

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 33D0883907	<b>(X3) Date Survey Completed</b> 07/15/2025
<b>Name of Provider or Supplier</b> Parkway Pediatric Associates	<b>Street Address, City, State</b> 1360 Ocean Parkway, Suite 1 E, Brooklyn, 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><b>CERTIFICATE OF WAIVER TESTS</b> CFR(s): 493.15(e)</p> <p>493.15(e) 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 direct observations, review of test records, standard operating procedures (SOPs), as well as interview with the Laboratory Director (LD), the laboratory failed to remove expired waived test kit reagents from inventory. FINDINGS: 1. The surveyor's observations in the laboratory confirmed on July 15, 2025, at approximately 2:00 P.M. the following waived test reagents were not removed from inventory: a. Roche Chemstrip 10 MD Urine Reagent Strip, expiration: June 30, 2024. 2. The LD informed the surveyor that the urine reagent strips were utilized for patient specimen processing. Approximately nineteen patient specimens were processed utilizing the expired urine reagent strips. 3. The current, approved SOPs did not include instructions for removing expired reagents from inventory. 4. The LD confirmed the findings on July 15, 2025, at 2:00 P.M.</p>