

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0671135	(X3) Date Survey Completed 10/26/2021
Name of Provider or Supplier Lab Clinico El Seniorial Inc	Street Address, City, State Ave Winston Churchill #180, Rio Piedras, 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
D2128	<p>HEMATOLOGY CFR(s): 493.851(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 Puerto Rico Proficiency Testing Program records reviewed and laboratory director interview on October 26, 2021 at 9:14 AM., it was determined that the laboratory failed to take and document corrective actions when it obtained unsatisfactory results in hematology specialties. The findings include: 1. Puerto Rico Proficiency Testing Program records were reviewed from February 2020 to October 2021. 2. Review of Proficiency Testing results showed that the laboratory obtained unsatisfactory results of 20 percent in differential white blood cell for 5 parameters instrument in March 2021. No remedial actions were taken. 3. The laboratory director confirmed on October 26, 2021, that the laboratory failed to take remedial actions when obtained unsatisfactory results of 20 percent in differential white blood cell for 5 parameters instrument in March 2021.</p>
D6018	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)</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, and record and report test results promptly, accurate, and proficiently</p>

and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

Based on Proficiency testing records review and laboratory director interview on October 26, 2021 at 9:14 AM, it was determined that the laboratory director did not fulfill her responsibilities to ensure that the laboratory failed to take remedial actions when obtained unsatisfactory results of 20 percent in differential white blood cell for 5 parameters instrument in March 2021. Refer D 2128.