

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0960584	(X3) Date Survey Completed 05/29/2024
Name of Provider or Supplier Laboratorio Clin Sangermeno Principal	Street Address, City, State Calle Principal # 19, Urb El Retiro, San German, 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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of general supervisor, testing personnel and clinical consultant records and laboratory director interview on May 29, 2024 at 10:20 AM , it was determined that the laboratory failed to follow written policies to assess the testing personnel, clinical consultant and general supervisor competency. The findings include: 1. The laboratoy schedule for testing personnel, general supervisor and clinical consultant competency evaluation showed that it must be done every year. Reviewed on May 29, 2024 at 10:20 AM. 2. The testing personnel, laboratory general supervisor and clinical consultant records were reviewed since January 2022. Reviewed on May 29, 2024 at 10:25 AM. 3. The personnnel records of the general supervisor showed that the last competence was performed in June 2022. Reviewed on May 29, 2024 at 10:28 AM. 4. The personnnel records of the clinical consultant showed that the last competence was performed in June 2022. Reviewed on May 29, 2024 at 10:33 AM. 5. The personnnel records of the testing personnel showed that the last competence was performed in June 2022. Reviewed on May 29, 2024 at 10:35 AM. 6. The laboratory technical supervisor failed to perform the annual competency evaluation to the testing personnel, general supervisor and clinical consultant since June 2022. 7. The laboratory director confirmed on May 29, 2024 at 10:45 AM did not perform the annual competency evaluation to the testing personnel, general supervisor and clinical consultant since June 2022.</p>
D6103	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)</p>

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 records review and laboratory director interview on May 29, 2024 at 10:20 AM, it was determined that the laboratory failed to follow the established schedule evaluation for testing personnel, clinical consultant and general supervisor laboratory. The findings include: 1. The director and the technical supervisor of this laboratory are the same person. 2. The laboratory schedule for testing personnel, general supervisor and clinical consultant competency evaluation showed that it must be done every year. 3. The laboratory director failed to perform the annual competency evaluation to the testing personnel, general supervisor and clinical consultant since June 2022. 4. The laboratory director confirmed on May 29, 2024 at 10:45 AM did not perform the annual competency evaluation to the testing personnel, general supervisor and clinical consultant since June 2022.