

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 40D0886478	<b>(X3) Date Survey Completed</b> 10/10/2018
<b>Name of Provider or Supplier</b> Laboratorio Clinico Metropolitano	<b>Street Address, City, State</b> 369 Domenech Street, San Juan, 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>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on lack of calibration records (year 2017) for the Cell Dyn 1600 system, lack of testing records (from January 2017 to March 2017) of general immunology and interview with the laboratory director on October 10, 2018 at 10:30 AM, it was determined that the laboratory failed to retain analytic system records during the year 2017. The findings include: 1. On October 10, 2018 at 9:00 AM, the laboratory did not have available testing records of general immunology from January 2017 to March 2017. 2. On October 10, 2018 at 10:30 AM, the laboratory did not have available the calibration records (year 2017) for the Cell Dyn 1600 system. 3. The laboratory director confirmed on October 10, 2018 at 10:30 AM, that those records were not available in the laboratory since the Hurricane Mara.</p>
<b>D3039</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(5)</p> <p>Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on quality assessment (QA) protocols, QA records (years 2017 and 2018) and interview with the laboratory director on October 10, 2018 at 9:20 AM, it was determined that the laboratory failed to retain in records the evidence of wick patients</p>

	<p>information were utilized to evaluate the per-analytic and post-analytic systems during the years 2017 and 2018. The findings include: 1. On October 10, 2018 at 9:20 AM, the QA protocols showed that the laboratory establish to evaluate the per-analytic and post-analytic systems with a sample of 20 patients information. 2. The QA records showed that the laboratory did not retain in records wich patients information were utilized to perform the evaluation of the per-analytic and post-analytic systems since January 2017. 3. The laboratory director confirmed on October 10, 2018 at 9:20 AM, that the laboratory did not document wich patients information were utilized to perform those evaluations since January 2017.</p>
<p><b>D5791</b></p>	<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) protocols, lack of QA record (years 2017 and 2018) for analytic system assessment and interview with the laboratory director on October 10, 2018 at 9:20 AM, it was determined that the laboratory failed to have and follow a protocol to evaluate the analytic systems from January 2017 to October 10, 2018. The findings include: 1. On October 10, 2018 at 9:20 AM, the QA protocols showed that the laboratory did not establish a protocol to evaluate the analytic systems from January 2017 to October 10, 2018. 2. The laboratory director confirmed on October 10, 2018 at 9:20 AM, that the laboratory did not to have nor follow a protocol to evaluate the analytic systems from January 2017 to October 10, 2018.</p>
<p><b>D5891</b></p>	<p><b>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1299(a)</p> <p>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 postanalytic systems specified in 493.1291.</p> <p>This STANDARD is not met as evidenced by: Based on quality assessment (QA) protocols, lack of QA record (years 2017 and 2018) for analytic system and laboratory's turn around time (TAT) assessment, and interview with the laboratory director on October 10, 2018 at 9:20 AM, it was determined that the laboratory failed to have and follow a protocol to evaluate the laboratory's turn around time (TAT) from January 2017 to October 10, 2018. The findings include: 1. On October 10, 2018 at 9:20 AM, the QA protocols showed that the laboratory did not establish a protocol to evaluate the laboratory reporting time frames (laboratory's TAT) from January 2017 to October 10, 2018. 2. The laboratory director confirmed on October 10, 2018 at 9:20 AM, that the laboratory did not to have nor follow a protocol to evaluate the laboratory's TAT from January 2017 to October 10, 2018.</p>
<p><b>D6079</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(a)(b)</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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:  
Based on lack of calibration records (year 2017) for the Cell Dyn 1600 system, lack of testing records (from January 2017 to March 2017) of general immunology and interview with the laboratory director on October 10, 2018 at 10:30 AM, it was determined that the laboratory director failed to ensure that the laboratory retain analytic system records and quality assessment (QA) records during the year 2017. Refer to D 3031. Refer to D 3039.

**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) protocols, lack of QA record (years 2017 and 2018) for analytic system and turn around time (TAT) assessment and interview with the laboratory director on October 10, 2018 at 9:20 AM, it was determined that the laboratory director failed to ensure that the laboratory have and follow a protocol to evaluate the analytic systems and the TAT assessment from January 2017 to October 10, 2018. Refer to D 5791. Refer to D 5891.