

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0658019	(X3) Date Survey Completed 05/31/2024
Name of Provider or Supplier Laboratorio Clinico Galeria Santa Cruz	Street Address, City, State St Cruz St B6 Urb Santa Cruz, Bayamon, 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
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on review of proficiency testing records (years 2023-2024), it was determined that the laboratory failed to attain successful participation in a Proficiency Testing Program for hematology subspecialty. Refer to D2130.</p>
D2130	<p>HEMATOLOGY CFR(s): 493.851(f)</p> <p>Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.</p>

This STANDARD is not met as evidenced by:
Based on review of proficiency testing records (years 2023-2024), it was determined that the laboratory failed to achieve satisfactory performance in two consecutive testing events for WBC (Whole Blood Cell) Diff 6 parameter tests. The finding includes: 1. The laboratory obtained unsatisfactory results for WBC (White Blood Cell) Diff 6 parameter in third testing event for year 2023 (23%) and first testing event for year 2024 (23%).

D6076

LABORATORY DIRECTOR
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:
Based on review of proficiency testing records (years 2023-2024), it was determined that the laboratory director failed to ensure the laboratory's successful participation in a Proficiency Testing Program for hematology tests. Refer to D2130.