SARS-CoV-2 Antigen Detection Kit

Sensitivity, Specificity and Accuracy Study Report

1. Experimental purpose

The purpose of this experimental was to investigate the clinical performance of SARS-CoV-2 antigen detection kit manufactured by Assut Europe SpA and to evaluate its clinical efficacy and safety.

2. Design of experiment

2.1 Description of the overall design and program of the experiment

During the experiment, the remaining samples after nucleic acid testing were collected and the relevant information of the test samples was collected according to the sample collection information record sheet, and the test samples were numbered. In the experiment, the statistician conducts random sampling on the samples and then sends them to the researcher for testing. The test results should be reviewed and counted by the person in charge of statistics.

2.2 Test sample size and sample type

45 cases positive samples of Novel Coronavirus (SARS-CoV-2) nucleic acid test and 116 cases negative samples of Novel Coronavirus (SARS-CoV-2) nucleic acid test. This verification test.

2.3 Inclusion, exclusion and exclusion criteria of test samples

Standard of inclusion

- The test result of nucleic acid test was positive, which confirmed the infection of novel coronavirus
- The test result of nucleic acid test was negative

Exclusion criteria

- The storage conditions for samples that not meet the requirements of the specification
- An insufficient sample size
- Samples of microbial contamination
- This sample demonstrates jaundice, hemolysis, and chylous disease
- Sample with missing sample information
- Any other reasons identified by the clinical staff of each institution

Elimination criteria

- Samples that violate the requirements of the experimental plan during the test
- Samples with invalid test results due to incorrect operation

ASSUT EUROPE spa - Sede legale: Via Giuseppe Gregoraci, 12 - 00173 Roma - Tel. +39 06 72677348 - Fax +39 06 72675380
Stabilimento di produzione: Zona Industriale • 67062 Magliano dei Marsi (AQ) • Tel. +39 0863.517956-515000 - Fax +39 0863.570084-515209
Codice Fiscale e Partita IVA n. 01262470667 - R.E.A. n. 1153837 Roma - Capitale sociale € 6.416.457,00 i. v.
www.assuteurope.com • www.unotecsrl.com Soggetta a direzione e controllo e-mail: customerservice@assuteurope.com

2.4 Requirements of test samples

Samples should be collected according to the technical specifications for nasal swab collection. The samples were pretreated according to standard procedure. Samples contaminated with microorganisms cannot be used for testing. The samples to be tested should avoid repeated freeze-thaw as far as possible. The samples should be refrigerated for 3 days at 2℃~8℃. Samples can be tentative stored for 6 months under -20°C. Cryopreservation samples should be balanced to room temperature and well mixed before use.

2.5 Information on diagnostic reagents for testing

Reagent to be tested
Product name: SARS-CoV-2 Antigen Detection Kit
Name of manufacturer: Assut Europe SpA
Specification: 20 tests/kit, 25 tests/kit, 40 tests/kit
Lot No.:20200203
Storage conditions: the detection card should be stored at 4℃~30℃ and protected from light, and the validity date is 12 months. The detection card should be used within 1 hour after being opened. If the temperature is higher than 30℃ or in a high humidity (greater than 60%) environment. It is better that out-of-the-box as possible. Manufacturing date and expiry date are shown on the label.
Manufacturing date: 2020-02-25
Expiry date: 2021-02-24

3. Experimental statistical analysis

3.1 Statistical analysis method

In the form of 2×2 table, the sensitivity, specificity, positive predictive value and negative predictive value of the tested reagent results and the nucleic acid test results were statistically analyzed, and Kappa consistency analysis was performed. Kappa value ≥0.75 is highly consistent and considered equivalent.

3.2 Evaluation statistical results

Method		PCR		Total Results
SARS-CoV-2 Antigen Detection Kit	Results	Positive	Negative	
	Positive	39 (a)	0 (b)	39
	Negative	6 (c)	116 (d)	122
Total Results		45	116	161

Sensitivity =39/(39+6) ×100%=86.67%

Specificity=116/(116+0)×100% =100.00%

Accuracy =(39+116)/161 ×100%=96.27%

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Calculation of the k coefficient

k = (Pa-Pe)/(1-Pe)

Pa = (a+d) / (a+b+c+d) = (39+116)/161= 0,9627

Pe = [(a+b)(a+c) + (c+d)(b+d)]/$(a+b+c+d)^2$ = 0,6137

==> k = (0,9627-0,6137)/(1-0,6137) = 0,9035

4. Discussion and conclusion

By comparing the results between tested reagents and nucleic acid reagents to analyze the effectivity of SARS-CoV-2 antigen detection kit. The product performance evaluation of SARS-COV-2 antigen detection kit manufactured by Assut Europe SpA was evaluated through its effectiveness.

The evaluation indexes were test results of the sensitivity, specificity, accuracy analysis and consistency test between SARS-CoV-2 antigen detection kit and nucleic acid:

sensitivity =86.67%, specificity =100.00%, accuracy =96.27%

Kappa value =0.9035 that can meet the requirements.

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