

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0997906	(X3) Date Survey Completed 03/15/2023
Name of Provider or Supplier La Clinica Del Nino Pc DbA Interntl Ped Clinic	Street Address, City, State 3780 Holcomb Bridge Road Suite C, Norcross, GA	
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	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on March 15, 2023. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
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 laboratory competency policy review and staff interview, the Laboratory Director (LD) failed to follow the 6-step criteria for competency for hematology testing. The Findings include: 1. Competency document review revealed the Laboratory Director failed to follow the 6-step criteria as required by regulation for the competency for the testing personnel. The competency that the facility performed was not detailed to cover all 6-step criteria including: direct observation of test performance, monitor results, review of worksheets, QC, PT, and maintenance records, direct observation of instrument maintenance reporting, assessment of proficiency testing, and assessment of problem solving. 2. During an interview on March 15, 2023 with the Testing Personnel #1(CMS-209), at 1:25 PM, in a back office, in the facility, confirmed that the Laboratory Director failed to follow the 6-step criteria for competency for hematology testing.</p>