

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D2084587	(X3) Date Survey Completed 09/04/2026
Name of Provider or Supplier Laboratorio Clinico Citka	Street Address, City, State Carr 109, Km 5 Hm 4 Bo Espino, Anasco, 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 Citka on September 4, 2026. 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 September 4, 2026.
D5451	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iii)(g) (d)(3)(iii) Test procedures producing graded or titered results, include a negative control material and a control material with graded or titered reactivity, respectively; This STANDARD is not met as evidenced by: Based on the Rheumatoid factor (RA) quality control records (2026), patient's worksheet records and interview with the laboratory director on September 4, 2026 at 11:15 A.M.; the laboratory fail to include control material with graded reactivity when processed and reported patient samples for RA dilutions. The laboratory processed and reported seven (7) patient's samples without the serial dilution quality control. The findings includeare: 1.The laboratoty begin to perform Rheumatoid factor (RA) test on May 2026. 2. The patient worksheet records were reviewed on September 4, 2026 at 11:15 A.M. and showed that the laboratory performed a serial dilution in every reactive patient's of RA. 2. The RA quality control records were reviewed on September 4, 2026 at 11:15 A.M. and showing that the laboratory did not include a control material with graded reactivity the following days : 5/14/26, 5/19/26, 6/6/26, 7/16/26, 7/20/26, 8/21/26 and 9/1/26. The laboratory processed and reported seven (7) patient's with graded reactivity. 3. The laboratory director confirmed onSeptember 4, 2026 at 11:20 A.M. that the laboratory fail to include a control material with graded reactivity when processed and reported patient's samples for RA graded reactivity those days. .

D6020

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

(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;

This STANDARD is not met as evidenced by:

Based on Rheumatoid factor (RA) quality control records review (2026) and laboratory director interview on September 4, 2026 at 11:30A.M., the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the RA quality control requirements. Refer to D5451.