The text in the box on this insert applies to US Customers only

Hologic, Inc.
Direct Load Capture Cap Collection Kit - FLOQSwabs®
Rx Only

For in vitro diagnostic use

This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.

For use under an Emergency Use Authorization (EUA) Only

When used with the Aptima SARS-CoV-2 assay, this product has been authorized for the collection and maintenance of mid-turbinate nasal and nasopharyngeal swab specimens as an aid in detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.

When used with the Aptima SARS-CoV-2/Flu assay, this product has been authorized for the collection and maintenance of nasopharyngeal swab specimens as an aid in detection of nucleic acid from SARS-CoV-2, Flu A, and/or Flu B, not for any other viruses or pathogens.

The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated, or authorization is revoked sooner.

The Direct Load Capture Cap Collection Kit - FLOQSwabs® is for use with the Aptima SARS-CoV-2 assay and Aptima SARS-CoV-2/Flu assay only.

The collection kit instructions for use describe how to perform specimen collection. The current electronic instructions for use for the Direct Load Capture Cap Collection Kit - FLOQSwabs® are available at https://www.hologic.com/package-inserts.

To request a paper copy of the instructions for use of the Direct Load Capture Cap Collection Kit - FLOQSwabs®, free of charge, please contact Hologic Technical Support at molecularsupport@hologic.com.

This product information card does not contain the full instructions for use.