Nanjing Norman Biological Technology Co.,Ltd

Novel Coronavirus (2019-nCoV) Antigen

Testing Kit (Colloidal Gold)

(Anterior Nasal swab)

Clinical Report

Norman Novel Coronavirus (2019-nCoV) Antigen Testing Kit (Colloidal Gold)

(Anterior Nasal swab)

Clinical Study Protocol

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1. Trial Objectives

The purpose of this evaluation is to establish the clinical specimens performance of the Novel Coronavirus (2019-nCoV) Antigen Testing Kit (Colloidal Gold), including performance on clinical Anterior Nasal swabs specimens. The data obtained will be used in the application for CE certification.

2. Administrative Information

1) The protocol should be read carefully, the protocol and 'Test Procedure' supplied with the reagents must be followed exactly unless explicitly stated.
2) The assays during the period of the evaluation should be double checked by another technicist.
3) The results for both Novel Coronavirus (2019-nCoV) Antigen Testing Kit (Colloidal Gold) and any alternative assay methods must be properly identified. The data should be clearly legible and marked with the name of the laboratory and initialed by Coordinator.
4) All original raw data must be made available for further information.

3. Study Design

3.1 Random blinding requirements: According rules of Random coding, Set blinding, and Unblind.

3.2 Time Scale of Evaluation

The evaluation should be completed within 24 weeks.

3.3 Materials Used

1) Target reagent: A lot of qualified Norman Novel Coronavirus (2019-nCoV) Antigen Testing Kit (Colloidal Gold) produced based on technological process and the outputted Standard Operating Procedure. Test result with no analyzer or reader.
2) Reference reagent: PCR, the comparator assay: Real-Time Fluorescent RT-PCR Kit for Detecting SARS-CoV-2 from BGI Genomics.

3.4 Enrollment criteria: Cases with fever, fatigue, nasal congestion, runny nose, sore throat or dry cough; Exclusion criteria: Samples that cannot be processed in parallel determination test due to sampling or human factors (samples contaminated during operation).

3.5 VTM type, as applicable, for the antigen test and PCR: Virus extraction tube for antigen, virus Sample preservation tube for PCR.

3.6 Specimens collection and testing site: Hebei Chest Hospital

3.7 User training: In case of the Antigen Test kit operator, training will be conducted on sample collection, transportation and treatment to ensure the correct use of the extract R1, sample processing, sample loading and result reading. The relevant operation video will also provide reference.

The applicant should be trained in the use of test reagents, especially the standardized training of random blind method according to the relevant national requirements.

3.8 Specimens to be tested

All the specimens used in this evaluation were form Hebei Chest Hospital, which is the Clinical Cooperation Unit of Norman.

1) Specimen types

Anterior Nasal swabs should be used.

2) Specimen quantity

Specimens above should be collected with known PCR positive and known PCR negative patients' samples after.

3）Specimen number:

All kinds of Positive samples should not less than 110.

All kinds of Negative samples should not less than 200.

3.9 Data analysis

The product of this research is a qualitative detection clinical trial. The detection results of the two methods will be summarized in the form of 2×2 spreadsheet, and the sensitivity (positive coincidence rate), specificity (negative coincidence rate), total coincidence rate and other indicators will be calculated based on this and its 95% confidence interval.

3.10 Storage and Reporting

All data will be filed both on hard copy and in electronically files. Data will be stored for at least 5 years. All laboratory results are strictly confidential. Copies of raw data were retained under the internal R&D department of Norman for future reference.

Norman Novel Coronavirus (2019-nCoV) Antigen Testing Kit (Colloidal Gold) (Anterior Nasal swab) Performance on clinical Study Report

1. Purpose

1.1To study the performance of the Norman Novel Coronavirus (2019-nCoV) Antigen Testing Kit (Colloidal Gold) with Anterior Nasal swabs specimens.

2. Method and material.

Specimen collected in hospital by qualified medical personnel and coded with random number blindly. The Novel Coronavirus (2019-nCoV) Antigen Testing Kit (Colloidal Gold) Test produced by Norman is used to screen COVID-19 PCR positive patient Samples and COVID-19 PCR negative patient Samples. Specimens collected according to proper procedure.

VTM type: Virus extraction tube for antigen, virus Sample preservation tube for PCR.

The test kits (LOT NO. RD0516 was used for evaluation.

Random blinding requirements: According rules of Random coding, Set blinding, and Unblind.

3. The results table (random blind testing)

3.1 results table

Clinical of Anterior Nasal swab

A total of 432 Anterior Nasal swab samples consisting of 172 positive, 260 negative Anterior Nasal swab specimens， were considered evaluable in this study. The performance of the Novel Coronavirus (2019-nCoV) Antigen Testing Kit (Colloidal Gold) as compared to the RT-PCR comparator method are presented in the table below:

Performance against the Comparator Method

Method: Anterior Nasal swab		PCR Test		Total Results
Norman Novel Coronavirus (2019-nCoV) Antigen Testing Kit (Colloidal Gold)	Results	positive	Negative	
	positive	160	2	162
	Negative	12	258	270
Total Results		172	260	432

Relative Sensitivity:	160/172	93.02% (88.13%～96.34%)
Relative Specificity:	258/260	99.23% (97.25%～99.91%)
Accuracy:	418/432	96.76% (94.62%～98.22%)

* 95% Confidence Interval

4. Discussion and Conclusion

The results above showed that there was a good consistency between the Norman Novel Coronavirus (2019-nCoV) Antigen Testing Kit (Colloidal Gold) and the PCR results. So the Norman Novel Coronavirus (2019-nCoV) Antigen Testing Kit (Colloidal Gold) has a good clinical performance.

R&D Approver

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