 at 12:35 PM, the bacteriology quality control records showed that the laboratory incubated the Microscan's microorganisms identification and susceptibility panels at temperature range of 36 C +/- 1 C from January 2, 2019 to August 16, 2019. 4. The general supervisor confirmed on August 16, 2019 at 12:35 PM, that the laboratory incubated the Microscan's microorganisms identification and susceptibility panels at temperature range of 36 C +/- 1 C from January 2, 2019 to August 16, 2019. 5. The laboratory processed and reported 129 out of 129 patients cultures specimens for the microorganisms identification and susceptibility panels by the Microscan method from January 2, 2019 to August 16, 2019.</p>

D5449

CONTROL PROCEDURES

CFR(s): 493.1256(d)(3)(ii)(g)

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 October 19, 2018 to August 14, 2019) review and interview with the technical supervisor on August 16, 2019 at 11:40 AM, it was determined that the laboratory failed to include each day of testing a negative and a positives control materials when 1,002 patients serum specimens were tested for qualitative Mycoplasma IgM by the Immuno Card Mycoplasma method from October 19, 2018 to August 14, 2019. The findings include : 1. The Mycoplasma IGM quality control records showed that the laboratory validated this method on October 15, 2018 and it placed in routine use the following lot numbers of Mycoplasma IgM by the Immuno Card Mycoplasma method: a. lot 709030K016 on October 19, 2018. b. lot 709030K022 on November 16, 2018. c. lot 709030K028 on December 18, 2018. d. lot 709030K028 on January 14 , 2018. e. lot 709030K038 on January 31, 2018. f. lot 709030K037 on February 7, 2019. g. lot 709030K041 on March 1, 2019. h. lot 709030L044 on March 20, 2019. i. lot 709030L046 on April 8, 2019. j. lot 709030L049 on May 9, 2019. k. lot 709030L052 on June 19, 2019. l. lot 709030L054 on July 10, 2019. 2. On August 16, 2019 at 11:40 AM, the Mycoplasma IGM quality control records showed that the laboratory did not include each day of testing a negative and a positive control materials when when 1,002 patients serum specimens were tested for qualitative Mycoplasma IgM by the Immuno Card Mycoplasma method from October 19, 2018 to August 14, 2019. 3. The general supervisor confirmed August 16, 2019 at 11:40 AM, that the laboratory did not include each day of testing a negative and a positive control materials when patients serum specimens were tested for qualitative Mycoplasma IgM, instead the laboratory includes a negative and a positive control materials when places in routine use every new lot of the Immuno Card Mycoplasma reagents Kit.

D5451

CONTROL PROCEDURES

CFR(s): 493.1256(d)(3)(iii)(g)

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-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on syphilis serology testing records(years 2018 and 2019) review and technical supervisor interview on August 16, 2019 at 12:10 PM, it was determined that the laboratory failed to include at least once a day, a negative control material besides a control material with tittered reactivity when 3 out of 3 patients specimens were tested for syphilis serology by rapid plasma reagin (RPR) quantitative tests by ASI method

from January 23, 2019 to August 12, 2019. The findings include: 1. The laboratory processed and reported the RPR quantitative tests by ASI method. 2. On August 16, 2019 at 12:10 PM, the syphilis serology testing records showed that the laboratory did not include at least once a day, the negative control material besides the control material with tittered reactivity when 3 out of 3 patients specimens were tested for syphilis serology by RPR quantitative tests by ASI method from January 23, 2019 to August 12, 2019: patient specimen 67235 on January 23, 2019, patient specimen 70209 on March 27, 2019 and patient specimen 75302 on August 12, 2019 . 3. The technical supervisor confirmed on August 16, 2019 at 12:10 PM, that the laboratory did not include the negative control material when it performed the quantitative RPR test. She stated that the laboratory includes this control material when it processing the qualitative RPR test.

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 Microscan manufacturer's instructions, bacteriology procedures manual, bacteriology quality control records (years 2018 -2019), Mycoplasma IGM quality control records (from October 19, 2018 to August 14, 2019), syphilis serology testing records(years 2018 and 2019) review and technical supervisor interview on August 16, 2019 at 12:35 PM, it was determined that the laboratory director failed to ensure compliance with the requirements for the analytic system. Refer to D 5405 (The laboratory did not follow the Microscan manufacturer's instruction when 129 out of 129 patients culture specimens were processed and reported for the microorganisms identification and susceptibility panels by the Microscan method from January 2, 2019 to August 16, 2019). Refer to D 5449 (The laboratory did not include each day of testing a negative and a positives control materials when 1,002 patients serum specimens were tested for qualitative Mycoplasma IgM by the Immuno Card Mycoplasma method from October 19, 2018 to August 14, 2019). Refer to D 5451 (The laboratory did not include at least once a day, a negative control material besides a control material with tittered reactivity when 3 out of 3 patients specimens were tested for syphilis serology by rapid plasma reagin (RPR) quantitative tests by ASI method from January 23, 2019 to August 12, 2019).

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 Microscan manufacturer's instructions, bacteriology procedures manual, bacteriology quality control records (years 2018 -2019), Mycoplasma IGM quality

control records (from October 19, 2018 to August 14, 2019), syphilis serology testing records (years 2018 and 2019) review and technical supervisor interview on August 16, 2019 at 12:35 PM, it was determined that the technical supervisor failed to ensure compliance with the requirements for analytic systems. Refer to D 5405 (The laboratory did not follow the Microscan manufacturer's instruction when 129 out of 129 patients culture specimens were processed and reported for the microorganisms identification and susceptibility panels by the Microscan method from January 2, 2019 to August 16, 2019). Refer to D 5449 (The laboratory did not include each day of testing a negative and a positive control materials when 1,002 patients serum specimens were tested for qualitative Mycoplasma IgM by the Immuno Card Mycoplasma method from October 19, 2018 to August 14, 2019). Refer to D 5451 (The laboratory did not include at least once a day, a negative control material besides a control material with tittered reactivity when 3 out of 3 patients specimens were tested for syphilis serology by rapid plasma reagin (RPR) quantitative tests by ASI method from January 23, 2019 to August 12, 2019).

D6177

TESTING PERSONNEL RESPONSIBILITIES
CFR(s): 493.1495(b)(3)

Each individual performing high complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.

This STANDARD is not met as evidenced by:
Based on Microscan manufacturer's instructions, bacteriology procedures manual, bacteriology quality control records (years 2018 -2019), Mycoplasma IGM quality control records (from October 19, 2018 to August 14, 2019), syphilis serology testing records (years 2018 and 2019) review and technical supervisor interview on August 16, 2019 at 12:35 PM, it was determined that the testing personnel failed to follow quality control procedures. Refer to D 5405 (The laboratory did not follow the Microscan manufacturer's instruction when 129 out of 129 patients culture specimens were processed and reported for the microorganisms identification and susceptibility panels by the Microscan method from January 2, 2019 to August 16, 2019). Refer to D 5449 (The laboratory did not include each day of testing a negative and a positive control materials when 1,002 patients serum specimens were tested for qualitative Mycoplasma IgM by the Immuno Card Mycoplasma method from October 19, 2018 to August 14, 2019). Refer to D 5451 (The laboratory did not include at least once a day, a negative control material besides a control material with tittered reactivity when 3 out of 3 patients specimens were tested for syphilis serology by rapid plasma reagin (RPR) quantitative tests by ASI method from January 23, 2019 to August 12, 2019).