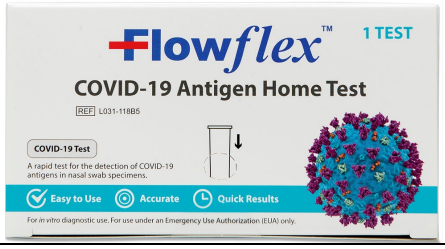
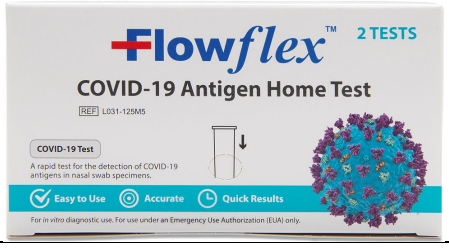
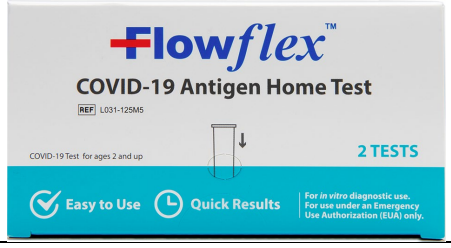
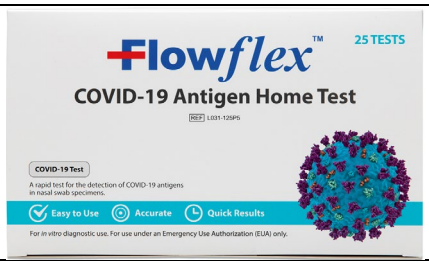
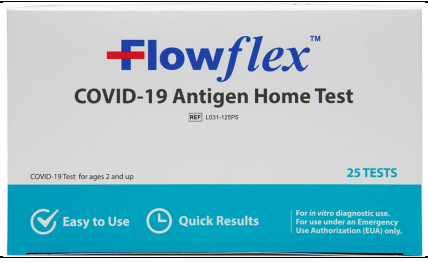
March 10, 2023

On November 1st, 2022, the U.S. Food & Drug Administration (FDA) issued a Repeat Testing Revision Letter titled "*Revisions Related to Serial (Repeat) Testing for the EUAs of Antigen IVDs*" to all Antigen *In Vitro* Diagnostics (IVDs) developers. That letter was intended to revise all current Emergency Use Authorizations (EUAs) for SARS-CoV-2 antigen IVD devices. The new intended use for the Flow*flex*® COVID-19 Antigen Home Test and all other COVID antigen tests includes serial testing at least twice over three days for individuals with symptoms of COVID-19, and serial testing at least three times over five days for individuals without symptoms of COVID-19.

ACON Laboratories, Inc. has conformed with FDA's request and updated Flow*flex* labeling has been accepted by the FDA. In the coming weeks, electronic (PDF) copies of the new OTC Instructions For Use (IFU) will be sent out and made available at FlowflexCOVID.com.

In addition to the new serial testing claim, ACON has introduced a fresh, new look to the Flow*flex* COVID-19 Antigen Home Test kit boxes. A side-by-side comparison of the old versus new packaging is shown below:

Kit Configuration	Old Packaging	New Packaging
1 Test/Kit REF#: L031-118B5 UPC: 682607660261		
		
2 Tests/Kit REF#: L031-125M5 UPC: 682607660278		

5 Tests/Kit REF#: L031-125N5 UPC: 682607660285		
25 Tests/Kit REF#: L031-125P5 UPC: 682607660476		

Note: The change in packaging will not affect the product's current Catalog Number (REF#) and the Universal Product Code (UPC).

For questions about the new intended use or Flow*flex* packaging, please email info@aconlabs.com or contact your sales representative.

We value your business and appreciate your patience as we make this transition.

Sincerely,

Michael Lynch
Vice President, Sales and Marketing