

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  33D0968835	<b>(X3) Date Survey Completed</b>  04/21/2023
<b>Name of Provider or Supplier</b>  Bambini Pediatrics Pc	<b>Street Address, City, State</b>  207 Washington St, Suite 103, Poughkeepsie, NY	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D1001</b>	<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 review of the Siemens Multistix 10SG package insert, lack of Quality Control (QC) records, and interviews with the technical consultant and practice manager, the laboratory failed to follow the Siemens Multistix reagent strip manufacturer's instructions for testing and documenting QC material when a new vial was opened or every 30 days. FINDINGS: 1. No Siemens urine Multistix 10SG test strip QC records were available from August 1, 2022, through the survey date. 2. The technical consultant and practice manager confirmed on April 21, 2023, at approximately 11:15 A.M. that the laboratory performed but did not document the results. 3. Approximately 300 patients were tested during the respective period.</p>