

COVID-19

Point-of-care test for rapid serological detection of SARS-COV2 antibodies (with CE Marking)

Colloidal Gold-Based SARS-CoV-2 IgM/IgG Detection Kit

(Cat # 81A225, **CE marking:** NL-CA002-2020-50880)

In Canada - RUO: not available for clinical diagnostic purposes



→ Rapid detection of SARS-Cov-2 NP antibodies (< 10 minutes) in one drop of blood/ serum/plasma;

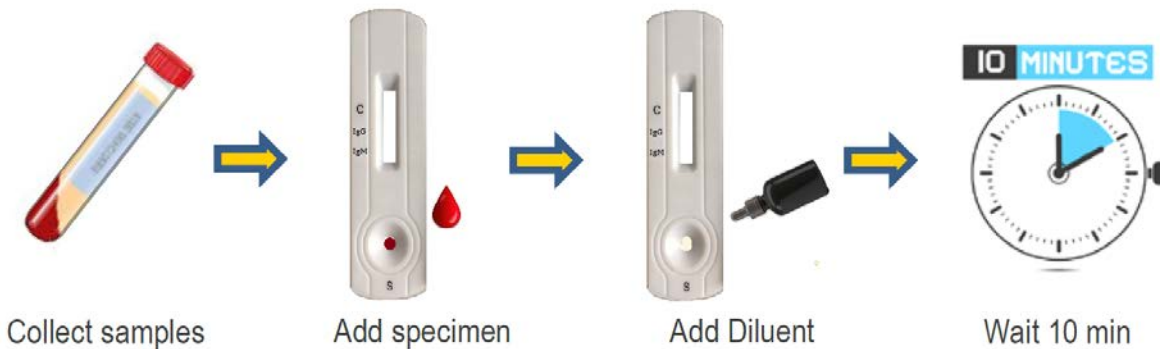
→ Multicenter validation in COVID-19 patients: **Total sensitivity (detection rate) >90%, specificity >99%**;

→ Visualization of IgM and IgG separately in a single test;

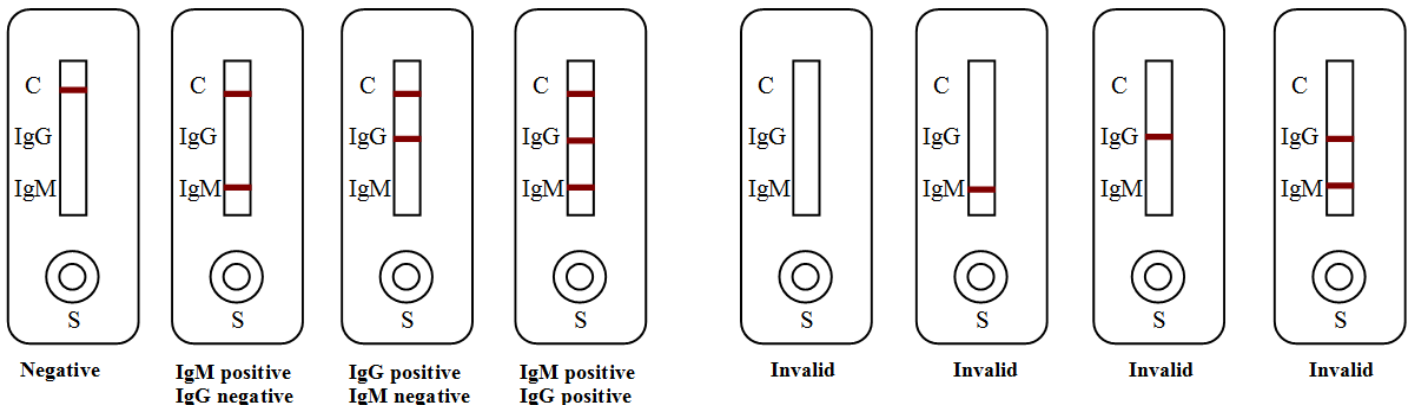
→ Simple protocols, no equipment required.



ASSAY PROCEDURES



INTERPRETATIONS OF THE RESULTS



ASSAY PERFORMANCE

1. Serum samples from clinic ally-diagnosed COVID-19 patients with different titer of SARS-COV-2 NP IgG detected by traditional ELISA (cut off : OD₄₅₀ value of 0.2) was tested by TBS colloidal gold-based SARS-COV-2 IgG/IgM detection kits and other commercially-available kits.

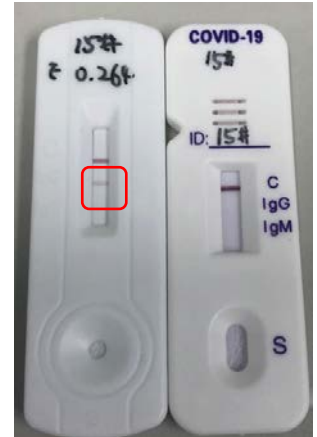
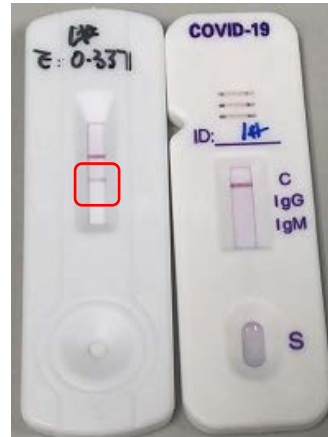
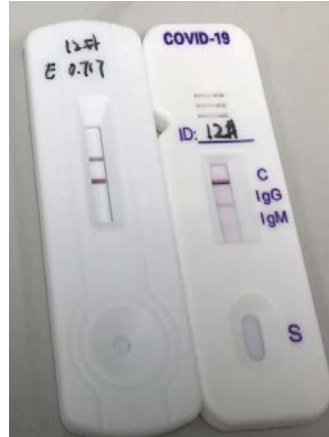
ELISA OD450 value:

1.253

0.717

0.337

0.264



TBS Kit Commercial Kit

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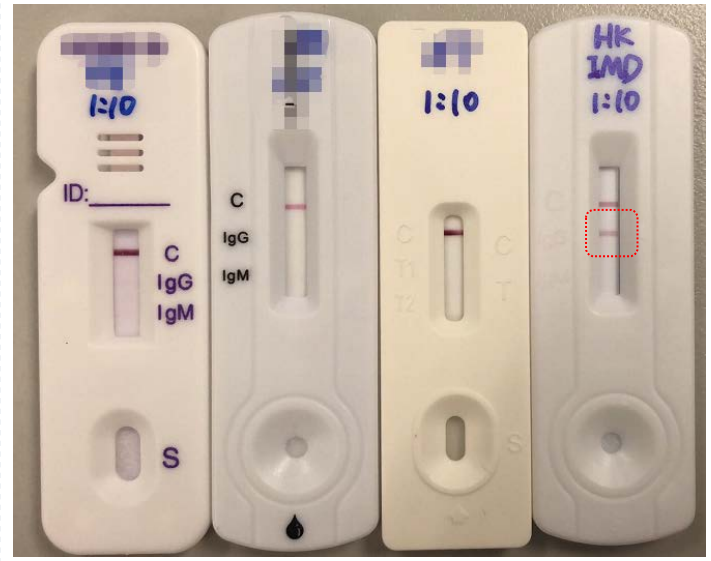
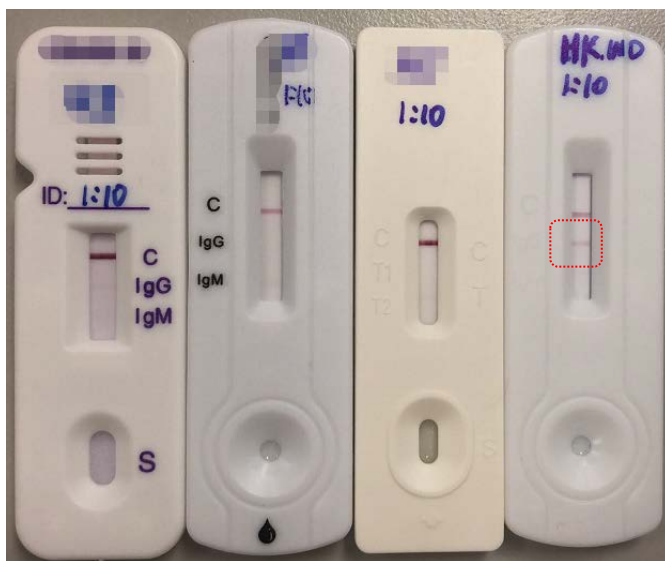
TBS Kit Commercial Kit

Conclusion: only TBS kit can detect NP antibodies in patients with weak titers (OD=0.337 & 0.264).

2. Comparison of detection sensitivity between TBS and kits from three other commercial vendors

Serum from a NP IgG-positive COVID-19 patient was diluted 10-fold and tested using different colloidal gold -based kits:

Humanized anti SARS-CoV-2 IgG as Quality control was diluted 10 fold and tested using different colloidal gold-based kits



Kits from other vendors

TBS kit

Kits from other vendors

TBS kit

Conclusion: only TBS kit can detect very low concentration of NP antibodies among four kits from different manufacturers.