NanoEntek

NESPI- FRCOD-001EN(V.0.1)

CE IVD

# FREND™ COVID-19 IgG/IgM Duo

Rapid qualitative assay for COVID-19 IgG and IgM

## Intended Use

The FREND™ COVID-19 IgG/IgM Duo is designed for the qualitative measurement of anti-coronavirus IgG and IgM in human serum and plasma (Li-heparinized, $K_3$-EDTA, or citrate) by fluorescence immunoassay (FIA) using the FREND™ System. FREND ™ COVID-19 IgG/IgM Duo is an *in vitro* diagnostic medical device that helps identify coronavirus disease 2019 (COVID-19) infections.

## Principle of the assay

A specimen is added to a sample dilution tube and mixed. A well-mixed sample 35 µL is transferred to the sample inlet of a single use FREND™ COVID-19 IgG/IgM Duo cartridge. The cartridge is then placed into the FREND™ System, which is programmed to begin analysis once the sample has reacted with the reagents. The reaction and analysis time is approximately 4 minutes. The anti-coronavirus IgG and IgM qualitative measurement is based on the ratio of fluorescence detected by the FREND™ System at the FREND™ Test and Reference zones. The magnitude of the fluorescent ratio is proportional to the presence and absence of IgG and IgM in the sample.

The FREND™ System is a bench-top fluorescence reader containing a touchscreen user interface. The System has a slot that accepts the FREND™ COVID-19 IgG/IgM Duo test cartridge (which contains the reagents and sample), and is programmed to analyze the test when the sample has fully reacted with the on-board cartridge reagents. Results of the test are displayed on the screen and can be printed on an optional printer.

## Material provided

| Q'ty | Contents | Catalogue number |
|---|---|---|
| 20 | Cartridges | FRCOD 020 |
| 20 | Dilution tubes | |
| 30 | Disposable pipette tips | |
| 01 | Code chip | |
| 01 | Package insert | |

## Warning and Precautions

- The FREND™ COVID-19 IgG/IgM Duo cartridges are intended for *in vitro* diagnostic use only.
- The FREND™ COVID-19 IgG/IgM Duo cartridges are only to be used on the NanoEntek FREND™ System.
- The FREND™ COVID-19 IgG/IgM Duo cartridges and dilution tubes are disposable, single use devices. Do not reuse them under any circumstances.
- Allow sealed cartridges to come to room temperature for 15-30 minutes prior to use.
- Cartridges and pretreatment tubes should not be frozen.
- Assure the humidity in the laboratory is in the 10-80% range when tests are run.
- Avoid cross-contamination between samples by using a new pipette tip for each new specimen.
- Avoid high humidity, direct sunlight or heat in the area used for cartridge storage.
- Inaccurate results are possible if the sample used is contaminated in any way.
- Using specimens containing clotted fibrin could result in erroneous results.
- Over or under loading the cartridge with sample may result in inaccurate results. Do not use the cartridges beyond the expiration date on the pouch.
- Do not use the cartridge if the pouch is damaged or the seal is broken.
- Perform testing as specified in the Package insert and User manual.
- Keep the cartridge sealed in the pouch until ready for use.
- Use the cartridge immediately after opening the pouch.
- Handle specimens in accordance with the OSHA Standard on Bloodborne Pathogens.
- Human specimens are not used in the preparation of this product, however, since human specimens will be used for samples and other quality control products in the laboratory may be derived from human materials, Use Universal Precautions when handling all specimens and controls. Wear disposable gloves when handling the cartridges and the samples.
- Wash hands thoroughly and often after handling reagent cartridges or samples.
- Do not ingest the silica gel packet found in the cartridge pouch.

## Storage and Stability

All unopened materials are stable until the expiration date on the label when stored at refrigerator temperature storage(2~8 ℃). Reagent stability has been demonstrated for three months from the date of manufacture.
The expiration date is clearly indicated on the product box and the cartridges.

## Specimen collection and handling

Serum or plasma (Li-heparinized, $K_3$-EDTA or citrate) is required for the assay. No special patient preparation is necessary. Collect the appropriate venous blood sample aseptically. For serum, allow the sample to clot for 30 minutes at room temperature. For lithium heparin, centrifuge after collection. Centrifuge the sample for 10 minutes at 3,000 rpm within 2 hours of collection and immediately separate the serum or plasma from the packed cells.

It is recommended to use separate samples immediately. However, if not immediately used, separated samples may be stored at 2-8 °C for up to 6 hours prior to analysis. If the analysis is scheduled to be done at some later time, the sample should be stored frozen at -20 ℃ or below for 30 days.

Repeated freeze-thaw cycles should be avoided. Turbid serum samples or samples containing particulate matter such as fibrin clots or visible strands should be re-centrifuged before being tested. Prior to assay, slowly bring frozen samples to room temperature and mix gently but thoroughly before testing.

For optimal results, avoid grossly hemolytic, lipemic, or turbid specimens. Specimens should be free of aggregated fibrin, red blood cells, or other particulate matter. When pipetting into the cartridge sample inlet, ensure that bubbles in the sample are avoided. Bubbles may restrict flow and result in an incomplete or erroneous test result.

## Procedure

- **Code chip installation**

Please refer to the FREND™ System User manual for more detailed instructions relative to the Code chip installation. Abbreviated instructions are as follows:

(1) Insert the FREND™ System electrical cord into an appropriate outlet.
(2) Insert the Code chip into the Code chip slot at the rear of the system following the arrows.
(3) Press the 'Setup' button on the 'Main' screen.
(4) Press the 'Code chip' button on the 'Setup' screen.
(5) The information embedded on the FREND™ COVID-19 IgG/IgM Duo Code chip is automatically saved on the FREND™ System.
(6) When the Code chip installation is completed, press the 'OK' button to go to the 'Setup' screen.
(7) Press the 'Item' button on the 'Setup' screen.
(8) Check the FREND™ COVID-19 IgG/IgM Duo cartridge lot number and the installation date of the Code chip.
(9) Press the 'Home' button to go to the 'Main' screen to begin running external quality control and patient samples.

- **Specimen processing**

Allow the tubes and the sealed pouches containing the FREND™ COVID-19 IgG/IgM Duo cartridges and dilution tubes to come to room temperature for 15-30 minutes prior to the start of the testing sequence.

If using refrigerated patient samples, remove those from the refrigerator and allow to them to come to room temperature prior to testing. If frozen samples will be utilized, be sure these are removed from the freezer, thawed naturally and then mixed gently but thoroughly prior to testing. Testing should not begin on previously from sample until they have reached room temperature.

- **Assay Procedure**

(1) Prepare the FREND™ COVID-19 IgG/IgM Duo and specimen.
(2) Record the Sample ID on the cartridge in the designated area.
(3) A specimen 35 µL is added to a sample dilution tube and mixed. A well-mixed sample (35 µL) drop into the sample inlet on the cartridge using a calibrated micro-pipette with a fresh tip.
(4) Press the 'Test' button on the 'Main' screen of the FREND™ System.
(5) The system moves to the Patient ID screen automatically.
(6) Type the Patient ID and press the 'Enter' button to begin the test.
(7) Insert the cartridge into the cartridge slot using the cartridge arrows as a guide.
*Caution: Please check the direction of the cartridge before insertion and assure the insertion is complete.*
(8) When the reaction in the cartridges is complete in 4 minutes, the FREND™ System will automatically begin the reading process.
(9) When the measurements are completed, the cartridge will automatically be expelled and the results displayed.
*Caution: Do not remove power from the FREND™ System while a cartridge is in the reading chamber. This may cause a system error.*
(10) If the FREND™ System is connected to the optional printer, press the 'Print' button and the results will be output on the printer paper.
(11) For more detailed instructions, please refer to the 'FREND™ System User manual'.

## Display of Results

| Displayed results | Description |
|---|---|
|  | IgG "Negative"<br>IgM "Negative" |
|  | IgG "Positive"<br>IgM "Negative" |
|  | IgG "Negative"<br>IgM "Positive" |
|  | IgG "Positive"<br>IgM "Positive" |

## Results Interpretation

**Precautions**

Since this product cannot completely exclude the possibility of false positive and false negative results, the final diagnosis should not be made only with the results of the product, and the final diagnosis should be made by expert judgment based on other test methods and clinical findings.

**Positive results**

Although it can be determined that the coronavirus IgM and IgG antibodies are present in the sample determined to be positive, this test is used for primary screening, so the final diagnosis should be made by expert judgment based on other test methods and clinical findings.

**Negative results**

Although it can be determined that the coronavirus IgM and IgG antibodies are not present in the negatively determined sample, the possibility of infection is not completely excluded.

## Performance characteristics

**Precision**

As a result of the repeated and reproducible test for FREND ™ COVID-19 IgG/IgM Duo, all negative samples were negative, and all positive samples were positive, which met the criteria.

**Interference**

In the FREND ™ COVID-19 IgG/IgM Duo test, it was confirmed that the following interferences were not affected.

| Endogenous substances | Interferent (concentration tested) |
|---|---|
| Bilirubin | 20 mg/dL |
| Hemoglobin | 500 mg/dL |
| Triglycerides | 3 g/dL |
| Total protein | 12 g/dL |

**Clinical sensitivity and specificity**

To analyze the positive percent agreement and negative percent agreement of FREND ™ COVID-19 IgG / IgM Duo, 384 clinical specimens were tested.

**The total result of all samples**

| Method | | Clinical Confirmation Sample | |
|---|---|---|---|
| | | Positive | Negative |
| FREND™ COVID-19 IgG/IgM Duo | Positive | 40 | 10 |
| | Negative | 3 | 331 |
| Total | | 43 | 341 |

- Positive Percent Agreement: 93.02% (40/43)
- Negative Percent Agreement: 97.07% (331/341)

**The test result collected specimens after 8 days from symptom onset**

| Method | | Clinical Confirmation Sample | |
|---|---|---|---|
| | | Positive | Negative |
| FREND™ COVID-19 IgG/IgM Duo | Positive | 40 | 10 |
| | Negative | 0* | 331 |
| Total | | 40 | 341 |

- Positive Percent Agreement: 100.0% (40/40)
- Negative Percent Agreement: 97.07% (331/341)

* The table shows result of specimens collected after 8 days from symptom onset. Three specimens were excluded in the original data.

## Glossary of symbols

| | | | |
|---|---|---|---|
|  | Caution, warning,<br>Consult accompanying documents |  | *In vitro* diagnostic medical device |
|  | Catalogue number/Reference number |  | Temperature limitation |
|  | Lot number/Batch number |  | Contains sufficient for <n> tests |
|  | Use by<br>YYYY-MM-DD or YYYY-MM |  | Do not reuse |
|  | Manufacturer |  | Do not use if package is damaged |
|  | Authorized representative in the European Community |  | For prescription is damaged |
|  | CE marking |  | Irritant |


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