Sensitivity, specificity and accuracy study report

Novel Coronavirus (2019-nCoV) Antibody IgG/IgM Assay (Colloidal Gold)

1. Sensitivity and specificity test protocol

Test purpose

The purpose of this study was to investigate the clinical performance of Novel Coronavirus (2019-nCoV) Antibody IgG/IgM Assay (Colloidal Gold) manufactured by Ergon Sutramed Srl and to evaluate its clinical efficacy and safety.

2. Test design

2.1 Description of the overall design and program of the test

During the experiment, the remaining samples after clinical test were collected by the researcher, 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

In total were collect 30 novel coronavirus (2019-nCoV) IgG positive serum samples, 30 novel coronavirus (2019-nCoV) IgM positive serum samples, 30 novel coronavirus (2019-nCoV) IgG/IgM positive serum samples, 30 novel coronavirus (2019-nCoV) IgG/IgM positive serum samples, and 30 novel coronavirus (2019-nCoV) infection-related negative serum samples.

Sample acquisition, retention, situation of the clinical test units according to institutions into the group of samples, based on the current domestic will be coronavirus epidemic has been brought under effective control, the clinical can sample into the samples Novel Coronavirus (2019-nCoV) Antibody IgG/IgM Assay (Colloidal Gold) of retrospective and prospective, specifically the number of each type of sample, sample situation of the clinical test units according to institutions into the group, part of the prospective clinical trials should be as far as possible into the group samples. In addition, according to the requirements of sample types in the instructions, a certain amount of homologous samples of serum, plasma and whole blood should be included in this clinical trial to verify that the kit has the same ability to detect samples of different types. The time of sample collection, the time of clinical manifestation and the diagnostic methods confirmed as infection samples shall be provided.

2.3 Inclusion, exclusion and exclusion criteria of test samples

Standard of collection

- ✓ The test result of nucleic acid reagent was positive, which confirmed the infection of novel coronavirus
- ✓ The results of nucleic acid reagents were negative, but the samples were diagnosed as novel coronavirus infection by clinical methods
- ✓ The clinical diagnosis was a negative sample of novel coronavirus

Exclusion criteria

- ✓ Keep samples whose conditions do 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 reason identified by the clinical staff of each institution

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Elimination criteria

- ✓ Samples that violate the requirements of the test plan during the test
- ✓ Samples with invalid test results due to operational errors
- ✓ Any other reason identified by the clinical staff of each institution

2.4 Test sample requirements

The serum/plasma samples to be tested should avoid repeated freeze-thaw as far as possible. The samples should be refrigerated for 3 days from 2°C to 8°C and frozen below -20°C for long-term storage.

The whole blood sample cannot be frozen, if not timely detection, should be stored in 2-8°C. Cryopreservation samples should be balanced to room temperature and well mixed before use.

2.5 Information on diagnostic reagents for testing

Product name: Novel Coronavirus (2019-nCoV) Antibody IgG/IgM Assay (Colloidal Gold)

Name of manufacturer: Ergon Sutramed Srl

Packing specification: 20 tests/Kit

Storage conditions: the test card should be stored in the dark at 4°C -30°C , and it is valid for 12 months.

The aluminum foil bag of test card should be used within 1 hour after opening; if the temperature is higher than 30°C or in a high humidity (more than 60%) environment, should be as out-of-the-box as possible.

Production date and expiry date are shown on the label.

3. Test statistical analysis

3.1 Statistical analysis method

The sensitivity, specificity and accuracy data are analyzed in the form of 2x2 table.

3.2 Evaluation statistical results

IgG Statistical Results		Nucleic acid test results		Total
		Positive	Negative	
Reagent to be tested	Positive	52	1	53
	Negative	4	39	43
Total		56	4	96

Sensitivity = 52/(52+4)*100% = 92.86%

Specificity = 39/(39+1)*100% = 97.50%

Accuracy = (52+39)/96*100% = 94.79%

Sensitivity, Specificity and accuracy ≥90%.

IgM Statistical Results		Nucleic acid test results		Total
		Positive	Negative	
Reagent to be tested	Positive	51	1	52
	Negative	5	39	44
Total		56	4	96

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Sensitivity = 51/(51+5)*100% = 91.07%

Specificity = 39/(39+1)*100% = 97.50%

Accuracy = (51+39)/96*100% = 93.75%

Sensitivity, Specificity and accuracy ≥90%.

4. Discussion and conclusion

Clinical evaluation of novel coronavirus (2019-nCoV) IgG/IgM antibody detection kit (colloidal gold method) by clinical comparison of detection kit and nucleic acid detection results.

The evaluation indexes were the sensitivity, specificity, accuracy analysis and consistency test between the tested reagent and nucleic acid detection results:

IgG index sensitivity =92.86%, specificity =97.50%, accuracy =94.79%, were all ≥90%.

IgM index sensitivity =91.07%, specificity =97.50%, accuracy =93.75%, were all ≥90%.

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