

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0689954	(X3) Date Survey Completed 01/25/2018
Name of Provider or Supplier Laboratorio Clinico Irizarry Guash	Street Address, City, State Calle Estacion #56, Aguada, 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
D5477	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on bacteriology culture media quality control records review from January 20, 2016 to December 9, 2017 and laboratory director and testing personnel interview on January 25, 2018 at 10:42 AM, it was determined that the laboratory failed to check each batch of cultures media plates used at the laboratory for selectivity and or inhibition and biochemical response since January 20, 2016. The findings include: 1. Review of the bacteriology culture media quality control records showed that the following agar plates were being used: Blood Agar (BA), Mac Conkey and Thioglycolate medium (THIO). 2. From January 20, 2016, the laboratory received the following: Media Total of different lot numbers a. Blood Agar (BA) 15 lots b. Mac Conkey 15 lots c. THIO 7 lots 3. The laboratory processed 1,018 patient's cultures samples from January 1, 2016. 4. The laboratory director and testing personnel stated that no evaluation of the ability to support growth was performed from January 20, 2016.</p>
D5791	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an</p>

ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on quality assessment (QA) records review and laboratory director and testing personnel interview on January 25, 2018 at 11:02 AM, it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the requirement for analytic systems. The findings include: 1. Review of the laboratory quality assessment manual showed that for each analytic process a log sheet was designate to keep track of the laboratory performance. 2. The laboratory did not evaluate aspects regarding the analytic system: a. to check each batch of culture media plates used at the laboratory for selectivity and or inhibition and biochemical response since January 20, 2016. Refer to D5477.

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 quality control records review and laboratory director and testing personnel interview on January 25, 2018 at 11:55 AM, it was determined that laboratory director failed to ensure compliance with the requirements for analytic systems. The finding includes: 1. The laboratory director did not assure that the laboratory: a. to check each batch of culture media plates used at the laboratory for selectivity and or inhibition and biochemical response since January 20, 2016. Refer to D5477.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment 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 Quality Assessment (QA) records review and laboratory director and testing personnel interview on January 25, 2018 at 11:48 AM, it was determined that laboratory failed to ensure compliance with quality assessment (QA) requirements. The finding includes: 1. The laboratory did not evaluate the established Quality Assessment Program to monitor and evaluate the requirement for analytic systems. Refer to D5791.

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 quality control records review and laboratory director and testing personnel interview on January 25, 2018 at 11:58 AM, it was determined that testing personnel failed to follow quality control procedures. The finding includes: 1. The laboratory testing personnel failed the following quality control procedures: a. to check each batch of culture media plates used at the laboratory for selectivity and or inhibition and biochemical response since January 20, 2016. Refer to D5477.