

**2019-Novel Coronavirus (2019-nCoV) IgG / IgM Detection Kit
(Colloidal Gold-Based)**

Clinical Test Report

Product Name	2019-Novel Coronavirus (2019-nCoV) IgG / IgM Detection Kit (Colloidal Gold-Based)			
Manufacturer	Nanjing Vazyme Medical Technology Co., LTD.			
Clinical Trial Organizations	Affiliated Hospital of Xuzhou Medical University, Southern Medical University Nanhai Hospital, The Fourth People's Hospital of Foshan City.			
Clinical Validation Method	The test results of 2019-Novel Coronavirus (2019-nCoV) IgG / IgM Detection Kit (Colloidal Gold-Based) were compared with the diagnosis results (based on nucleic acid detection method) obtained by the above clinical trial organization. Then, the positive rate, negative rate, total coincidence rates and KaPPa were analyzed.			
Analysis of Clinical Data	Serum, Plasma and Whole Blood Samples (n = 570)	Clinical Diagnosis		
		Positive	Negative	
	2019-Novel Coronavirus (2019-nCoV) IgG / IgM Detection Kit	Positive	189	11
		Negative	12	358
Total Sensitivity = 94.03% (95%CI 89.86 – 96.55)				
Total Specificity = 97.02% (95%CI 94.74 – 98.33)				
Total Conformity = 95.96% (95%CI 94.02 – 97.30)				
Conclusion	The test results show that the Vazyme 2019-Novel Coronavirus (2019-nCoV) IgG / IgM Detection Kit has a high specificity and is one of the effective methods for the diagnosis of 2019-nCoV.			
Report Provided by	Nanjing Vazyme Medical Technology Co., LTD.			
Date	March 2nd, 2020			

