

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0929576	(X3) Date Survey Completed 11/16/2018
Name of Provider or Supplier Laboratorio Clinico Espinosa	Street Address, City, State Carretera #2 Km 27 5 Barrio Espinosa, Dorado, 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
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> <p>This STANDARD is not met as evidenced by: Based on the monthly preventive maintenance of the Chem Well system record (years 2017 and 2018) review, lack of the Chem Well printouts for the alignments procedures and filter voltage checks and laboratory general supervisor interview on November 16, 2018 at 9:35 AM, it was determined that the laboratory did not retain printouts of the Chem Well system to demonstrate that the monthly preventive maintenance (the alignments procedures and filter voltage checks) were performed from February 2017 to August 2017 and from October 2018 to September 2018. The findings include: 1. The laboratory processed the glucose test and the lipid profile by the Chem Well system. 2. On November 16, 2018 at 9:35 AM, the preventive maintenance of the Chem Well system record showed that the laboratory did not retained the printouts of the Chem Well system for the the monthly preventive maintenance (the alignments procedures and filter voltage checks) from February 2017 to August 2017 and from October 2018 to September 2018. 3. The general supervisor confirmed November 16, 2018 at 9:35 AM, that the laboratory did not retained the printouts of those preventive maintenance.</p>
D6079	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b)</p> <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,</p>

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 the monthly preventive maintenance of the Chem Well system record (years 2017 and 2018) review, lack of the Chem Well printouts for the alignments procedures and filter voltage checks and laboratory general supervisor interview on November 16, 2018 at 9:35 AM, it was determined that the laboratory director failed to comply with the laboratory records retention requirements. Refer D 3031. (The laboratory did not retain printouts of the Chem Well system to demonstrate that the monthly preventive maintenance (the alignments procedures and filter voltage checks) were performed from February 2017 to August 2017 and from October 2018 to September 2018).

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 personnel competence records (years 2017 and 2018) review and interview with the laboratory supervisor on November 16, 2018 at 12:10 PM, it was determined that the laboratory director failed to establish and follow a protocol to ensure the annual competency evaluations of the following positions in the laboratory since January 2017: general supervisor, technical supervisor and technical consultant. The findings include: 1. On November 16, 2018 at 12:10 PM, the personnel competence records showed that the laboratory director did not evaluate since January 2018, the annual competence of the testing personnel who also fill the followings positions in the laboratory: general supervisor, technical supervisor and technical consultant. The laboratory director evaluated the competence of this personnel for the testing personnel responsibilities. 2. The laboratory supervisor confirmed on November 16, 2018 at 12:10 PM, that the laboratory director did not evaluated her for the responsibilities as general supervisor, technical supervisor and technical consultant.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether

supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of personnel records files and interview with the laboratory supervisor on November 16, 2018 at 12:10 PM, it was determined that the laboratory director did not specify the duties of the laboratory general supervisor and technical supervisor. The finding includes: 1. On November 16, 2018 at 12:10 PM, the general supervisor personnel files showed on November 16, 2018 at 12:10 PM, that the laboratory director did not specify on writing her duties and responsibilities as technical supervisor and technical consultant. 2. The general supervisor confirmed on November 16, 2018 at 12:10 PM, that her personnel file did not includes the require information.