

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  40D0658123	<b>(X3) Date Survey Completed</b>  10/11/2019
<b>Name of Provider or Supplier</b>  Laboratorio Clinico Universal	<b>Street Address, City, State</b>  Calle Munoz Rivera 56 Suite 1, Juncos, 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 urinalysis quality control records reviewed form years 2018 and 2019, and laboratory supervisor interview on October 11, 2019 at 10:30 AM., it was found that the laboratory did not retain the Clinitek 500 quality control printout records since January 2, 2019. . The findings include: a. The laboratory performed the semiquantitative urinalysis procedure by the Clinitek 500 instrument. b. Although the laboratory had a Laboratory Information System (LIS) the urinalysis quality control results were not captured. c. On October 11, 2019 at 10:30 AM the general supervisor stated that the laboratory read the quality control results from the instrument screen and then the results were documented on the quality control (QC) sheet. The laboratory did not print the QC results since January 2, 2019.</p>
<b>D5014</b>	<p><b>GENERAL IMMUNOLOGY</b> CFR(s): 493.1208</p> <p>If the laboratory provides services in the subspecialty of General immunology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on Mycoplasma pneumoniae quality control records patient records review and interview with the laboratory supervisor on October 11, 2019 at 10:40 AM, it was</p>

	<p>determined that the laboratory failed to meet the requirements in the subspecialty of General Immunology. The finding includes: a. The laboratory did not include an external positive and a negative control material each day of patient testing. Refer to : 5449- The laboratory did not include positive and negative control material</p>
<b>D5449</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of Mycoplasma pneumoniae IgM quality control results, patient test results records and interview with the laboratory supervisor on October 11, 2019 at 10:40 AM, it was found that the laboratory did not include a positive and a negative control material each day of patient testing. The findings include: a. The laboratory began to perform patient's test for Mycoplasma pneumoniae on November 30, 2018. b. Review of the quality control and patient test results records, on October 11, 2019 at 10:40 AM, showed that positive and negative controls were included when a new reagent box was opened. c. The quality control and patient test results records showed that from November 30, 2018 to October 10, 2019 the laboratory had a total of 115 days of sample testing. d. During 106 out of 115 days of testing the laboratory did not include a positive not a negative quality control material. e. The laboratory supervisor stated that they included a negative and a positive control material when a new reagent box was opened and documented the procedural control with each patient. f. The patient test records showed that the laboratory performed a total of 183 patient's samples.</p>
<b>D5891</b>	<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 review of the Quality Assessment (QA) Program and interview with the laboratory director on October 11, 2019 at 11:55 AM, it was found that the laboratory did not evaluate the following aspects included in the QA Laboratory Program. The findings include: a. The laboratory QA program was reviewed on October 11, 2019 at 11:55 AM, the program showed that the following evaluations must be done every year: Evaluation of the laboratory turn around time Evaluation of the patient's final test reports b. Review of the laboratory QA program for year 2017, 2018 and 2019 showed that the laboratory did not evaluate the laboratory turn around time nor the patient's test reports since year 2017. c. The laboratory director stated on October 11, 2019 at 12:05 PM that the evaluations were not performed.</p>
<b>D6076</b>	<b>LABORATORY DIRECTOR</b>

	<p>CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on quality control and quality assessments records review and laboratory supervisor interview on October 11, 2219, it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory quality control and quality assessment requirements. Refer to D6093 and D6094</p>
<b>D6093</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(5)</p> <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.</p> <p>This STANDARD is not met as evidenced by: Based on Mycoplasma pneumonia IgM quality control records and interview with the laboratory supervisor on October 11, 2019 at 10:40 AM, it was determined that the laboratory director did not make sure to include a positive and a negative control material each day of patient testing for Mycoplasma pneumonia tests. Refer to D5449.</p>
<b>D6094</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on Quality Assessment (QA) records review and laboratory director interview on October 11, 2019 at 12:05 PM, it was determined that laboratory director failed to ensure compliance with quality assessment (QA) requirements. The finding includes: a. The laboratory director did not evaluate indicators of the postanalytic system. Refer to D5891.</p>