Panther Fusion®

REF PRD-06391

SARS-CoV-2 Primer Probe Reagent Mix

<u>Σ</u>₁₆₀

For Use Under an Emergency Use Authorization (EUA) Only





(01) 15420045513440 (17) 250715 (10) 123456PV

LOT 123456PV

- 2025-07-15
- 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 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 current electronic instructions for use are available at
- https://www.hologic.com/package-inserts
 To request a paper copy of the instructions for

use free of charge, please contact Hologic Technical Support at molecularsupport@hologic.com

Hologic, Inc.

10210 Genetic Center Drive San Diego, CA 92121 USA

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