

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 rámečku 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.

AW-26037 Rev. 001

HOLOGIC® Direct Load Tube Collection Kit

Hologic, Inc.

- Rx Only
- For *in vitro* diagnostic use
- For use under an Emergency Use Authorization (EUA) Only
- 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
- 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 Tube collection kit 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 Tube collection kit are available at <https://www.hologic.com/package-inserts>
- To request a paper copy of the instructions for use of the Direct Load Tube collection kit, free of charge, please contact Hologic Technical Support at molecularsupport@hologic.com
- This product information card does not contain the full instructions for use