

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  34D0992586	<b>(X3) Date Survey Completed</b>  09/09/2021
<b>Name of Provider or Supplier</b>  Cpn, Inc, DbA Atrium Health Primary Care	<b>Street Address, City, State</b>  2700 Providence Road South, Suite 300, Waxhaw, NC	
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 surveyor observation, review of manufacturer instructions and interview with technical consultant (TC) 9/9/21, the laboratory failed to dispose of one expired test kit for the Acceava Strep A testing. One patient was tested after the expiration date of 8/31/21. Findings: Surveyor observed one Acceava Strep A test kit, Lot #STA9092004, available for use on the laboratory counter top with an expiration date of 8/31/21. Review of manufacturer instructions revealed "Storage and Stability...Do not use beyond the expiration date.". Interview with surveyor at approximately 12:00 p.m. confirmed the test kit for Acceava Strep A expired on 8/31/21. She also confirmed one patient was tested on 9/1/21.</p>