

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0880382	(X3) Date Survey Completed 05/04/2021
Name of Provider or Supplier Comprehensive Pediatrics Pc	Street Address, City, State 1407 West 6th Street, Brooklyn, NY	
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
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor's review of the ESA Lead Care II Quality Control (QC) records, analyzer manual and an interview with the testing person, the laboratory failed to follow the Magellan Diagnostic Lead Care manufacturer's QC requirements from 1/2 /2019 through survey date. FINDINGS: The testing person confirmed on May 4, 2021 at approximately 2:30 PM, the laboratory did not perform and document the QC results for Lead Care II Controls I & II for the following lots Lot # 1806M expiration date 10-03-2019 and Lot# 2012M expiration date 04/08/2022. Approximately 75 patient specimens were tested and reported 1/2/2019 through survey date.</p>