

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  40D2275917	<b>(X3) Date Survey Completed</b>  11/27/2024
<b>Name of Provider or Supplier</b>  Laboratorio Clinico Familiar Zarza	<b>Street Address, City, State</b>  Carr 2, Km 90 Interior Sector Zarza Bo Puente, Camuy, PR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The Centers for Medicare & Medicaid Services (CMS) conducted an unannounced CLIA recertification survey at Laboratorio Clinico Familiar Zarza on November 27, 2024. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. The following standard level deficiencies were found during the unannounced routine CLIA recertification survey ending on November 27, 2024.
<b>D5787</b>	<p><b>TEST RECORDS</b> CFR(s): 493.1283(a)</p> <p>The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).</p> <p>This STANDARD is not met as evidenced by: Based on Human Chorionic Gonadotropin (hCG) patient's test worksheet records review and interview with the laboratory director on November 27, 2024 at 10:35 AM; it was determined that the laboratory failed to include the the final patients test result in the worksheet used to document the hCG patient's samples. From August 10, 2023 to November 22, 2024 the laboratory processed and reported 18 patients specimen result. The findings include: 1. On November 27, 2024 at 10:05 AM,the hCG testing records were reviewed. Showing that the laboratory did not include the final patient's test result in the worksheet. The laboratory documented the patient identification and the procedural controls, but not the final test result. 2. On November 27, 2024 at 10:35 AM; the laboratory director confirmed that the laboratory failed to</p>

include the patients final test result in the worksheet, from August 10, 2024 to November 22, 2024. The laboratory processed and reported 18 patients specimen samples.

**D6020**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(5)

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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:  
Based on hCG patient test records review and interview with the laboratory director on November 27, 2024 at 10:35 AM; it was determined that the laboratory director (sole personnel) did not ensure that the final test results were documented on the worksheet records. Refer to D5787.