

GenBody COVID-19 IgM/IgG Rapid Diagnostic Kits

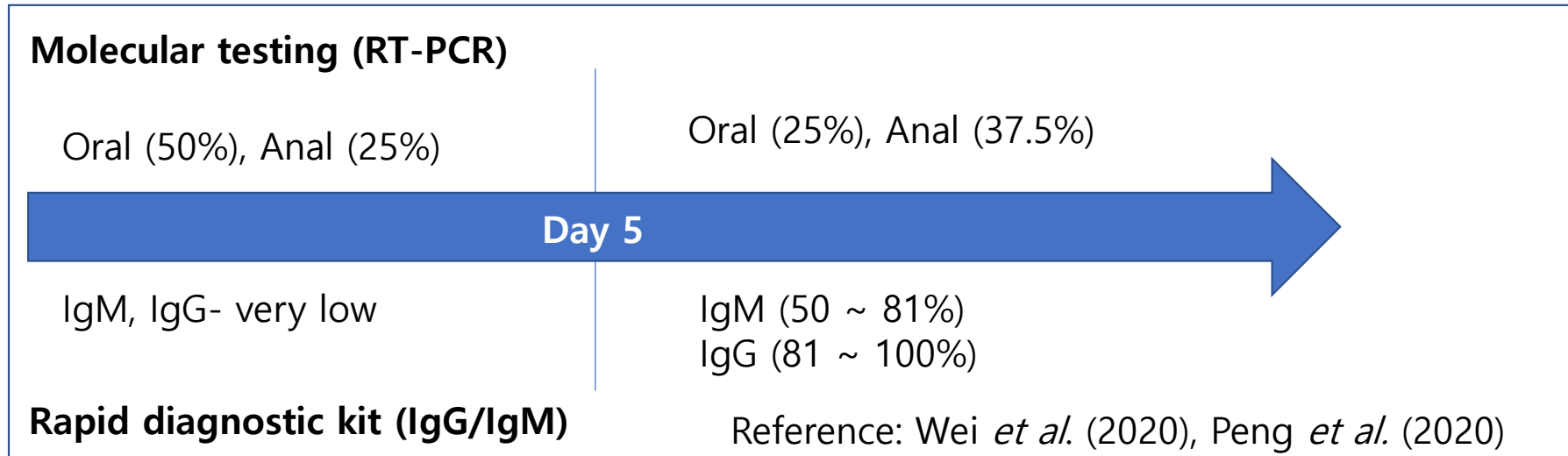
For bulk screening
For sero-epidemiologic investigations
For testing in asymptomatic, weak symptomatic or latent periods
For complement of molecular testing



James Chong, Ph.D

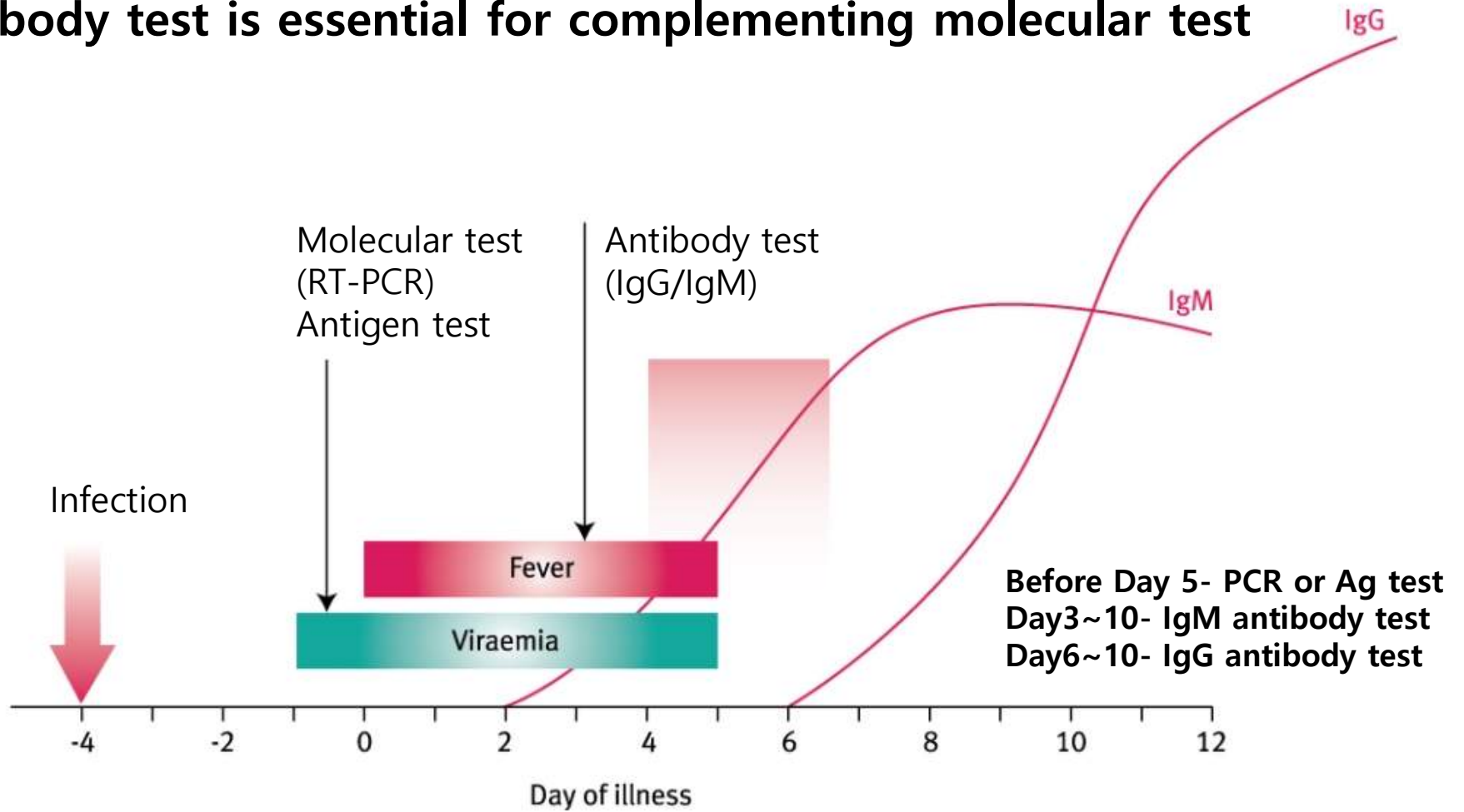
	Molecular Testing (RT-PCR)	Rapid Diagnostic Test for IgG/IgM
Principle	Nucleic acid test of COVID-19	Antibody detection in the bloods
Accuracy in house	High (known as 95%)	Medium (80 ~ 90% in the limited reports)
Accuracy in the fields	-China: 30 ~ 50% (Jungangilbo.2020.02.13) -Depending on the specimen swab, position and yield of gene extraction	-No report
Test time	6 hours	10~20 minutes
Test cost	Very expensive (~150 USD/T)	Economic (~10 USD/T)
User level	Skilled & trained	Normal
Specimen	Throat, anal, nasopharyngeal, sputum, blood → different accuracy at specimen type.	Blood
Test capacity	Limited	Possible to bulk testing
Adv/disadvantages	Impossible to detect at latent or asymptomatic period. Good accurate at early stage	Possible to detect at latent or asymptomatic period. Inaccurate at from 0 to 5~10 day after infection
	Appropriate for early stage (1~10 day) with limited cases of patients	Appropriate for 5 day-after with bulk cases of patients

Accuracy of each method

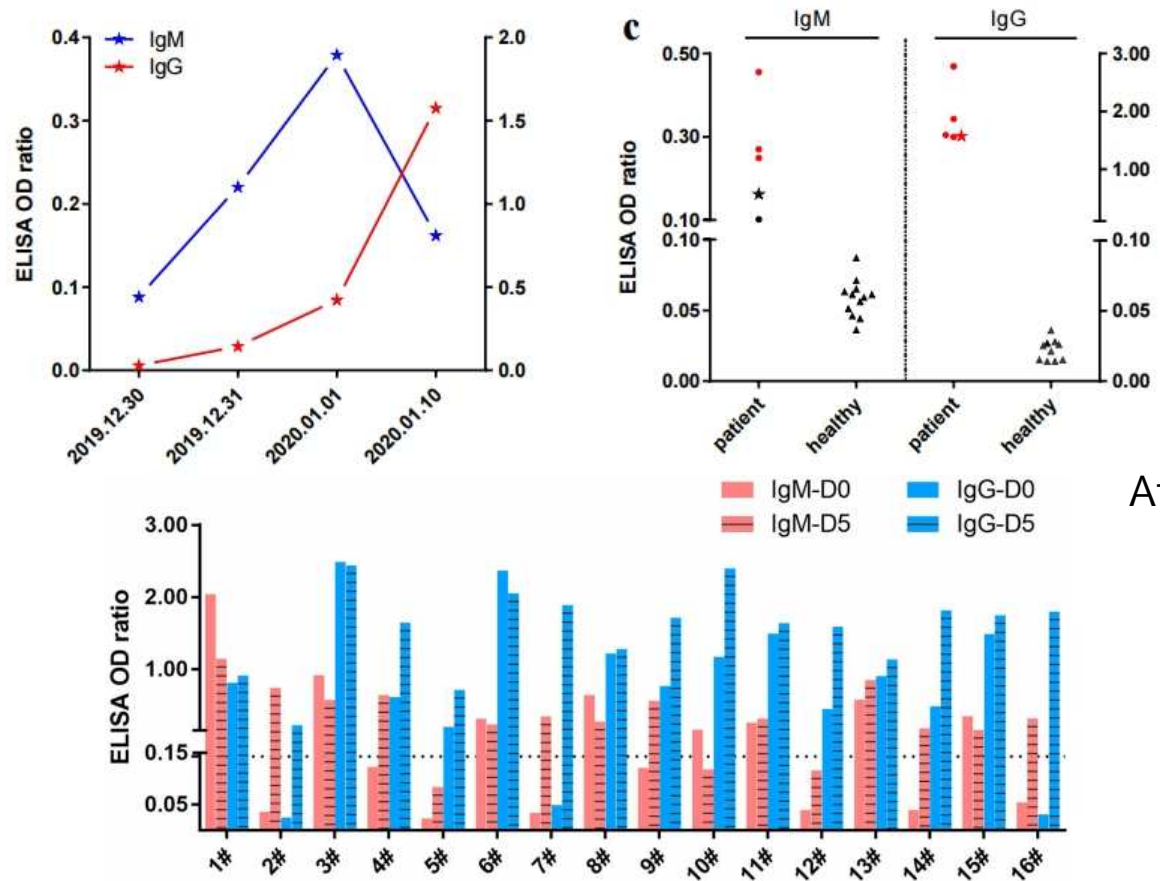


- Rapid diagnostic test**
- 1) For supplementation of molecular testing (More accurate after Day 5)
 - 2) For sero-epidemiologic investigations
 - 3) For testing in asymptomatic, weak symptomatic or latent periods

Antibody test is essential for complementing molecular test



Diagnostic accuracy of Antibody test



Reference: Peng *et al.* (2020)

After Day 5, antibody test is meaningful.

Reference: Wei *et al.* (2020)

Figure 1. Serological detection of 2019-nCoV. Dashed line indicates cutoff, which was determined based on data from healthy controls.

Principle and kit composition

(GenBody COVID-19 IgM/IgG Rapid Diagnostic Kit)

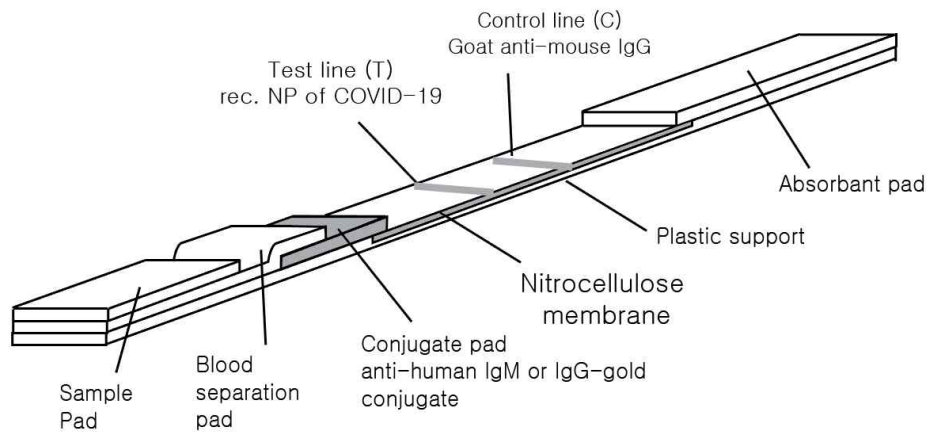


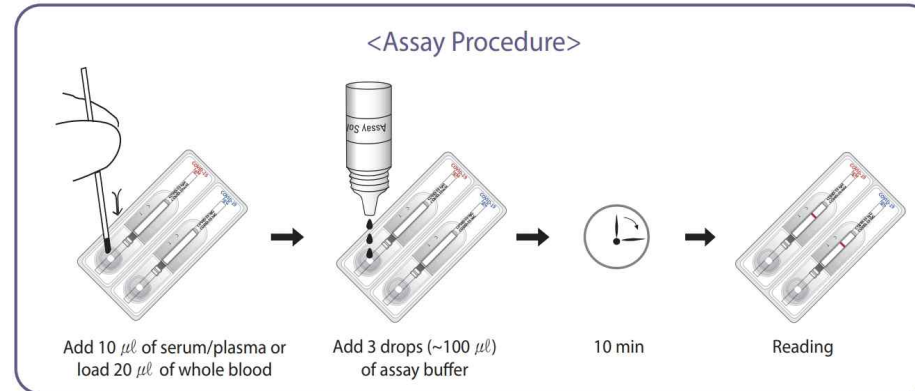
Diagram of the reaction strip



1. Test device individually foil-pouched with a desiccant
2. Assay solution in dropping bottle
3. Capillary tube for sample loading
4. Instructions for Use

Test method

(GenBody COVID-19 IgM/IgG Rapid Diagnostic Kit)



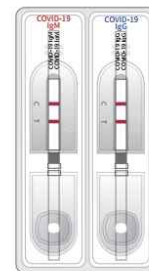
Negative



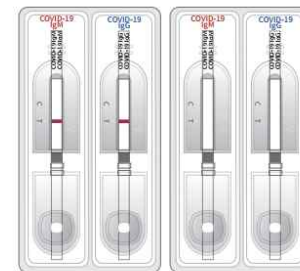
IgM
Positive



IgG
Positive



IgM/IgG
Positive



Invalid

Results of Clinical Evaluation

(GenBody COVID-19 IgM/IgG Rapid Diagnostic Kit)

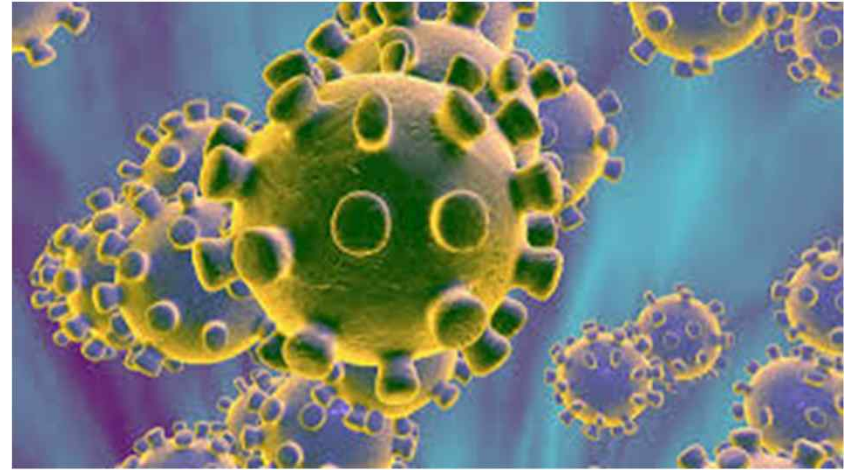
Test kit: GenBody's rNP (COVID-19)

Study site: Dankook University Hospital (Korea) and Dongbang Hospital Shanghai (China)

Testing date: Feb. 15 2020 ~ Mar. 05, 2020.

For IgM N= 159		Molecular test (RT-PCR)			Sensitivity= 30% at phase I and 80% phase II Specificity= 99%
		Positive		Negative	
		Phase I (Day 1 ~ 6)	Phase II (Day 7 ~)		
GenBody COVID IgM/IgG	Positive	3	25	1	
	Negative	6	5	119	
Sum		9	30	120	

For IgG N= 159		Molecular test (RT-PCR)			Sensitivity= 0% phase I and 100% phase II Specificity= 100%
		Positive		Negative	
		Phase I (Day 1 ~ 6)	Phase II (Day 7 ~)		
GenBody COVID IgM/IgG	Positive	0	30	0	
	Negative	9	0	120	
Sum		9	30	120	



- Thank you -