FORMOSA BIOMEDICAL TECHNOLOGY CORP.

CONFIDENTIAL

PROTOCOL SYNOPSIS

I. Objectives

To evaluate the performance of "Formosa One Sure SARS-CoV-2 Ag Rapid Test Kit" in comparison with RT-PCR for detecting Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2).

II. Executive laboratory

The laboratory must be certified by CLIA or CAP or ISO 17025.

III. Endpoints

1. Primary endpoint:

To evaluate the overall consistency (positive and negative samples) between Formosa One Sure SARS-CoV-2 Ag Rapid Test Kit and RT-PCR in nasopharyngeal (NP) and oropharyngeal (OP) swab specimens tested individually from subjects

2. Secondary endpoints:

a. To evaluate the specificity between Formosa One Sure SARS-CoV-2 Ag Rapid Test Kit and RT-PCR in nasopharyngeal (NP) and oropharyngeal (OP) swab specimens tested individually from subjects

b. To evaluate the sensitivity between Formosa One Sure SARS-CoV-2 Ag Rapid Test Kit and RT-PCR in nasopharyngeal (NP) and oropharyngeal (OP) swab specimens tested individually from subjects

IV. Selection criteria

1. Inclusion criteria

For subjects who can donate **positive specimen**:

(1) Subjects who have been confirmed positive results of SARS-CoV-2 using RT-PCR testing within 7 days prior to enrollment

(2) Subjects who can understand the requirements of the study and provide informed consent

For subjects who can donate **negative specimen**:

(1) Subjects who DO NOT suffer from Coronavirus disease 2019 (COVID-19)

(2) Subjects who can understand the requirements of the study and provide informed consent

2. Exclusion criteria

(1) Subjects who refuse to undergo study procedures

(2) Clinical condition requiring urgent medical assessment

V. Study procedures

This is an open-label study to evaluate the clinical performance of an *in vitro* diagnostic device—Formosa One Sure SARS-CoV-2 Ag Rapid Test Kit for detecting Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2).

We aim to compare the consistency between Formosa One Sure SARS-CoV-2 Ag Rapid Test Kit and RT-PCR, the golden standard for the diagnosis of COVID-19, in detecting the infection of SARS-CoV-2.

Subjects who have been diagnosed with COVID-19 by RT-PCR OR subjects who do not have COVID-19 will be enrolled. For each subject, the specimen can be collected via nasopharyngeal (NP) swab and/or oropharyngeal (OP) swab specimens by investigators or study personnel. For either region (NP or OP), the specimen will be collected twice—one for Formosa One Sure SARS-CoV-2 Ag Rapid Test Kit and one for RT-PCR. These specimens will be separately measured using Formosa One Sure SARS-CoV-2 Ag Rapid Test Kit and RT-PCR. The results of Formosa One Sure SARS-CoV-2 Ag Rapid Test Kit will be compared with RT-PCR testing separately for NP and OP specimens

Figure 1 presents the overall study design.

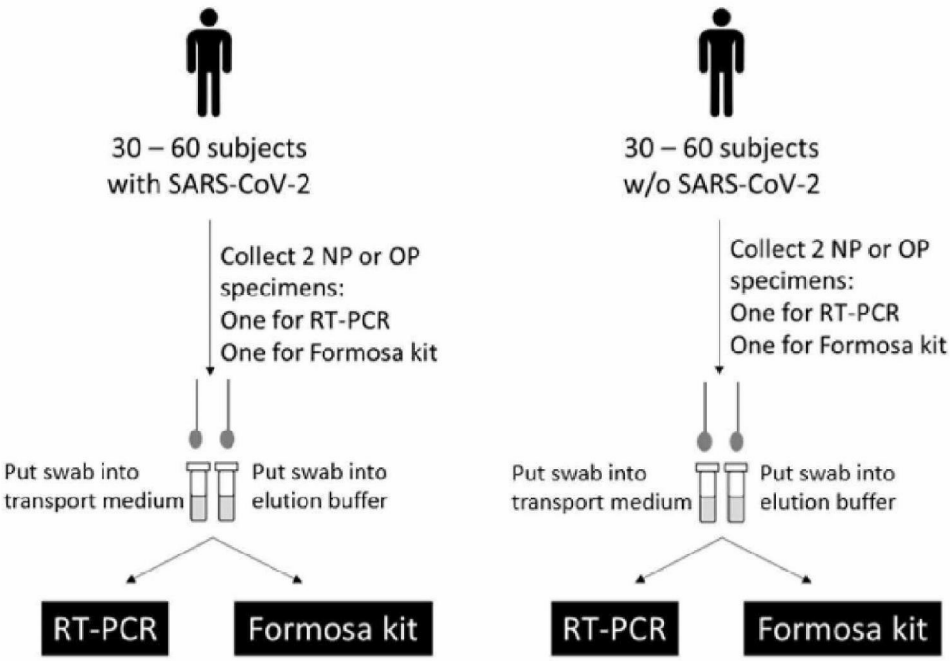

Figure 1 Study design

VI. Statistics

1. Primary hypothesis: ☐superiority ☐non-inferiority ☒equivalence ☐other

2. Sample size:

- Enrolled subjects: approximately 60 – 120 subjects
- Evaluable samples:
  for NP specimens: at least 30 positive samples* and 30 negative samples
  for OP specimens: at least 30 positive samples* and 30 negative samples
  *Evaluable positive sample: RT-PCR also reveals positive in this study.

3. Analyzed samples: all evaluable specimens

4. Statistical methods:

All eligible samples will be included in the analysis for primary and secondary endpoints. Positive and negative percent agreement between Formosa One Sure SARS-CoV-2 Ag Rapid Test Kit and RT-PCR testing results will be calculated. Agreement will also be calculated for the discriminatory assay results. Agreement will be calculated as shown below and reported as a percentage. The percentage will be reported with a 95% binomial two-sided confidence interval by Clopper-Pearson (Exact) method.

		RT-PCR	
		Positive	Negative
Test product	Positive	A	B
	Negative	C	D

<u>For primary endpoint:</u>

Overall consistency (positive and negative samples) will be calculated as follows:

$100\% \times (a + d) / (a + b + c + d)$

<u>For secondary endpoints:</u>

- Specificity (true negative rate): $100\% \times d / (b + d)$
- Sensitivity (true positive rate): $100\% \times a / (a + c)$

5. Planned interim analysis: ☐yes ☒no

VII. Assessment procedure

- Specimen collection and viral detection process

1. After providing the signed informed consent, subjects will be swabbed to collect two NP and/or OP specimens. (Note: Test specimens immediately. If a delay in testing is expected, or store specimens at 2 – 8°C for up to 24 hours after collection.)
2. One of the specimens collected from the same subject will be tested by RT-PCR according to standard procedures.
3. The other one specimen will be tested using Formosa One Sure SARS-CoV-2 Ag Rapid Test Kit according to the instruction as below.
4. Compare the results between RT-PCR and Formosa One Sure SARS-CoV-2 Ag Rapid Test Kit

- Instruction for use

Figure 2 displays the instruction for Formosa One Sure SARS-CoV-2 Ag Rapid Test Kit.

1. Bring all materials and specimens to room temperature.
2. Put the Elution Tube into Racks. Vertically add 10 drops of Elution Buffer to the Elution Tube. (see Step 1)
3. Put the swab to be tested into Elution Tube. Rotate the swab vigorously (without making a lot of bubbles) ten (10) times in the liquid. (see Step 2)
4. Press the swab against the side of the Elution Tube and turn as you remove it from the tube. This removes sample from the swab. (see Step 3)
5. Discard the swab into a container intended for contagious material.
6. Close the cap. (see Step 4)
7. Remove the test card from the sealed foil pouch and place it on a dry surface.
8. Hold the Elution Tube in a vertical position over the sample well of the test card and deliver 3 drops of sample into the sample well. (see Step 5)
9. Place the test card flat on a dry surface.
10. Read the results between 15 and 20 minutes after adding the sample.

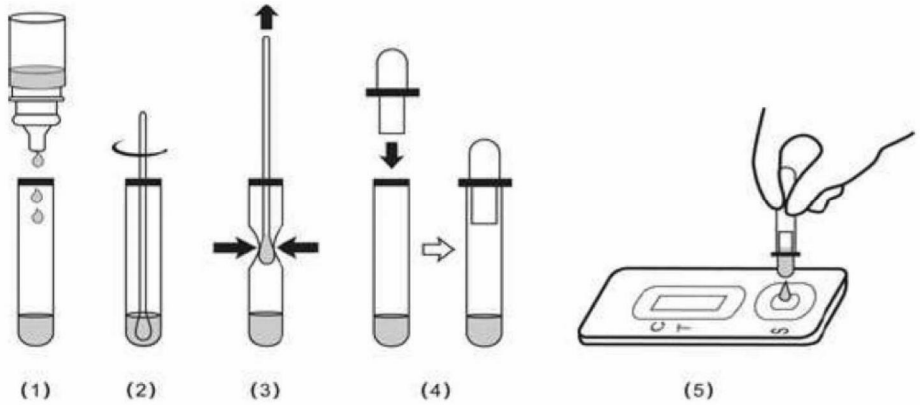

Figure 2 Instruction for Formosa One Sure SARS-CoV-2 Ag Rapid Test Kit