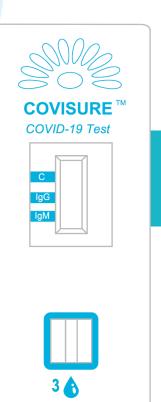
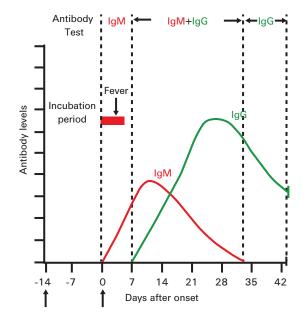
# **COVISURE**<sup>TM</sup>

# COVID-19 IgM/IgG Rapid Test

- Testresultat på 10-15 minutter
- Kan benyttes på helblod/serum/plasma
- IgM og IgG combotest
- En screeningstest





When humans are infected by Corona Virus, the immune system will generate antibodies. IgM is an antibody which appears early on in the blood of those infected by COVID-19. IgG is the subsquent antibody that shows up when the patient is in recovery. Therefore, this test can detect whether a patient was previously infected and thus able to spread the virus, or diagnose a new infection.

- The IgM antibody can be detected in patient blood after 3-6 days
- Positive result indicates a recent infectioon
- Negative result indicates no infection, the incubation period, or recovery.

| Analytes    | 2019-nCOV |
|-------------|-----------|
|             | lgG/lgM   |
| Sensitivity | 93.3%     |
| Specificity | 100%      |
| Accuracy    | 99.2%     |







#### Rapid Test vs. Nucleic Acid

| Test Results               | Colloidal gold  | Fluorescence-PCR  |  |
|----------------------------|---|---|--|
| Test Time                  | 10-20 minutes   | More than 5 hours   |  |
| Operation<br>Method        | Simple without supporting equipment required  | Complex with supporting equipment required  |  |
| PCR Card                   | No need   | Need  |  |
| Professional<br>Laboratory | No need   | Laboratory above P2 level   |  |
| Safety                     | Safer   | High temperature causees aerosol volatilization, which can cause cross infection of operators. The collected samples need to be transported, which may cause pollution. |  |
| Portability                | Easy to be taken<br>along with a small<br>pack and can be used<br>for bedside diagnosis | Needs professional laboratory, so can't be taken along.   |  |

### SARS-COV-2 Antigen and IgG/IgM Antibody **Test Results & Clinic Significance**

| Test Results  |        | ts     |   |
|---------------|--------|--------|---|
| PCR (Ag test) | IgM Ab | IgG Ab | Significance  |
| +             | -      | -      | Patients may be in the "window period" of SARS-COV-2 infection.   |
| +             | +      | -      | Patient may be in the early stage of infection, and the body's immune response first produced the antibody IgM, but no IgG was produced or the IgG content did not reach the detection limit of the diagnostic reagent. |
| +             | -      | +      | Patients may be in late or recurrent stage of infection.  |
| +             | +      | +      | Patient is in the active phase of infection, but the human body has developed some immunity to SARS-COV-2 (the persistent antibody IgG has been produced).  |
| -             | +      | -      | Patient may be in the acute phase of SARS-COV-2 infection. At this time, nucleic acid test result need to be considered (PCR may be false negative).  |
| _             | -      | +      | Patient may have been infected with SARS-COV-2 in the past, but the patient has been recovered or the virus in body has been cleared.   |
| -             | +      | +      | Patient has recently been infected with SARS-COV-2 and is in the recovery stage. Or the nucleic acid test result is false negative and the patient is in the active infection stage.                                    |

#### Finger Stick/Whole Blood Sampling Procedure



Collect 20ul whole blood and add sample to the "sample well" on the test.

Place 2-3 drops of buffer into the "sample well."

3.





1 

Wait 10-15 minutes.

Read results.

#### **Serum Plasma Testing Procedure**





Collect 10 ul of serum/plasma.

Add plasma sample to "sample well."

3.







Place 2-3 drops of buffer in "sample well."

Read results after 10-15 minutes.

## **Results**



