SENSITIVITY AND SPECIFICITY TEST REPORTS
2019-nCoV IgG/IgM Rapid Test (1-363-K025)

METHOD

The diagnostic sensitivity and diagnostic specificity of the 2019-nCOV IgG / IgM Rapid Test (LFA) were analysed by using clinically confirmed and excluded samples.

Comparative analysis of IgG antibody test results and clinical diagnosis results:

Method		Clinical diagnosis results		Total Results
2019-nCoV IgG/IgM Rapid Test	Results	**Positive**	**Negative**	Total Results
	Positive	66 (A)	4 (B)	70
	Negative	8 (C)	103 (D)	111
Total Result		74	107	181

Diagnostic sensitivity (positive coincidence rate)

A/(A+C)×100% ＝89,19%

Diagnostic specificity (negative coincidence rate)

D/(B+D) 96,26 %

Total coincidence rate

(A+D)/(A+B+C+D) 93,37%

Comparative analysis of IgM antibody test results and clinical diagnosis results:

Method		Clinical diagnosis results		Total Results
2019-nCoV IgG/IgM Rapid Test	Results	**Positive**	**Negative**	Total Results
	Positive	65 (A)	5 (B)	70
	Negative	9 (C)	102 (D)	111
Total Result		74	107	181

Diagnostic sensitivity (positive coincidence rate)

A/(A+C)×100% ＝87,83%

Diagnostic specificity (negative coincidence rate)

D/(B+D) 95,32 %

Total coincidence rate

(A+D)/(A+B+C+D) 92,26%

CONCLUSION

The 2019-nCov IgG/IgM Rapid Test products have been compared with a commercial PCR using clinical specimen. The diagnostic sensitivity of the 2019-nCOV IgG / IgM Rapid Test (LFA) for IgG antibody detection is 89.19%, the diagnostic specificity is 96.26%, and the total coincidence rate is 93.37%; the diagnostic sensitivity for IgM antibody detection is 87.83 %, The diagnostic specificity is 95.32%, and the overall coincidence rate is 92.26%.