

ARTWORK SPECIFICATION

1 The supplier will use the following information:

- 1.1 ARTWORK: AW-25579 Rev. 001
- 1.2 COLOR(s): PMS 2756
- 1.3 PRINT REGISTRATION TOL.: ± 0.03125"

NOTES TO SUPPLIER: TWO SIDE PRINTING

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 přibalového letáku uvedená v rámciku se týká pouze zákazníků v USA. **da** Teksten i fellet 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 selosteeseen kuulussa 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 įtarpų langelio tekstas 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 rámciku sa týka len zákazníkov v USA. **sl** Besedilo v okencu tega vstavka velja samo za kupce v ZDA. **es** 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-25579 Rev. 001

Side 1

- 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 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 controls kit is for use with the Aptima SARS-CoV-2 assay only. The Aptima SARS-CoV-2 assay instructions for use describe how to perform controls testing. The current electronic instructions for use for the Aptima SARS-CoV-2 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 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.

Side 2