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Clinical Test Report

Project Name (Code): 2019-nCoV Ab Test (Colloidal Gold)

Item Name (Code): Clinical Test Report

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Objective

To evaluate the quality performance and clinical application value of 2019-nCoV Ab Test (Colloidal Gold) produced by Innovita(Tangshan) Biological Technology Co., Ltd. The product passed the clinical assessment study of three hospitals.

Management of clinical assessment

Before the clinical assessment, the personnel of the R&D department of Innovita (Tangshan) Biological Technology Co., Ltd. and the technical director of the assessment unit (director of the department) will train the laboratory personnel. The training includes the purpose, operation method, and precautions of the clinical test, laboratory quality control standards and statistical analysis methods.

Clinical Evaluation Process

Sample collection and storage

Serum sample: Sample collection and storage according to clinical routine sterile venous blood collection was collected and distributed according to routine tests in the hospital. 2 ℃-8 ℃ and not more than 72 hours.

Test method

Comparison tests with test kit of the same type listed on the market

Innovita test kits were used, including “2019-nCoV Ab Test (Colloidal Gold)”, and the commercial PCR test which”performs simultaneous detection of all collected samples and reads the results within the specified time. After the test, the test results of the test kits were compared with the test results of the comparative test kits.

Background

Clinical research was conducted in 5 institutions and the total cases were 447.We do three experiments

1. Compare with clinical confirmed and uninfected cases(126 cases in all)
2. Compare with PCR result(221 samples in all)
3.Interference analysis on other pathogen samples(100 samples in all)

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1. Sensitivity and specificity analysis of assessment reagents

Among the clinical confirmed 126 subjects, 85 samples were positive for the test reagent IgM antibody test, the sensitivity was 67.46% (95% confidence interval 58.9% - 75.0%);Among the clinical 62 uninfected subjects, 62 samples were negative for the test reagent IgM antibody test, the specificity is 100%(a 95% confidence interval of 94.2% - 100%); An overall agreement is 78.19% (95% confidence interval of 71.8% -83.5%).

Among the clinical confirmed 126 subjects, 104 samples were positive for the test reagent IgG antibody test, the sensitivity was 82.54% (95% confidence interval 75% - 88.2%);Among the clinical 62 uninfected subjects, 62 samples were negative for the test reagent IgG antibody test, the specificity is 100%(a 95% confidence interval of 94.2% - 100%); An overall agreement is 88.30% (95% confidence interval of 82.9% -92.1%).

Comprehensive analysis of IgM and IgG sensitivity: Among 126 subjects were confirmed by the clinical research, 110 samples were positive for the test reagent IgG and IgM antibodies test, the sensitivity was 87.3%(95% confidence interval was 80.4%-92%); Among 62 uninfected subjects, 62 samples with negative IgG and IgM antibodies test, the specificity was 100%(95% confidence interval 94.2%-100%); An overall consistency 91.49%(95% confidence interval 86.6%-94.7%).

2. Statistical analysis between Innovita test results and existed marketed PCR products

Among 126 subjects who get positive result for PCR products, 85 samples were positive for the test reagent IgM antibody test; Among 221 subjects who get negative result for PCR product, 137 samples were negative for test reagent IgM antibody. The positive coincidence rate was 67.46%, the negative coincidence rate was 61.99%, and the overall coincidence rate was 63.98%.

Among 126 subjects who get positive result for PCR products, 104 samples were positive for the test reagent IgG antibody test; Among 221 subjects who get negative result for PCR product, 100 samples were negative for test reagent IgG antibody test. The positive compliance rate was 82.53%, the negative compliance rate was 45.25%, and the overall compliance rate was 58.79%.

3. Comprehensive analysis of IgM and IgG antibodies

Among 126 subjects with positive by PCR products, 79 are positive for both IgM and IgG antibodies, 16 are negative for both IgM and IgG antibodies, 6 are IgM positive and IgG negative, and 25 are IgM negative and IgG positive.

Among 221 subjects with negative PCR products, 84 are positive for both IgM and IgG antibodies, 100 are negative for both IgM and IgG antibodies, none is IgM positive and IgG negative, and 37 are IgM negative and IgG positive.

4.Interference analysis on other pathogen samples

Among 100 subjects, all of them were infected by other pathogens (influenza virus, respiratory syncytial virus, etc.). One case was positive for respiratory syncytial virus IgM antibody; one case was positive for adenovirus IgM antibody; 63 cases were positive for influenza A virus IgM antibody; 66 cases were positive for influenza B virus IgM antibody; parainfluenza virus Two cases were positive for IgM antibodies; 8 cases were positive for Chlamydia pneumoniae IgM antibodies; 1 case was positive for Legionella pneumoniae IgM antibodies; 44 cases were positive for Mycoplasma pneumoniae IgM antibodies.

In the cross-reaction experiment, the test results of the IgM antibodies tests were all negative; the results of IgG antibody test were all negative. It shows that the product has better anti-interference performance.

5.1 Sensitivity and specificity analysis

5.1.1 Sensitivity and specificity analysis of IgM antibody

Table sensitivity and specificity analysis for IgM antibody

Innovita Test	Infection situation		All
	Confirmed	uninfected	
2019-nCoV IgM Positive	85	0	85
2019-nCoV IgM Negative	41	62	103
Total	126	62	188

Sensitivity	67.46%	95%CI	58.9% -75.0%
Specificity	100%	95%CI	94.2% -100%
Overall compliance	78.19%	95%CI	71.8% -83.5%

5.1.2 Sensitivity and specificity analysis of IgG antibody

Table sensitivity and specificity analysis for IgG antibody

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Innovita Test	Infection situation		All
	Confirmed	uninfected	
2019-nCoV IgG Positive	104	0	104
2019-nCoV IgG Negative	22	62	84
Total	126	62	188

Sensitivity	82.54%	95%CI	75% -88.2%
Specificity	100%	95%CI	94.2% -100%
Overall compliance	88.30%	95%CI	82.9% -92.1%

5.1.3 Comprehensive analysis of sensitivity and specificity for IgM and IgG antibody

Table Comprehensive analysis of sensitivity and specificity for IgM and IgG antibody

Innovita Test	Infection situation		All
	Confirmed	uninfected	
2019-nCoV IgG Positive	110	0	110
2019-nCoV IgG Negative	16	62	78
Total	126	62	188

Sensitivity	87.3%	95%CI	80.4% - 92%
Specificity	100%	95%CI	94.2% - 100%
Overall compliance	91.49%	95%CI	86.6% - 94.7%

5.2 Statistical analysis of Innovita test and used marketed PCR products

5.2.1 Comparative analysis of IgM antibody test results and PCR products

Table Comparative analysis of IgM antibody test results with PCR products

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Innovita Test	PCR		Total
	Positive	Negative	
2019-nCoV IgM Positive	（A）85	（B）84	（A+B）169
2019-nCoV IgM Negative	（C）41	（D）137	（C+D）178
Total	（A+C）126	（B+D）221	（A+B+C+D）347

Positive coincidence rate	67.46%	95%CI	58.9%~75%
Negative coincidence rate	61.99%	95%CI	55.4%~68.1%
Total coincidence rate	63.98%	95%CI	58.8%~68.8%

5.2.2Comparative analysis of IgG antibody test results and PCR products

Table Comparative analysis of IgG antibody test results with PCR products

Innovita Test	PCR		Total
	Positive	Negative	
2019-nCoV IgG Positive	（A）104	（B）121	（A+B）225
2019-nCoV IgG Negative	（C）22	（D）100	（C+D）122
Total	（A+C）126	（B+D）221	（A+B+C+D）347

Positive coincidence rate	82.54%	95%CI	75%~88.2%
Negative coincidence rate	45.25%	95%CI	38.8%~51.8%
Total coincidence rate	58.79%	95%CI	53.5%~63.8%