

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0658298	(X3) Date Survey Completed 06/10/2025
Name of Provider or Supplier Laboratorio Clinico Risan	Street Address, City, State Ave Roberto Sanchez Vilella Urb Country Club, Carolina, 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
D0000	The Centers for Medicare & Medicaid Services (CMS) conducted an unannounced CLIA Recertification survey at the Laboratorio Clinico Risan on June 10, 2025. 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 June 10, 2025.
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>(b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on review of the general immunology specialty test, verification of performance specifications, Mycoplasma pneumoniae IgM laboratory worksheet records and laboratory testing personnel interview on June 10, 2025 at 10:35 AM, it was determined that the laboratory failed to performed the verification specifications when introduces new test system before reporting patient results. The laboratory processed and reported four (4) patient samples from May 28, 2025 to June 2, 2025. The findings include: 1. The Mycoplasma pneumoniae IgM test by Meridian was implemented on May 28, 2025. 2. On June 10, 2025 at 10:31 AM, the verification of performance specifications were requested. The testing personnel stated that the verification of performance specifications was not performed. 3. On June 10, 2025 at 10:35 AM, review of the laboratory worksheet record of Mycoplasma pneumoniae</p>

	<p>IgM by Meridian and showed that the laboratory performed and reported four (4) patient samples from May 28, 2025 to June 2, 2025. 4. The laboratory testing personnel confirmed that laboratory failed to performed the verification specifications when introduces a new test system before reporting patient results. The laboratory processed and reported four (4) patient samples from May 28, 2025 to June 2, 2025.</p>
<p>D5445</p>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>(d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for:</p> <p>This STANDARD is not met as evidenced by: Based on the syphilis serology quality control records reviewed, manufacturer instructions and laboratory testing personnel interview on June 10, 2025 at 11:25 AM, it was determined that the laboratory did not include the reactive; weakly-reactive and non-reactive control material each day of patients testing. The laboratory processed and reported 37 patients sample from May 3, 2025 to June 9, 2025. The findings include: 1. The manufacturer's instructions were reviewed on June 10, 2025 at 11:02 AM; the manufacturer established that the reactive; weakly-reactive and non-reactive control material must be performed every day of patients testing. 2. Review of the syphilis serology quality control records on June 10, 2025 at 11:05 AM, showed that the laboratory did not perform the reactive; weakly-reactive and non-reactive control material each day of patient testing. The laboratory processed and reported 37 patients sample from May 3, 2025 to June 9, 2025. 3. The laboratory testing personnel confirmed on June 10, 2025 at 11:25 AM, that the laboratory failed to include the reactive; weakly-reactive and non-reactive control material each day of patients testing. The laboratory processed and reported 37 patients sample from May 3, 2025 to June 9, 2025.</p>
<p>D6020</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;</p> <p>This STANDARD is not met as evidenced by: Based on review of the quality control records, verification of performance specifications and interview with the laboratory testing personnel on June 10, 2025 at 12:20 PM; it was determined that the laboratory director did not ensure that the quality control and that were establish were follow. D5421; D5445.</p>
<p>D6068</p>	<p>TESTING PERSONNEL RESPONSIBILITIES</p>

CFR(s): 493.1425

The testing personnel are responsible for specimen processing, test performance, and for reporting test results.

This STANDARD is not met as evidenced by:

Based on the Rapid Reagin Plasma (RPR) quality control records, patient worksheet records and interview with the testing personnel on June 10, 2025 at 12:28 PM; it was determined that the laboratory testing personnel fail to include a control material when processed and reported patient's samples for RPR from May 3, 2025 to June 9, 2025. The laboratory processed and reported 37 patient samples without the control material. Refer to D5445.