## .: 4U Health

## Ith COVID-19 Self-Collected Antibody Test System

• For in vitro diagnostic only

- For prescription use only
- For Emergency Authorization Use Only For use by individuals age 18 years or older or by adults collecting specimens from individuals 5 years of age and older.



• This self-collection kit is used as part of a test system. This test system has not been FDA cleared or approved but has been authorized for emergency use by FDA under an EUA for use by Symbiotica Inc., located at 1350 Burton Drive, Vacaville, CA 95687;

• This test system has been authorized only for detecting IgG antibodies to SARS-CoV- 2, not for any other viruses or pathogens; and

• The emergency use of this test system 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.

Testing services performed by 🛞 symbiotica

Questions or Concerns? Contact 4U Health, Inc. at help@4uhealth.com or call 866-610-1200.