

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D1031290	(X3) Date Survey Completed 07/26/2018
Name of Provider or Supplier Grefi Instituto De Fertilizacion En Vitro	Street Address, City, State 1519 Ave Ponce De Leon Oficina 705, San Juan, 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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing records review from February 2016 to June 2018 and laboratory testing personnel interview on July 26, 2018 at 9:28 AM, it was determined that the laboratory failed to maintain the proficiency testing event records. The findings include: 1. Review of proficiency testing records from February 2016 to June 2018, showed that the laboratory did not maintain the following proficiency testing event records: February 2017 and February 2018. 2. The laboratory testing personnel confirmed on July 26, 2018, that the laboratory did not maintain these proficiency testing event records.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p>

This STANDARD is not met as evidenced by:
Based on observations, preventive maintenance records review and laboratory testing personnel interview on July 26, 2018 at 10:22 AM, it was determined that the laboratory failed to follow manufacture's instructions for the preventive maintenance of the microscopes (Nikon Stereoscopic and Nikon Eclipse TE 200), flow cabinet (2), centrifuge incubator and eye wash station. The findings includes: 1. The manufacturer's instructions establishes that the laboratory must be verify the RPM of the centrifuge annually, perform the preventive maintenance of the microscopes (Nikon Stereoscopic and Nikon Eclipse TE 200) annually, change the HEPA filters and verify Air Velocity profile test of the Flow Cabinet annually and perform the preventive of eye wash solutions periodically. 2. The laboratory did not perform the preventive maintenance of centrifuge from September 4, 2014, microscopes from October 2013, Flow Cabinet from November 2012 and eye wash solutions from January 2017. 3. The laboratory testing personnel confirmed on July 26, 2018, that this preventive maintenance did not perform.

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 testing personnel interview on July 26, 2018 at 10:34 AM, it was determined that the laboratory director failed to ensure compliance with the requirements for analytic systems. The finding includes: 1. The laboratory director failed to ensure compliance with requirements for the preventive maintenance established by the manufacturer's instructions. Refer to D5429.