

Hologic, Inc.

Direct Load Capture Cap Collection Kit - CLASSIQSwabs™

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

bg Текстът в полето на тази вложка важи само за клиенти от САЩ **hr** Tekst u kutiji na ovom umetku primjenjuje se samo za kupce u SAD **cz** Tato část textu příbalového letáku uvedená v rámečku se týká pouze zákazníků v USA. **da** Teksten i feltet på denne indlægsseddel gælder kun for kunder i USA **nl** De omkaderde tekst in deze bijsluiter geldt alleen voor klanten in de VS **et** Infolehel olev raamiga ümbritsetud tekst kehtib üksnes USA klientidele **fi** Tämän selosteen ruudussa oleva teksti koskee vain USA:ssa olevia asiakkaita **fr** Le texte encadré sur cette notice s'applique uniquement aux clients des États-Unis **de** Der eingerahmte Text in der Packungsbeilage betrifft nur Kunden in den USA **el** Το κείμενο στο πλαίσιο σε αυτό το ένθετο ισχύει μόνο για πελάτες των Ηνωμένων Πολιτειών **hu** A betegtájékoztató a keretben lévő szöveg csak az amerikai ügyfelekre vonatkozik **it** Il testo nella casella in questo inserto si applica solo ai clienti statunitensi **lv** Šajā instrukcijā iezīmētais teksts attiecas tikai uz ASV klientiem. **lt** Šio intarpo langelio tekstas taikomas tik JAV klientams **no** Teksten i i feltet på denne innleggsseddelen gjelder bare kunder i USA **pl** Tekst umieszczony w ramce na tej wkładce dotyczy tylko klientów z USA **pt** O texto na caixa deste folheto aplica-se apenas aos clientes dos EUA **ro** Textul din caseta din acest prospect este valabil exclusiv pentru clienții din SUA. **sk** Táto časť textu písomnej informácie pre používateľov uvedená v rámčeku sa týka len zákazníkov v USA. **sl** Besedilo v okvirčku tega priloženega navodila velja samo za kupce v ZDA. **ei** El texto contenido en el cuadro de este prospecto se aplica únicamente a los clientes de EE. UU. **sv** Texten i rutan på denna bipacksedel gäller endast för kunder i USA.

- 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 anterior nasal (nasal) and oropharyngeal 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 anterior nasal (nasal) 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 - CLASSIQSwabs™ 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 -CLASSIQSwabs™ 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 - CLASSIQSwabs™, free of charge, please contact Hologic Technical Support at molecularsupport@hologic.com
- This product information card does not contain the full instructions for use