

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0994189	(X3) Date Survey Completed 10/25/2018
Name of Provider or Supplier Coreplus Servicios Clinicos Y Patologicos,Llc	Street Address, City, State Ave Sanchez Vilella Esq Pr-190, Suite #2-6, Carolina, 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
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on clinical cytogenetics quality control records review from December 29, 2017 to October 25, 2018 and laboratory testing personnel interview on October 25, 2018 at 1:55 PM, it was determined that the laboratory failed to follow manufacturer's instructions for the fluorescence microscope preventive maintenance (Olympus BX61). The findings include: 1. The laboratory did not perform the mercury lamp usage time of the fluorescence microscope preventive maintenance since December 29, 2017 to October 22, 2018. 2. The laboratory testing personnel confirmed on October 25, 2018, that those preventive maintenance did not perform since December 29, 2017. 3. The laboratory perform 97 patients tests from December 29, 2017 to October 25, 2018.</p>
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>

This STANDARD is not met as evidenced by:
 Based on bacteriology culture media quality control records review from January 3, 2017 to October 25, 2018 and laboratory testing personnel interview on October 25, 2018 at 11:22 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 3, 2017. The findings include: 1. Review of the bacteriology culture media quality control records showed that the following agar plates were being used: Blood Agar 5 % (BA). 2. From January 3, 2017, the laboratory received the following: Media lot # open date expiration date 1. Blood Agar 17009 January 30, 2017 04/09/2017 2. Blood Agar 17023 March 4, 2017 04/25/2017 3. Blood Agar 17052 May 1, 2017 05/22/2017 4. Blood Agar 17129 July 10, 2017 08/07/2017 5. Blood Agar 17178 August 14, 2017 09/25/2017 6. Blood Agar 17199 September 18, 2017 10/16/2017 7. Blood Agar 17242 October 10, 2017 11/25/2017 8. Blood Agar 404025 December 04, 2017 01/25/2018 9. Blood Agar 415522 December 26, 2017 02/19/2018 10. Blood Agar 407603 January 15, 2018 03/28/2018 11. Blood Agar 409791 March 14, 2018 05/02/2018 12. Blood Agar 411522 April 09, 2018 05/13/2018 13. Blood Agar 416265 June 11, 2018 08/13/2018 14. Blood Agar 419034 August 06, 2018 09/24/2018 15. Blood Agar 420710 September 04, 2018 10/23/2018 3. The laboratory processed 12861 patient's cultures samples from January 3, 2017. 4. The laboratory testing personnel stated on October 25, 2018, that the laboratory did not perform the evaluation of the ability to support growth was performed from January 3, 2017.

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 testing personnel interview on October 25, 2018 at 1:55 PM, 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. follow manufacturer's instructions for the fluorescence microscope preventive maintenance (Olympus BX61). Refer to D5429. b. to check each batch of cultures media plates used at the laboratory for selectivity and or inhibition and biochemical response since January 3, 2017. Refer to 5477.

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 testing personnel interview on

October 25, 2018 at 1:58 PM, 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. follow manufacturer's instructions for the fluorescence microscope preventive maintenance (Olympus BX61). Refer to D5429. b. to check each batch of cultures media plates used at the laboratory for selectivity and or inhibition and biochemical response since January 3, 2017. Refer to 5477.