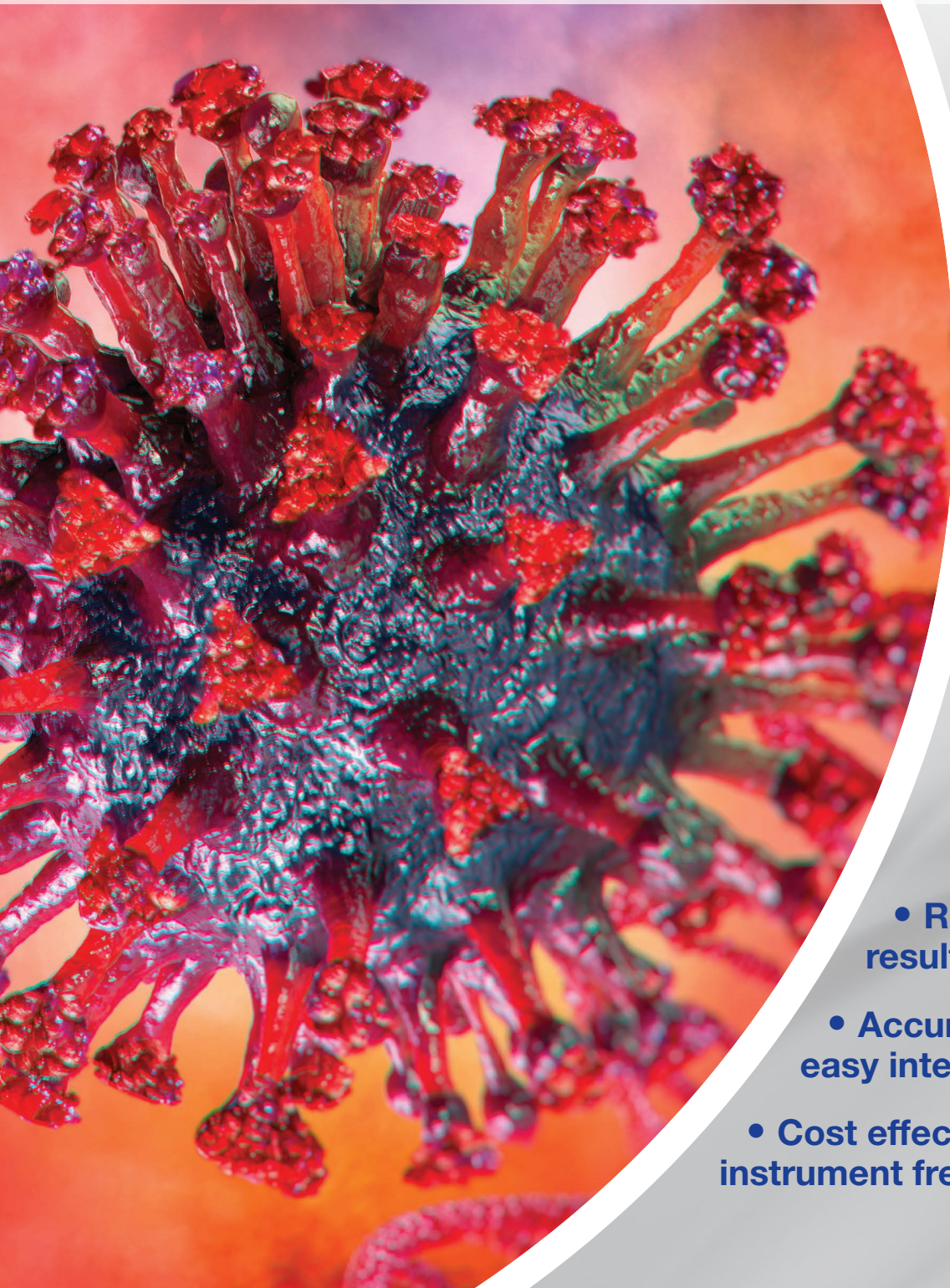




ESPLINE® SARS-CoV-2

Rapid detection of COVID-19 antigens



- **Rapid & reliable results in <30 minutes**
- **Accurate screening & easy interpretation**
- **Cost effective, convenient, instrument free POC testing**

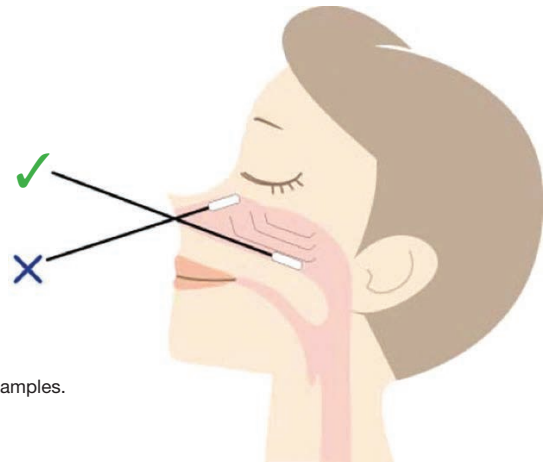
ESPLINE® SARS-CoV-2

ESPLINE® SARS-CoV-2 is a rapid *In vitro* diagnostic test, with a immunochromatographic assay for the detection of SARS-CoV-2 antigen directly from nasopharyngeal swab. World Health Organization (WHO) approval in progress.

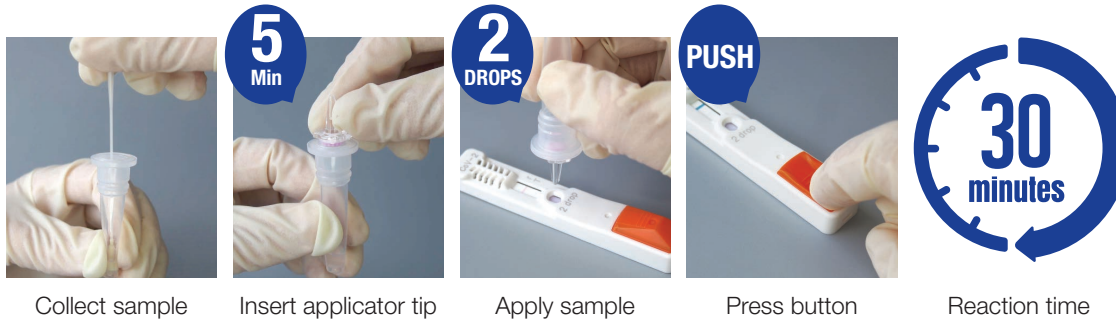
Sample collection

Insert a sterile swab deeply into the nostril so that the swab is at a depth equal to distance from nostrils to outer opening of the ear. Gently rub and roll the swab.

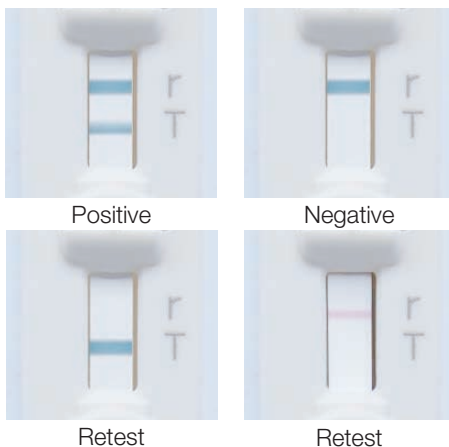
*To prevent infection, wear a mask, goggles or face shield and disposable gloves when collecting samples.



Sample assay procedure



Results



Data

1. Cross reactivity

No cross reactivity with Influenza viruses as follows;

Influenza virus H1N1 Influenza virus H3N2 Influenza virus B

No cross reactivity with in-house recombinant human coronavirus antigens as follows;

MERS-CoV HCoV-229E HCoV-OC43
HCoV-NL63 HCoV-HKU1

2. Comparison with RT-PCR

ESPLINE® SARS-CoV-2 antigen test has a comparable detection rate to qRT-PCR for clinical samples with Ct30 or less.

Sensitivity 80% (50/62)

Specificity 100% (100/100)

Positive Predictive Value (PPV) 100% (50/50)

Negative Predictive Value (NPV) 89.3% (100/112)

Ordering Information

Order Code	Product	Pack Size
213906	ESPLINE® SARS-CoV-2	100 tests

* Product contains Reaction cassettes, Sample Extraction Solution and Applicator tips

Limitations and Precautions

1. Negative results do not preclude SARS-CoV-2 and other virus infection.
2. Do not rely only on the result of this product but also consider clinical symptoms according to the government's guidelines for comprehensive diagnosis.
3. For sample collection and handling device, ensure necessary biohazard measures are in place.

Ref. Omi, Kazuya & Takeda, Yuta & Mori, Masatoshi (2020) SARS-CoV-2 qRT-PCR Ct value distribution in Japan and possible utility of rapid antigen testing kit. 10.1101/2020.06.16.20131243.

Manufactured by Fujirebio Inc., Japan.

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