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As part of our commitment to complying with FDA's Emergency Use Authorization (EUA), we request that you carefully review FDA EUA Letter and package insert attached to ensure that you and your customers adhere to the requirements outlined in the EUA.

By purchasing and using/distributing this product you acknowledge that:

- This is test is for non-prescription home use for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 from individuals within 7 days of symptom onset or without symptoms of COVID-19 infection.
- This test is authorized for non-prescription home use with self-collected anterior nasal swab specimens directly from individuals aged 14 years and older or with adult-collected anterior nasal samples directly from individuals aged 2 years or older.
- This test has not been FDA cleared or approved, but has been authorized by FDA under an EUA.
- This product has been authorized only for the detection of proteins 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. § 360bbb3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
- Negative results should be treated as presumptive, and do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.
- You will inform parties about the EUA for this product, including the terms and conditions herein, and any updates made, and authorized labeling.
- Through a process of inventory control, you will maintain records of the where the tests are distributed and number of tests distributed.
- You will report to FDA any suspected occurrence of false positive and false negative results and significant deviations from the established performance characteristics of the product of which you become aware.