

Patient Enrollment & Sample Collection Overall Schematics for **COV03**, **COV04S** and **COV05**

Patient admits to the hospital
(with or without COVID-19 related symptoms)

Informed Consent for **COV03**, **04S**, and **05**

⇒ STOP

Yes

No

① Saliva
Self-test

② Nasopharyngeal Swab
Performed by the authorized personnel

③ Finger Prick
Self-test

④ Venous Blood
venipuncture by nurse

Extraction Buffer
↓
Proceed with **COV04S** test
Patient completes a survey

VTM
↓
RT-PCR*
(FDA EUA-authorized, Obtain Ct value)
↓
If RT-PCR POSITIVE

Extraction Buffer
↓
Proceed with **COV05** test
Patient completes a survey

Proceed with **COV03** Test
Patient completes a survey

Whole Blood
↓
Serum
↓
Plasma
↓
Proceed with **COV03** Test
By the designated operator

Ask the patient to come to the clinic twice more (with one week interval)

↓ If, yes

Same patient re-admits to the hospital

① Saliva
Self-test

② Finger Prick
Self-test

③ Venous Blood
venipuncture by nurse

Extraction Buffer
↓
Proceed with **COV04S** test

Proceed with **COV03** Test

Whole Blood
↓
Serum
↓
Plasma
↓
Proceed with **COV03** Test
By the designated operator

PROTOCOL

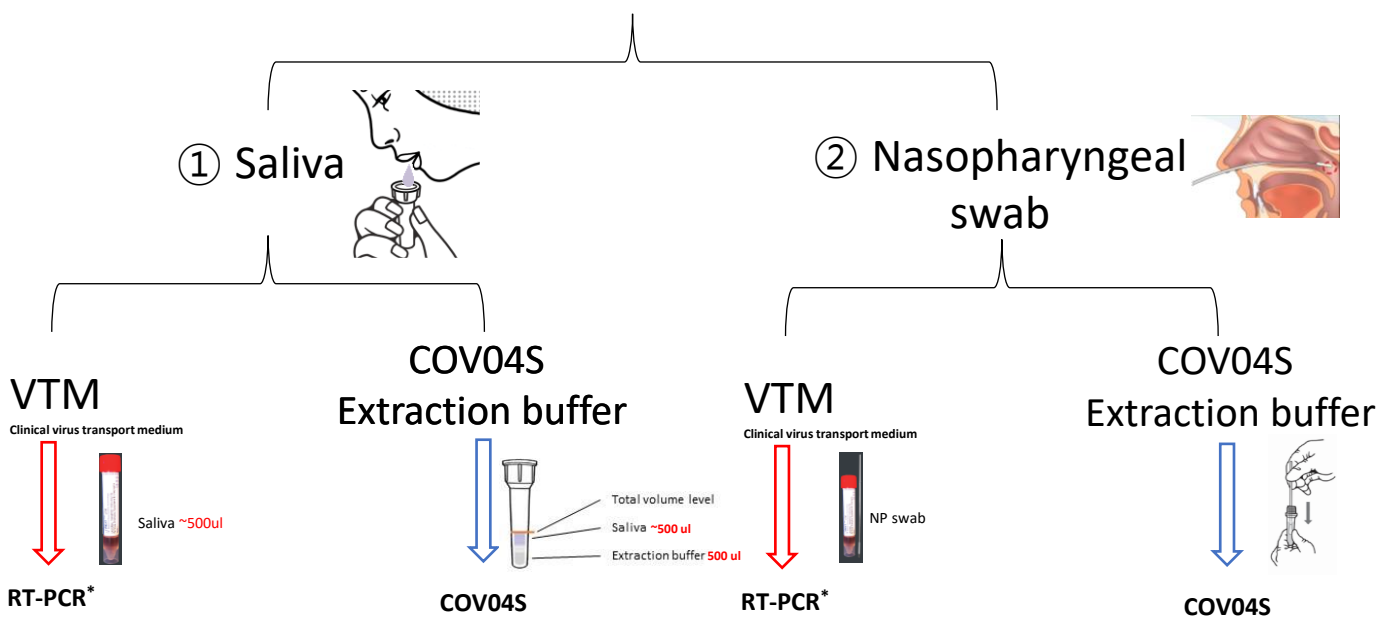
POSITIVE

[COV04S]
PCL COVID19 Ag Gold Saliva

**Must be performed by minimally trained operators (at least 5) at 1 to 2 non-laboratory (CLIA waived) sites.*

30 positive samples
(based on RT-PCR)

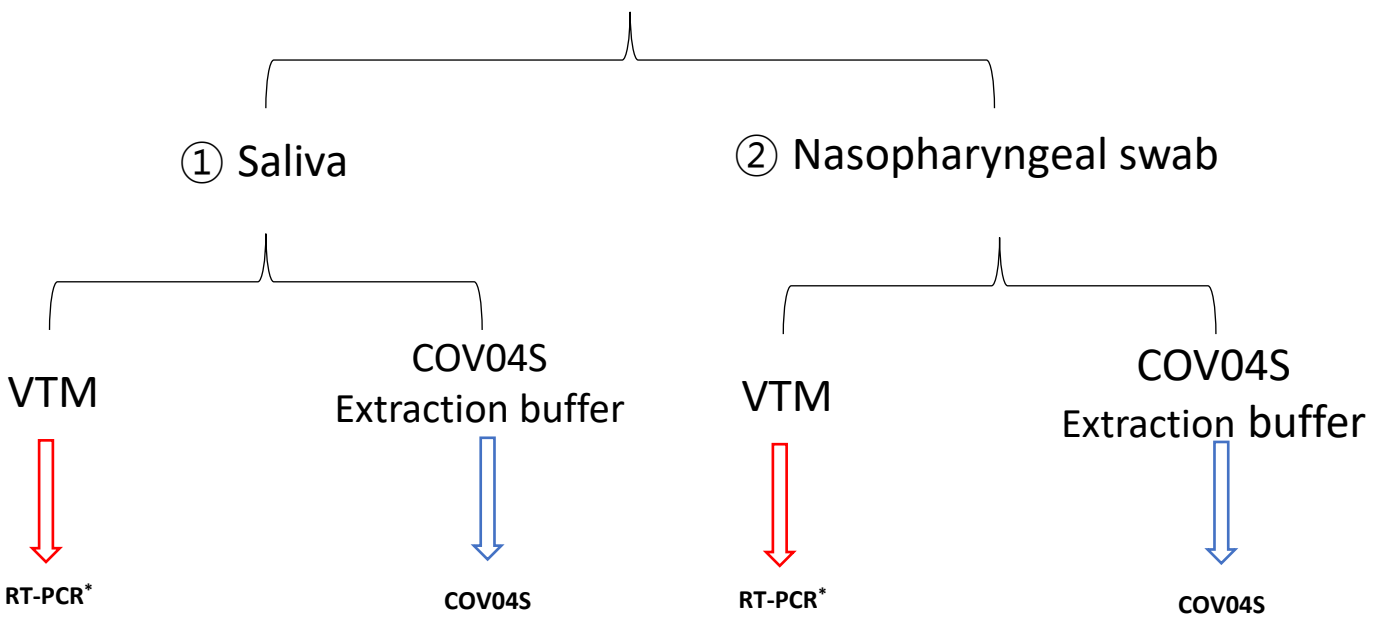
Subjects presenting at hospital within seven (7) days of symptom onset



NEGATIVE

30 negative samples
(based on RT-PCR)

Subjects confirmed with no COVID-19 infection history


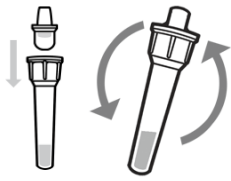




*saliva and nasopharyngeal swab in VTM are only used for RT-PCR (comparator method, FDA-EUA authorized) test.
If the RT-PCR does not allow saliva VTM sample type, then proceed with nasopharyngeal swab in VTM for RT-PCR test.

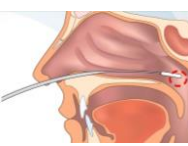
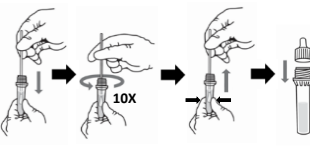


TEST PROCEDURE

Reagents and frozen/cold samples are allowed to stand at room temperature for 20-30 minutes prior to testing.
Expiration date: Check expiration date on the kit labels. Do not use the kit after the expiration date.

Saliva Test Procedure

<p>1 Collecting Specimen</p> <ul style="list-style-type: none">Collect saliva directly into the tube up to the indicated line. 	<p>2 Mixing Specimen</p> <ul style="list-style-type: none">Insert the filter cap tightly onto the tube.Mix by turning upside down 10 times. 	<p>3 Loading mixture</p> <ul style="list-style-type: none">Add 2-3 drops (110ul) of the mixture of buffer and saliva into the sample hole of the test card. 	<p>4 Reading results</p> <ul style="list-style-type: none">Read results after 10-15 minutes.  <p>Do not read results after 20 minutes.</p>
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Nasopharyngeal Swab Test Procedure

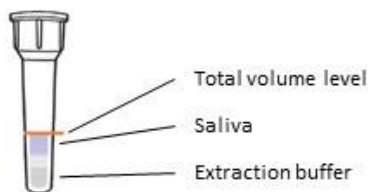
<p>1 Collecting Specimen</p> <ul style="list-style-type: none">Insert the sampling swab through the nostril and gently push the swab into the posterior nasopharynx.Rotate the sampling swab three times and then remove the swab.Put the swab into the extraction buffer tube for immediate use.  <p>Nasopharyngeal swab collection</p>	<p>2 Specimen Extraction</p> <ul style="list-style-type: none">Place the patient swab sample into the extraction buffer tube.Hold the swab and spin 10 times, remove the swab while squeezing the liquid from the swab.Put the filter cap on the tube and screw the cap tightly. 	<p>3 Loading mixture</p> <ul style="list-style-type: none">Add 2-3 drops (110ul) of the extracted sample into the sample hole of the test card. 	<p>4 Reading results</p> <ul style="list-style-type: none">Read results after 10-15 minutes.  <p>Do not read results after 20 minutes.</p>
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PAY ATTENTION for Sample collection

Different specimen types have been validated with the PCL COVID19 Ag Gold Saliva test. At least two hours before the collection, do not eat, smoke or drink any beverages apart from water.

Saliva specimens

- When using the kit with 100 tests included, transfer 500 μ L of Extraction buffer to an empty tube (included) for each sample to be tested.
- The person to be tested collects saliva in the mouth on the tip of the tongue for 30 seconds (approximately 0.5 mL); see also illustration below.



- Spit the collected saliva into the extraction buffer tube directly for immediate use. The applicator can be used to assist this step. By adding the saliva, the volume in the tube should approximately double.
- Do not use stored specimens. Long-term storage may result in a signal decrease.
- Do not freeze the sample. Multiple freeze/ thaw cycles may result in a signal decrease.

Nasopharyngeal swab specimens

- Insert the sampling swab through the nostril and gently push the swab into the posterior nasopharynx.
- Rotate the sampling swab three times
- Put the swab into the extraction buffer tube for immediate use.
- Do not freeze the sample. Multiple freeze/ thaw cycles may result in a signal decrease.

POSITIVE

30 individual subjects

- Each subject must be confirmed COVID-19 positive by unique RT-PCR test (*FDA EUA-authorized, Ct value*)
 - ≥ 14 days post symptom onset

Positive

(30 positive finger prick samples)

At least 5-6 operators, complete a survey

Finger Prick
(Self test)

TEST PROCEDURE

Using Capillary whole blood

1 Specimen Collection Use a disposable to collect 20ul of capillary whole blood	2 Specimen Loading Add the collected specimen to the sample hole of the TEST CARD
3 Buffer Dropping Add 2 drops (60ul) of sample diluent into the sample hole of the TEST CARD	4 Result Reading Read the result after 10-15 minutes Do not read After 15 minutes Do not read test results after 15 minutes. It may lead to false positive results. CAUTION LED lamp with white light for reading results.

PCL

Positive

(30 positive isolated serum or plasma samples)

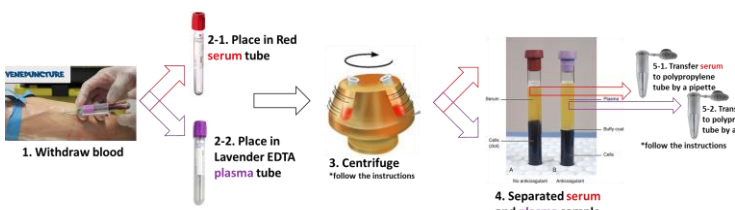
Venous Blood (serum or plasma)
(venipuncture by nurse)

TEST PROCEDURE

Using serum/plasma

1 Specimen collection Use a micropipette to collect 20ul of serum, plasma	2 Specimen Loading Add the collected specimen to the sample hole of the test card	3 Buffer Dropping Add 2 drops (60ul) of sample diluent into the sample hole of the test card	4 Result Reading Read the result after 10-15 minutes. Do not read After 15 minutes. Do not read test results after 15 minutes. It may lead to false positive results. CAUTION LED lamp with white light for reading results.
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PCL



1. Withdraw blood

2-1. Place in Red serum tube

2-2. Place in Lavender EDTA plasma tube

3. Centrifuge *follow the instructions

4. Separated serum and plasma sample

5-1. Transfer serum to polypropylene tube by a pipette

5-2. Transfer plasma to polypropylene tube by a pipette

*follow the instructions

*Open the test card pouch just before use. If the pouch is left unopened for more than 2 hours after opening, it may cause inaccurate results.

Person who collects and loads the samples should be separated from the person who reads the result visually .

NEGATIVE

75 individual subjects

- Each subject must be confirmed confirmed COVID-19 negative by unique RT-PCR test (*FDA EUA-authorized*) with no COVID-19 infection history and the serology specimen should be collected within 1 week of the RT-PCR collected specimen.

Negative

(75 negative finger prick samples)

Finger Prick
(Self test)

Negative

(75 negative isolated serum or plasma samples)

Venous Blood (serum or plasma)
(venipuncture by nurse)

Person who collects and loads the samples should be separated from the person who reads the result visually .