

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  40D0710502	<b>(X3) Date Survey Completed</b>  03/09/2018
<b>Name of Provider or Supplier</b>  Laboratorio Clinico Aymat	<b>Street Address, City, State</b>  Tren Street Number 52, Catano, PR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5479</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(e)(5)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on manufacturer's instructions, general immunology quality control records review and laboratory director and general supervisor interview on March 9, 2018 at 10:22 AM, it was determined that the laboratory failed to follow manufacturer's instruction when patient's samples were tested for qualitative MONO by the Monocol/lex (Immunostics) method. The findings include: 1. The Monocol/lex - MONO manufacturer's instructed the laboratory to check all negative seras by retesting at 1:10 dilution due to a prozone phenomena. 2. The laboratory director and general supervisor confirmed on March 9, 2018 at 10:22 AM, that the laboratory did not check all MONO negative seras by retesting at 1:10 dilution before it reported as negative result. 3. From January 4, 2016 to December 2017, the MONO testing records showed that the laboratory did not dilute 29 out of 29 MONO patient's specimens before it reported as negative result.</p>
<b>D5791</b>	<p><b>ANALYTIC SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an 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.</p>

	<p>This STANDARD is not met as evidenced by: Based on quality assessment (QA) records review and laboratory director and general supervisor interview on March 9, 2018 at 11:42 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 systems: a. to follow manufacturer's instruction when patient's samples were tested for qualitative MONO by the Monocol /lex (Immunostics) method. Refer to D5479.</p>
<p><b>D6020</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(5)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on quality control records review and laboratory director and general supervisor interview on March 9, 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 follow manufacturer's instruction when patient's samples were tested for qualitative MONO by the Monocol/lex (Immunostics) method. Refer to D5479.</p>
<p><b>D6021</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(5)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on Quality Assessment (QA) records review and laboratory director and general supervisor interview on March 9, 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.</p>
<p><b>D6072</b></p>	<p><b>TESTING PERSONNEL RESPONSIBILITIES</b> CFR(s): 493.1425(b)(3)</p>

Each individual performing moderate 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 general supervisor interview on March 9, 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 follow manufacturer's instruction when patient's samples were tested for qualitative MONO by the Monocol/lex (Immunostics) method. Refer to D5479.