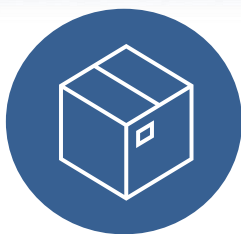
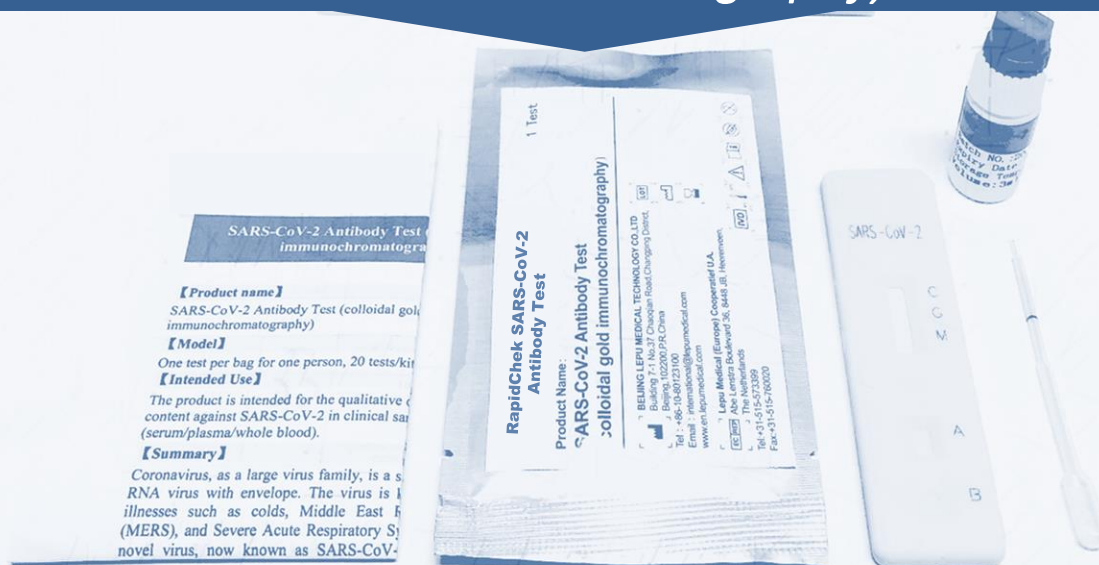




SARS-CoV-2 Antibody Test (colloidal gold immunochromatography)



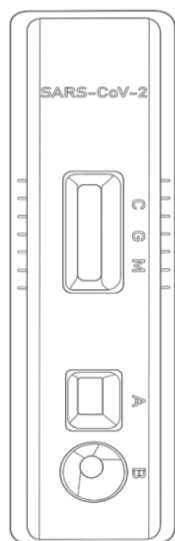
KIT CONTENT

- Model of 20 tests
- 1 bottle of desiccant for 20 tests
- For each test :
 - One testing strip
 - Gold Standard mat (colloidal gold labeled COVID-19 recombinant protein)
 - Sample mat
 - Cellulose nitrate membrane IgM & IgG
- One dropper



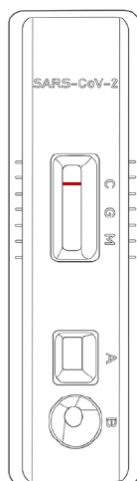
BENEFITS

- Product compliant with high-level of development and manufacturing (ISO 13485 certified)
 - CE IVD (registered)
 - FDA EUA (under review)
 - ANVISA (Brazil) (registered)
- High purity antibody with high accuracy
- Result available within 15 minutes
- Shelf life 12 months
- Suitable for finger prick / lancet blood specimen
- Storage at 4°C – 30°C

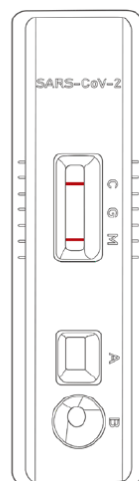


To be valid, the control indicator (C) shall be positive.

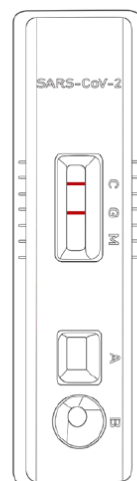
C: Quality control
G: IgG detection line
M: IgM detection line



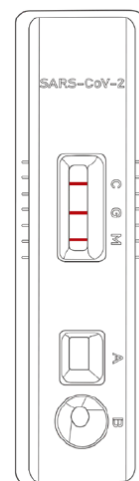
Negative



IgM Positive



IgG Positive



IgM / IgG Positive

ANALYTICAL PERFORMANCES

Diagnostic sensitivity: 98.90%

Diagnostic specificity: 97.60%

Negative Percent Agreement

Detection of negative reference material - detection rate = **100%**

Positive Percent Agreement

Detection of positive reference material - detection rate = **100%**

- IgM+ / IgG+ : Recent SARS-CoV-2 infection
- IgM+ / IgG- : Recent SARS-CoV-2 infection
- IgM- / IgG+ : Older SARS-CoV-2 infection
- IgM- / IgG- : No SARS-CoV-2 infection or no antibodies detection at the beginning of the SARS-CoV-2 infection

Test device	Positive Nucleic acid method (PCR)	Negative Nucleic acid method (PCR)	Total
IgM Positive	2	0	0
IgG Positive	20	3	23
IgM & IgG Positive	70	0	70
IgM & IgG Negative	1	124	125
Total	93	127	220



Leccurate SARS-CoV-2 Antibody Test Kit
Colloidal Gold Immunochromatography

Ref.: K-20-RC-CoV-2
134A20



Distributed by :
Advanced Biological
Laboratories (ABL) S.A.
17 Rue des Jardiniers
L-1835 Luxembourg

Ref.: K-20-RC-CoV-2
134A20



Distributed by :
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Improve Disease Management