

Guidance on Rapid antibody kits for COVID-19

Not recommended for diagnosis of COVID-19 infection

- Can be done on blood/serum/plasma samples
- Test result is available within 30 minutes
- Test comes positive after 7-10 days of infection
- The test remains positive for several weeks after infection
- Positive test indicates exposure to SARS-CoV-2
- Negative test does not rule out COVID-19 infection

These tests are not recommended for diagnosis of COVID-19 infection

List of CE-IVD approved antibody based rapid kits

1. COVID-19 IgM-IgG Dual Antibody Rapid Test (CE-IVD): **BioMedomics** (+1- 9198903070, info@biomedomics.com, USA)
2. One Step Test for Novel Coronavirus (2019-nCoV) IgM/IgG antibody (Colloidal Gold) (CE-IVD): **Getein Biotech** (+86-25-68568594, sales@getein.com, overseas@getein.com.cn, Nanjing, China)
3. COVID 19 Rapid Test Kit (IgM/IgG) (CE-IVD) (**Sensing Self Ltd**, Singapore.), also validated by NIV, Pune
4. COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) (CE- IVD): **Hangzhou Biotech Biotech Co.,Ltd.** (info@alltests.com.cn, +86-57- 158120625, China)
5. COVID-19 IgM/IgG test kit (CE-IVD) (**AmonMed Biotechnology Co. Ltd**, info@amonmed.com)
6. COVID-19 Antibody (IgG/IgM)Test Kit (CE-IVD) (**Beijing Abace Biology Co., Ltd.**, huanqi.cheng@rd.abace-biology.com)
7. Tigsun COVID-19 Combo IgM/IgG Rapid Test (CE-IVD) (**Beijing Tigsun Diagnostics Co.,Ltd.**, hu.duan@tigsun.com)
8. 2019-nCoV IgG/IgM Rapid Test Cassette (CE-IVD) (**BIOMAXIMA S.A**, Poland, export@biomaxima.com)
9. OnSite COVID-19 IgG/IgM Rapid Test (CE-IVD) (**CTK Biotech, Inc.**, USA, sparker@ctkbiotech.com)
10. COVID-19 IgG/IgM Detection Kit (Colloidal Gold) (CE-IVD) (**Hunan Lituo Biotechnology Co., Ltd.**)
11. VivaDiag SARS-CoV-2 IgM/IgG rapid test. (CE-IVD) **Vivacheck Lab** (91- 4448544811, info@vivacheck.com, vivachek.india@gmail.com India office: Tamil Nadu)
12. COVID-19 Antibody Kit Serological Test. (CE-IVD) **GenSure Biotech Inc.**, <https://www.ozo.life> (+91 7021901240, tarshant@ozo.life India Office: Bangalore)

Antibody based rapid kit are validated by ICMR-NIV, Pune

1. SARS-CoV-2 Antibody Test: **Wondfo** (+86-3032296083, sales@wondfo.com.cn, China), validated by NIV, Pune

This is an evolving list, and kits which will get CE/FDA approval or validated by NIV Pune will be added.