

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0684519	(X3) Date Survey Completed 02/27/2018
Name of Provider or Supplier Laboratorio Clinico Avanzado Emmanuel, Inc	Street Address, City, State Calle Palmer #58, Toa Alta, 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
D5451	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iii)(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-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on syphilis serology quality control and patient records review from January 4, 2016 to February 27, 2018 and interview with the laboratory director on February 27, 2018 at 11:15 AM, it was determined that the laboratory did not include a control material with tittered reactivity when the laboratory processed and reported patients with tittered results. The findings include: 1. The laboratory processed syphilis serology patient tests by VDRL (Venereal Disease Research Laboratory) method. 2. Review of quality control and patient log book records showed that from January 4, 2016 to February 28, 2018 the laboratory reported the following patients with tittered test results: Patient # Date Result P2016-322 July 05, 2016 R 1:2 dils P2016-324 July 05, 2016 R 1:2 dils P2016-325 July 05, 2016 R 1:4 dils 2016-711 September 20, 2016 R 1:1 dils 2016-712 September 20, 2016 R 1:1 dils 2016-713 September 20, 2016 R 1:1 dils 2016-A072 December 22, 2016 R 1:1 dils 2016-A073 December 22, 2016 R 1:2 dils 2016-A074 December 22, 2016 R 1:1 dils 2017-322 April 10, 2017 R 1:2 dils 2017-323 April 10, 2017 R 1:1 dils 2017-325 April 10, 2017 R 1:1 dils 2017-A071 December 19, 2017 R 1:1 dils 2017-A073 December 19, 2017 R 1:2 dils 2017-A075 December 19, 2017 R 1:1 dils 3. The laboratory did not include a tittered quality control material when patient tests were performed. 4. The laboratory director confirmed on February 27, 2018, that the titled control material was not included.</p>

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(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.

This STANDARD is not met as evidenced by:

Based on quality assessment (QA) records review and laboratory director interview on February 27, 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. that the laboratory did not include a control material with tittered reactivity when the laboratory processed and reported patients with tittered results. Refer to D5451.

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 February 27, 2018 at 11:45 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. included a control material with tittered reactivity when the laboratory processed and reported patients with tittered results. Refer to D5451.

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 interview on February 27, 2018 at 11:48 AM, it was determined that laboratory failed to ensure compliance with quality assessment (QA) requierements. The finding includes: 1. The laboratory did not evaluate the established Quality Assessment Program to monitor and evaluate the requirement for analytic systems (that the laboratory did not include a control material with tittered reactivity when the laboratory processed and reported patients with tittered results). 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 syphilis serology quality control records review and laboratory director interview on February 27, 2018 at 11:48 AM, it was determined that testing personnel failed to follow quality control procedures. The finding includes: 1. The laboratory testing personnel did not include a control material with tittered reactivity when the laboratory processed and reported patients with tittered results. Refer to D5451.