

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0707568	(X3) Date Survey Completed 03/15/2018
Name of Provider or Supplier Laboratorio Clinico Ling Inc	Street Address, City, State Calle Pedro Mora Esq Calle Fraternidad Bo Hato, Arecibo, 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 quality control records review and laboratory technical supervisor interview on March 15, 2018 at 10:20 AM, it was determined that the laboratory failed to follow the Microscan manufacturer's instruction when 158 out of 158 patients urine specimens were processed and reported for the microorganisms identification and susceptibility panels by the Microscan method from January 2, 2017 to March 14, 2018. 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 quality control records showed that the laboratory incubated the Microscan's microorganisms identification and susceptibility panels at temperature range of 37 C +/- 1 C from January 2, 2017 to March 14, 2018. 3. The laboratory technical supervisor confirmed on March 15, 2018 at 11:20 AM, that the laboratory incubated the Microscan's microorganisms identification and susceptibility panels at temperature range of 37 C +/- 1 C from January 2, 2017 to March 14, 2018. 4. The laboratory processed and reported 158 out of 158 patients urine specimens for the microorganisms identification and susceptibility panels by the Microscan method from January 2, 2017 to March 14, 2018.</p>
D6093	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p>

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 quality control records review and laboratory technical supervisor interview on March 15, 2018 at 10:20 AM, it was found that the laboratory director failed to ensure compliance with the analytic system requirements for the bacteriology specialty when 158 out of 158 patients urine specimens were processed and reported for the microorganisms identification and susceptibility panels by the Microscan method from January 2, 2017 to March 14, 2018. The finding includes: 1. The laboratory director failed to ensure compliance with the analytic system requirements of bacteriology specialty. Refer to D 5405. (The laboratory did not follow the Microscan manufacturer's instruction for the incubation temperature of the patients urine specimens microorganisms identification and susceptibility panels by the Microscan method from January 2, 2017 to March 14, 2018.)

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 quality control records review and laboratory technical supervisor interview on March 15, 2018 at 10:20 AM, it was determined that technical supervisor failed to ensure compliance with the requirements for the bacteriology specialty analytic systems when 158 out of 158 patients urine specimens were processed and reported for the microorganisms identification and susceptibility panels by the Microscan method from January 2, 2017 to March 14, 2018. Refer to D 5405. (The laboratory did not follow the Microscan manufacturer's instruction for the incubation temperature of the patients specimens microorganisms identification and susceptibility panels by the Microscan method from January 2, 2017 to March 14, 2018.)