

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D2117678	(X3) Date Survey Completed 10/24/2018
Name of Provider or Supplier Laboratorio Clinico Healthpromed	Street Address, City, State Ave Borinquen 2018, Bo Obrero, 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
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 Puerto Rico Proficiency Testing Program records review and laboratory director and general supervisor interview on October 24, 2018 at 9:55 A.M., it was determined that the laboratory failed to take and document corrective actions when it obtained an unsatisfactory results in routine chemistry specialties. The findings include: 1. Puerto Rico Proficiency Testing Program records and results were reviewed since February 2017 to July 2018. 2. Review of Proficiency Testing records showed that the laboratory obtained unsatisfactory results of 0 percent for Albumin tests in June 2018 (second testing event). No remedial actions were taken. 3. The laboratory director and general supervisor confirmed on October 24, 2018, that the laboratory did not take corrective actions in this event.</p>
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,</p>

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.

This STANDARD is not met as evidenced by:
Based on Puerto Rico Proficiency Testing Program records review and laboratory director and general supervisor interview on October 24, 2018 at 9:58 AM, it was determined that the laboratory failed to take and document corrective actions when it obtained an unsatisfactory results in hematology specialties. The findings include: 1. Puerto Rico Proficiency Testing Program records and results were reviewed from February 2017 to July 2018. 2. Review of Proficiency Testing records showed that the laboratory obtained unsatisfactory results of 52 percent in Differential White Blood Cell tests on March 2017 (Puerto Rico first testing event). No remedial actions were taken. 3. The laboratory director and general supervisor confirmed on October 24, 2018, that the laboratory did not take corrective actions in this event.

D6019

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iv)

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 and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:
Based on Puerto Rico proficiency testing records review and laboratory director and general supervisor interview on October 24, 2018 at 9:55 AM, it was determined that the laboratory director failed to establish and follow a corrective action plan when the laboratory obtained an unsatisfactory result. The finding includes: 1. The laboratory obtained 52 percent in Differential White Blood Cell tests on March 2017 (Puerto Rico first testing event) and 0 percent for Albumin tests in June 2018 (second testing event). No remedial actions were taken nor document.