

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D2083497	(X3) Date Survey Completed 09/23/2026
Name of Provider or Supplier Cdt Maricao Medical Center, Llc	Street Address, City, State Ave Luchetti # 11, Maricao, 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 Clinical Laboratory Improvement Amendments (CLIA) recertification survey at CDT Maricao Medical Center, LLC on September 23, 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 23, 2026.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on review of the CMS-209 Laboratory Personnel Report, laboratory personnel record, the laboratory's competency assessment policy, and interview with Testing Personnel (TP) #3 on September 23, 2026, at 9:00 a.m., the Technical Consultant failed to follow its established annual competency assessment schedule for 1 of 1 Clinical Consultant (CC #1) for year 2025. The findings include: 1. The CMS-209 Laboratory Personnel Report identified employee #1 as the Clinical Consultant (CC). 2. The laboratory personnel record included a competency assessment for the Clinical Consultant covering January through December 2024. The assessment was signed in February 2025. 3. The laboratory's competency assessment policy stated that the laboratory personnel would receive a competency assessment annually. 4. On September 23, 2026, at 9:05 a.m., the Clinical Consultant's competency assessment documentation was requested. The laboratory did not provide documentation of an annual competency assessment for year 2025. 5. During an interview on September 23, 2026, at 9:10 a.m., TP #3 confirmed that no competency assessment was completed for the Clinical Consultant for year 2025.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

(b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on review of the CMS-209 Laboratory Personnel Report, laboratory personnel record, the laboratory's competency assessment policy, and interview with Testing Personnel (TP) #3 on September 23, 2026, at 9:20 a.m., the Technical Consultant failed to evaluate and document the TP #3 competency at least semiannually during the first year of patient testing (February 2025 through February 2026). The findings include: 1. The CMS-209 Laboratory Personnel Report identified employee #3 as Testing Personnel (TP). 2. The laboratory personnel record showed that TP #3 was hired in February 2025. 3. The laboratory's competency assessment policy stated that the laboratory personnel would receive a competency assessment annually and newly hired personnel would receive competency assessments twice during their first year of employment. 4. On September 23, 2026, at 9:25 a.m., TP #3 competency assessment documentation was requested. The laboratory personnel record showed only an initial competency assessment completed in February 2025. The laboratory did not provide documentation of a subsequent competency assessment at approximately six months (August 2025) or at the completion of the first year of patient testing (February 2026). 5. During an interview on September 23, 2026, at 9:30 a.m., TP #3 confirmed that no additional competency assessments were completed after the initial competency assessment in February 2025.