

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D2003637	(X3) Date Survey Completed 05/10/2018
Name of Provider or Supplier Laboratorio Clinico Ocean Front	Street Address, City, State Road Pr 686 Km 9 Hm 5 Bo Yeguada, Vega Baja, 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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of general supervisor records and laboratory general supervisor interview on May 10, 2018 at 10:00 A.M , it was determined that the laboratory failed to follow written policies to assess the general supervisor competency. The findings include : 1. General supervisor (testing personnel) records were reviewed since January 2017. 2. The laboratory written procedures established that the laboratory evaluate the competency of general supervisor (testing personnel) following the 6 competency assessment criteria. 3. The laboratory director (technical supervisor) failed to perform the annual competency evaluation to the testing personnel (general supervisor) that include at least the following requirements since January 2017: a. Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b. Monitoring, recording and reporting of test results. c. Review of intermediate test results or worksheets, quality control records, proficiency testing results and preventive maintenance records. d. Direct observation of performance of instrument maintenance and function checks. e. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. 4. This deficiency was cited on the last survey performed on May 12, 2016.</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</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 general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:

Based on Quality Assessment (QA) records review and laboratory general supervisor interview on May 10, 2018 at 10:00 A.M, it was determined that laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the requirements for general laboratory systems. The findings include: 1. The laboratory quality assessment records showed that personnel competence must be performed every year. 2. The laboratory did not evaluate the personnel competence since January 2017. Refer to D5209.

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 general supervisor interview on May 10, 2018 at 10:00 A.M., it was determined that laboratory director failed to ensure compliance with the general quality assessment (QA) requirements. Refer to D5291.

D6103

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(13)

The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:

Based on review of laboratory general supervisor (testing personnel) records and laboratory general supervisor interview on May 10, 2018 at 10:00 A.M., it was determined that the laboratory director did not evaluate the testing personnel competence. The findings include: 1. The General Supervisor (testing personnel) records files included competence evaluations. Refer to D 5209. 2. This deficiency was cited on the last survey performed on May 12, 2016.