

## SARS-CoV-2 Neutralizing Antibody Rapid Test Kit (Colloidal Gold)

For In-Vitro Diagnostic and Professional Use Only

Untuk Kegunaan Diagnostik In-Vitro dan Kegunaan Profesional Sahaja

**Rapid Detection of Antibody - Available Now**

**Ujian Rapid Keberkesanan Antibodi - Boleh Didapati Sekarang**

This product utilizes the chromatographic immunoassay to qualitatively detect the neutralizing anti-S antibody in human whole blood, serum, and plasma to SARS-CoV-2.

Produk ini menggunakan immunoassay kromatographi untuk mengesan antibodi peneutralan anti-S secara kualitatif terhadap jangkitan SARS-CoV-2 dalam darah, serum dan plasma.



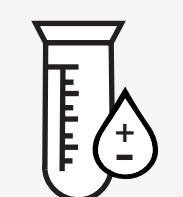
**HIGH ACCURACY**, high sensitivity and specificity  
**KETEPATAN YANG TINGGI**, kepekaan dan spesifikasi yang tinggi



**FAST RESULTS** within 20 minutes  
**HASIL UJIAN YANG CEPAT** dalam 20 minit



**RELIABLE**, clinically approved for detection of neutralizing anti-S antibody  
**DIYAKINI**, diluluskan secara klinikal untuk pengesanan antibodi peneutralan anti-S



**SIMPLE ASSAY PROCEDURE**, using fingertip whole blood/serum/plasma  
**PROSEDUR UJIAN YANG RINGKAS**, dengan menggunakan darah jari/serum/plasma



**10 cassettes per kit | 10 kaset setiap kit**

### Materials Provided

1 x Instruction for Use (Manual)  
10 x Test Cassette (sealed in foil pouch)  
10 x Sample Diluent  
10 x Blood Lancet  
10 x Disposable Micropipette  
1 x Bulb for Pipet  
10 x Alcohol Pad

### Bahan yang dibekalkan

1 x Arahkan Penggunaan (Manual)  
10 x Alat Ujian (dalam kantung foil)  
10 x Sampel Pencair  
10 x Lanset Darah  
10 x Mikropipet Pemandahan Pakai Buang  
1 x Mentol untuk Pipet  
10 x Pad Alkohol

MDA Reg.No: IVDC3593722-105274

### Clinical Performance | Prestasi Klinikal:

|             |             |        |
|-------------|-------------|--------|
| Specificity | Spesifikasi | 97.50% |
| Sensitivity | Sensitiviti | 98.14% |
| Consistency | Konsistensi | 97.83% |

\*Confidence Interval 95.00%  
95.00% Selang Keyakinan

### Interpretation of Anti-S Antibody Results Based On Vaccination Status

| Vaccination Status | Anti-S Antibody | Interpretation                             |
|--------------------|-----------------|--------------------------------------------|
| Vaccinated         | +               | Vaccinated and previously infected         |
| Vaccinated         | +               | Vaccinated and not previously infected     |
| Unvaccinated       | +               | Not vaccinated and previously infected     |
| Unvaccinated       | -               | Not vaccinated and not previously infected |



\*Disclaimer: A +ve antibody result will not indicate if it is due to vaccination or a previous COVID-19 infection