

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 Teks 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 Vahelehel 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 betegájékoztatón 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 įtarpas langelio teksta taikomas tik JAV klientams

no Teksten i denne esken på dette vedlegget 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 se aplică exclusiv clienților din SUA.

sk Táto časť textu písomnej informácie pre používateľov uvedená v rámečku sa týka len zákazníkov v USA.

sl Besedilo v okencu tega vstavka 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.
- This product has been authorized only for the 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 Aptima SARS-CoV-2/Flu controls kit is for use with the Aptima SARS-CoV-2/Flu assay only. The Aptima SARS-CoV-2/Flu assay instructions for use describe how to perform controls testing. The current electronic instructions for use for the Aptima SARS-CoV-2/Flu assay are available at <https://www.hologic.com/package-inserts>
- To request a paper copy of the instructions for use of the Aptima SARS-CoV-2/Flu assay, free of charge, please contact Hologic Technical Support at molecularsupport@hologic.com
- This product information card does not contain the full instructions for use.