

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D2026068	(X3) Date Survey Completed 06/21/2018
Name of Provider or Supplier Laboratorio Clinico Expreso	Street Address, City, State Road Pr-188 Street 22, Barrio Canovanas, Canovanas, 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
D2094	<p>ROUTINE CHEMISTRY CFR(s): 493.841(e)</p> <p>(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on P.R. Proficiency Testing Program records review (years 2016, 2017 and 2018) and laboratory director interview on June 21, 2018 at 10:00 AM, it was determined that the laboratory failed to take and document remedial actions when it obtained an unsatisfactory score of 60 per cent for glucose in the first event of the year 2017. The findings include: 1. On June 21, 2018 at 10:00 AM, the P.R. Proficiency Testing Program records showed that the laboratory did not take nor document remedial actions when it obtained an unsatisfactory score of 60 per cent for glucose in the February 2017's event. 2. The laboratory director confirmed on June 21, 2018 at 10:10 AM, that the laboratory did not take nor document remedial actions for the February 2017's event.</p>
D3031	<p>RETENTION REQUIREMENTS 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>

This STANDARD is not met as evidenced by:
 Based on lack of quality control records (years 2016 and 2017), laboratory director interview on June 21, 2018 at 10:20 AM, it was determined that the laboratory failed to retain analytic system records quality in the following laboratory areas: routine chemistry and hematology from January 2016 to September 2017. The findings include: 1. The laboratory did not retained the following records of the routine chemistry area from January 2016 to September 2017: a. Glucose testing records. b. Glucose quality control records. c. Stat Fax calibration records (Redi-check linearity plot and repeatability chart) 2. The laboratory did not retained the hematology records (Cell Dyn 3000 system - quality control chart) from march 2017 to September 2017. 3. The laboratory director confirmed on June 21, 2018 at 10:30 AM, that those records were not available in the laboratory. He stated that the routine chemistry records were lost due to Maria Hurricane Flash flood and the hematology records were lost due to problems with the hard disc of the Cell Dyn 3000 system.

D3039

RETENTION REQUIREMENTS
 CFR(s): 493.1105(a)(5)

Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years.

This STANDARD is not met as evidenced by:
 Based on lack of quality assessment records (years 2016 and 2017), laboratory director interview on June 21, 2018 at 10:20 AM, it was determined that the laboratory failed to retain quality assessment records from January 2016 to September 2017. The findings include: 1. The laboratory did not retained the retain quality assessment records (preanalytic, analytic and post analytic) from January 2016 to September 2017. 2. The laboratory director confirmed on June 21, 2018 at 10:30 AM, that those records were not available in the laboratory. He stated that the quality assessment records were lost due to Maria Hurricane Flash flood.

D6079

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1445(a)(b)

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 reapporions 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 quality control records (years 2016 and 2017), on lack of quality assessment records (years 2016 and 2017), laboratory director interview on June 21, 2018 at 10:20 AM, it was determined that the laboratory director failed to ensure that

the laboratory retained quality control and quality assessment records from January 2016 to September 2017 Refer to D 3031 (The laboratory failed to retain analytic system records quality in the following laboratory areas: routine chemistry and hematology from January 2016 to September 2017). Refer to D 3039 (The laboratory failed to retain quality assessment records from January 2016 to September 2017).

D6092

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(4)(iv)

The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Based on P.R. Proficiency Testing Program records review (years 2016, 2017 and 2018)and laboratory director interview on June 21, 2018 at 10:00 AM, it was determined that the laboratory director failed to take and document remedial actions when it obtained an unsatisfactory score of 60 per cent for glucose in the first event of the year 2017. Refer to D 2094.