Specificity Study

(I) Purpose

To evaluate the specificity of CRT IgG/IgM test device.

(II) Sample Preparation

Samples infected by the following diseases were used in the specificity study: Influenza A Virus, Influenza B Virus, Adenovirus, Rotavirus and Mycoplasma Pneumoniae. Each sample was tested in three triplicates by using one lot of CRT IgG/IgM tests.

(III) Procedure

Each sample was tested in three triplicates by using one lot of CRT IgG/IgM tests.
Read results at 15 minutes.

(IV) Results

CRT IgG/IgM Test

Lot# 20N0080

Sample Type	Number of samples tested	Negative		Positive	
		IgG	IgM	IgG	IgM
Samples infected by Influenza A Virus	3	3	3	0	0
Samples infected by Influenza B Virus	3	3	3	0	0
Samples infected by Adenovirus	3	3	3	0	0
Samples infected by Rotavirus	3	3	3	0	0
Samples infected by Mycoplasma Pneumoniae	3	3	3	0	0

(V) Conclusion

All the samples showed no affect on the specificity of CRT IgG/IgM test device.

Interference Study

(I) Purpose

To evaluate the interference compounds commonly appeared in human blood specimens.

(II) Sample Preparation

All compounds were prepared in three levels of CRT IgG/IgM controls to defined concentration. Each compound in each level of controls was tested in three triplicates by using one lot of CRT IgG/IgM tests.

(III) Procedure

Add the following substances to negative, weak positive and positive controls, to reach the defined concentration.

Substances	Concentration
Rheumatoid Factor	80 IU/ml
Bilirubin	342 µmol/L
Triglyceride	37 mmol/L
Hemoglobin	10 mg/mL

Acceptance criteria: No effect of listed substances at defined concentration in blood samples. If a compound shows interference that either cause negative to become positive or positive to become negative, do 2-fold dilution until the expected result is obtained. The non-interference concentration is set as the lowest concentration that gives expected result.

(IV) Results

CRT IgG/IgM Rapid Test Part#

Lot# 20N0080

Substance	Concentration Tested	Negative		Weak Positive		Positive		Interfere (Y/N)
		IgG	IgM	IgG	IgM	IgG	IgM	
Rheumatoid Factor	80 IU/ml	N	N	P	P	P	P	N
Bilirubin	342 µmol/L	N	N	P	P	P	P	N
Triglyceride	37 mmol/L	N	N	P	P	P	P	N
Hemoglobin	10 mg/mL	N	N	P	P	P	P	N

(V) Conclusion

The tested compounds were found not to interfere when tested at the desired concentrations.

Interference Study

(I) Purpose

To evaluate the interference compounds commonly appeared in common drugs.

(II) Sample Preparation

All compounds were prepared in three levels of 2019-nCoV IgG/IgM controls. Each compound in each level of controls was tested in three triplicates by using one lot of 2019-nCoV IgG/IgM rapid tests.

(III) Procedure

Add the following substances to negative, weak positive and positive controls.

Histamine Hydrochloride	Oseltamivir	Arbidol	Meropenem
Interferon-α	Peramivir	Levofloxacin	Tobramycin
Zanamivir	Lopinavir	Azithromycin	
Ribavirin	Ritonavir	Ceftriaxone	

(IV) Results

CRT IgG/IgM Rapid Test Part#

Lot# 20N0080

Substance	Negative		Weak Positive		Positive		Interfere (Y/N)
	IgG	IgM	IgG	IgM	IgG	IgM	
Histamine Hydrochloride	N	N	P	P	P	P	N
Interferon-α	N	N	P	P	P	P	N
Zanamivir	N	N	P	P	P	P	N
Ribavirin	N	N	P	P	P	P	N
Oseltamivir	N	N	P	P	P	P	N
Peramivir	N	N	P	P	P	P	N
Lopinavir	N	N	P	P	P	P	N
Ritonavir	N	N	P	P	P	P	N
Arbidol	N	N	P	P	P	P	N
Levofloxacin	N	N	P	P	P	P	N
Azithromycin	N	N	P	P	P	P	N
Ceftriaxone	N	N	P	P	P	P	N
Meropenem	N	N	P	P	P	P	N
Tobramycin	N	N	P	P	P	P	N

(V) Conclusion

The tested compounds were found not to interfere when tested.

Accuracy Study

(I) Materials

1. Three hundred and five specimens from healthy persons.
2. Two hundred and fourteen specimens from COVID-19 confirmed patients.
3. CRT IgG/IgM Tests

(II) Method and Report

1. Test the three hundred and five specimens from healthy persons with the provided CRT IgG/IgM tests according to the instructions for use.
2. Test the two hundred and fourteen specimens from COVID-19 confirmed patients with the provided CRT IgG/IgM tests according to the instructions for use.
3. Record the results at 15 minutes.

(III) Acceptance Criteria

Clinical sensitivity:
≥85%

Clinical specificity: ≥
85%

(IV) Results and Calculation

CRT IgG/IgM Rapid Test Part#

Lot# 20N0080

Calculation:
From 305 healthy patients 302 were correctly diagnosed as negative and 3 of them as positive (1 IgM positive and 2 IgG positive)

Specificity of IgG = IgG negative/ total number of samples= (305-2) / 305 *100%
=**99.3%**
Specificity of IgM = IgM negative/ total number of samples= (305-1) / 305 *100%
=**99.7%**
Both IgG and IgM specificity meet the acceptance criteria.

Calculation:
From 214 positive patients 203 were correctly diagnosed as positive and 11 of them as negative.

Sensitivity of IgG/IgM = IgG/IgM positive/ total number of samples= (214-11) / 214 *100% **=94.86%**
Sensitivity of IgG/IgM meet the acceptance criteria

Overall Accuracy = (302+203)/(214+305)*100 = 97.30%

(V) Conclusion

1. No invalid results were reported. Human error has been minimized so that CRT IgG/IgM test can be used easily.
2. Based on the calculation that specificity of IgG is 99.3% and IgM is 99.7%, the study results demonstrate CRT IgG/IgM tests meet the acceptance criteria and reach the high agreement with expected results.
3. With the facts that sensitivity of IgG/IgM is 94.86%, we conclude that CRT IgG/IgM rapid tests succeed in sensitivity performance with accurate results.
4. The Overall Accuracy rate was determined as 97.30 %.