Summary on

Clinical Evaluation Report for SARS-CoV-2 Rapid Antigen Test (Immunochromatography Assay) Manufactured by Sansure Biotech Inc.

1. Background

Since the beginning of the COVID-19 pandemic, laboratories have been using nucleic acid amplification tests (NAATs), such as real time reverse transcription polymerase chain reaction (RT-PCR) assays, to detect SARS-CoV-2, the virus that causes the disease. In many countries, access to this form of testing has been challenging. The search is on to develop reliable but less expensive and faster diagnostic tests that detect antigens specific for SARS-CoV-2 infection. Antigen-detection diagnostic tests are designed to directly detect SARS-CoV-2 proteins in respiratory secretions and have been developed as both laboratory-based tests, and for near-patient use, so called rapid diagnostic tests, or RDTs. The diagnostic development landscape is dynamic, with nearly a hundred companies developing or manufacturing rapid tests for SARS-CoV-2 antigen detection [1].

Our SARS-CoV-2 Rapid Antigen Test (Immunochromatography Assay) is used for self-testing, which can provide a simple and fast method to detect SARS-CoV-2 nucleocapsid protein in human nasal swab.

2. Clinical purpose

The purpose of this research is to compare the SARS-CoV-2 Rapid Antigen Test (Immunochromatography Assay) (hereinafter candidate kit) manufactured by Sansure Biotech Inc. with SARS-CoV-2 Test Kit (Real-time PCR) of Vitassay qPCR SARS-CoV-2 (hereinafter reference kit) manufactured by Vitassay Healthcare S.L.U. that approved for listing in the EU, to evaluate the clinical effectiveness of candidate kit.

3. Study content

Nasal swabs collected from COVID-19 suspected participants are tested by a COVID-19 antigen rapid test, namely SARS-CoV-2 Rapid Antigen Test (Immunochromatography Assay) by Sansure Biotech Inc. Nasopharyngeal swab specimens collected at the same time were tested by a SARS-CoV-2 RT-PCR detection reagent, namely the Vitassay qPCR SARS-CoV-2 by Vitassay Healthcare S. L. U. (Spain) as the reference kit. The sensitivity, specificity, and total accuracy of the SARS-CoV-2 Rapid Antigen Test (Immunochromatography Assay) are calculated using SARS-CoV-2 RT-PCR detection reagent as the reference method.

4. Sample requirement

4.1 Sample type: nasal and nasopharyngeal swab

1) Positive specimens: 110 nasal swab samples from RT-PCR confirmed SARS-CoV-2 positive cases, which are collected within the first 7 days after symptom onset. 5 samples containing the Delta viral mutant (B.1.617.2) are included in the study.

2) Negative specimens: 460 nasal swab samples from RT-PCR confirmed SARS-CoV-2 negative cases, within which there are 302 non-infected individuals negative samples, 102 from hospitalised patients and 56 of potentially interfering and cross-reactive samples.

The clinical performance evaluation conducted in the European population complies with the requirements of MDCG 2021-21 Guidance on performance evaluation of SARS-CoV-2 in vitro diagnostic medical Devices (August 2021).

5. Result analysis

Test results of the candidate kit and the reference kit are summarized in 2×2 table below.

		Vitassay qPCR SARS-CoV-2		Total
		Positive	Negative	
SARS-CoV-2 Rapid Antigen Test (Immunochromatography Assay)	Positive	104	0	104
	Negative	6	460	466
Total		110	460	570

Statistic	Value	95% CI
Sensitivity	94.55%	88.51% to 97.97%
Specificity	100.00%	99.20% to 100.00%
Accuracy (*)	98.95%	97.72% to 99.61%

The 95% Confidence Intervals of sensitivity, specificity, and total accuracy are calculated following the binomial distribution.

Analysis results by Kappa consistency test shows that the Kappa value = 0.9655 (95% CI: 0,9380~0,9929). As Kappa ≥ 0.75, it suggests good consistency between the candidate kit and the reference kit.

Test results of the candidate kit and the third-party control kit are summarized in 2×2 table below.

		Xpert Xpress SARS-CoV-2		Total
		Positive	Negative	
SARS-CoV-2 Rapid Antigen Test (Immunochromatography Assay)	Positive	0	0	0
	Negative	6	0	6
Total		6	0	6

In this study, 6 cases have been reported inconsistent antigen test results with RT-PCR test. Nasopharyngeal swab samples from these cases were retested with a third-party control kit, and the

results of these 6 samples tested by the third-party control kit were reported identical with the reference kit.

The inconsistent test results might be caused by sampling bias of nasal swab samples, that is, the amount of viral antigens sampled in these nasal swab samples is insufficient for antigen test, or the virus is not collected in these samples.

6. Conclusion

In the present study, the SARS-CoV-2 Rapid Antigen Test (Immunochromatography Assay) manufactured by Sansure Biotech Inc. has shown high sensitivity, specificity, and total accuracy on nasal swab samples from SARS-CoV-2 suspects. The test results are highly accurate and not affected by other respiratory pathogens that commonly found in clinical samples. The test result complies with the MDCG-21/2021 standard.

As the antigen tests take only 20 to 30 minutes, they are feasible for use in emergency scenarios where a test result is demanded immediately. Also, the rapid antigen tests doesn't require special instruments and training to use, they are also capable for resource limited scenarios like point-of-care testing and self-test by laypeople. Therefore, the implementation of rapid antigen test may totally change the strategies to control COVID-19. Community residents can conduct the rapid antigen test in a frequent manner, like twice or three times a week, to identify COVID-19 cases in the early stage of infection. This strategy may help to stop the transmission of COVID-19 as early as possible.

In summary, the SARS-CoV-2 Rapid Antigen Test (Immunochromatography Assay) has shown satisfying sensitivity, specificity, and total accuracy in the present evaluation. It can be used as a rapid tool to assist the early diagnosis of COVID-19 cases.

7. Reference

[1] Foundation for Innovative New Diagnostics. SARSCoV-2 Diagnostic Pipeline 2020 [Available from: https://www.finddx.org/covid-19/pipeline/.]

[2] MDCG 2021-21 Guidance on performance evaluation of SARS-CoV-2 in vitro diagnostic medical devices