

About Us



Objective: Entrusted by GenSure Biotch Inc. to conduct clinical testing and research on its noval coronavirus (2019-nCoV) IgM / IgG antibody detection kit (latex beads) according to the approved clinical protocols, comparing the clinical diagnostic standards, the relevant indicators such as sensitivity, specificity, and compliance rate with the clinical diagnosis results are counted to verify the applicability and effectiveness of the products developed by GenSure Biotch Inc. in clinical diagnosis.

Beads: Collect clinical blood samples of suspected cases of noval coronavirus infection pneumonia in our center, use new coronavirus (2019-nCoV) IgM / IgG antibody detection kit (latex beads) of GenSure Biotch Inc. to test, record the test results, and compare and analyze the clinical diagnosis results

Conclusion

The noval coronavirus (2019-nCoV) IgM/IgG antibody detection kit (Latex beads) produced by GenSure Biotch Inc, compared with the clinical diagnosis results, the clinical use research is as follows: the total clinical sensitivity of the evaluated reagents is 94.56%(95% confidence interval 89.56%-97.62%), and the clinical specificity is 100% (95% confidence interval 99.08% ~ 100.00%), the total coincidence rate is 98.54% (95% confidence interval 97.14% ~ 99.37%); the clinical sensitivity of the evaluated reagent of noval coronavirus IgM antibody is 87.07% (95% confidence interval 80.55% ~ 92.04%) , the clinical specificity is 100% (95% confidence interval 99.08% ~ 100.00%), and the total coincidence rate is 96.53% (95% confidence interval 94.63% ~ 97.90%); the clinical sensitivity of the noval coronavirus IgG antibody evaluated reagent is 91.16 % (95% confidence interval 85.35% ~ 95.21%), the clinical specificity is 100% (95% confidence interval 99.08% ~ 100.00%), the total coincidence rate is 97.62% (95% confidence interval 95.62% ~ 98.73%). Moreover, the products produced by GenSure Biotch Inc. have the same test results of homologous whole blood, serum and plasma samples, and there is no difference in sample types.

After clinical verification, the noval coronavirus (2019-nCoV) IgM / IgG antibody detection kit (latex beads) produced by GenSure Biotch Inc. can be used to

qualitatively detect new coronavirus in human whole blood, serum, and plasma samples in vitro (2019-nCoV) IgM / IgG antibody and assist in the diagnosis of new coronavirus (2019-nCoV) infection

Clinical trial results

In this clinical trial, a total of 547 suspected cases (147 confirmed cases and 400 excluded cases) were evaluated, of which 22 confirmed cases had continuous serum samples collected at different times, and 140 cases (70 confirmed cases and 70 excluded cases) Example) Contains homologous whole blood and plasma samples
A total of 147 confirmed cases, the statistical results are shown in the table below

	IgM/IgG	IgM	IgG
Positive	139	128	134
Negative	8	19	13
Total	147	147	147

1. IgM/IgG clinical sensitivity= $139/147 \times 100\% = 94.56\%$, 95% confidence interval 89.56%~97.62%.
2. IgM clinical sensitivity= $128/147 \times 100\% = 87.07\%$, 95% confidence interval 80.55%~92.04%.
3. IgG clinical sensitivity= $134/147 \times 100\% = 91.16\%$ 95% confidence interval 85.35%~95.21%.

A total of 400 suspected cases were excluded, the statistical results are shown in the table below

	IgM/IgG	IgM	IgG
Positive	0	0	0
Negative	400	400	400
Total	400	400	400

1. IgM/IgG clinical specificity= $400/400 \times 100\% = 100\%$ 95% confidence interval 99.08%~100.00%
2. IgM clinical specificity= $400/400 \times 100\% = 100\%$ 95% confidence interval 99.08%~100.00%
3. IgG clinical specificity= $400/400 \times 100\% = 100\%$ 95% confidence interval 99.08%~100.00%

Summary statistical analysis of suspected cases

1. IgM/IgG Total coincidence rate= $(139+400) / (139+8+0+400) \times 100\% = 98.54\%$ 95% confidence interval 97.14%~99.37%
2. IgM Total coincidence rate= $(128+400) / (128+30+0+400) \times 100\% = 96.53\%$ 95% confidence interval 94.63%~97.90%
3. IgG Total coincidence rate= $534 / (131+16+0+400) \times 100\% = 97.62\%$ 95% confidence interval 95.62%~98.73%.