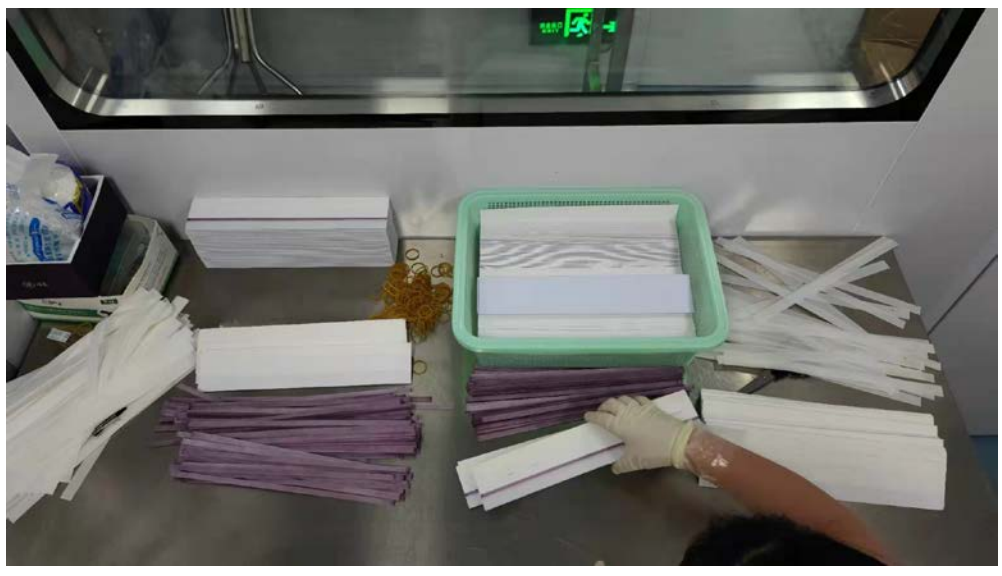
BALLYA

Uncut Sheet Of RTK Swab Test

For SARS-CoV-2 Antigen Test Kit Manufacturing



BALLYA COVID-19 ANTIGEN RAPID TEST PERFORMANCE CHARACTERISTICS

Clinical trial from European

Sensitivity and Specificity

Clinical study was performed to compare the results obtained by The kit and PCR. The results indicated that The kit has a high sensitivity and specificity as summarized below:

Nasal swabs		PCR		Total Results
Antigen Rapid Test	Results	Positive	Negative	
	Positive	757	23	780
	Negative	13	1021	1034
Total Results		770	1044	1814
Throat swab		**PCR**		**Total Results**
Antigen Rapid Test	Results	Positive	Negative	
	Positive	763	21	784
	Negative	13	1043	1056
Total Results		776	1064	1840

Clinical sensitivity = (757+763)/(757+23+763+21)=98.32%
(95%CI* 97.55% to 98.90%)

Clinical specificity = (1021+1043)/(1021+13+1043+13)=97.91 %
(95%CI* 97.21% to 98.48%)

Accuracy: (757+763+1021+1043)/ (757+23+763+21+1021+13+1043+13) =98.08%
(95%CI* 97.24% to 98.33%)

Minimum detection limit

The minimum detection limit for The kit is 200 TCID50/ml.

Clinical trial from Malaysia

Test Kit

The evaluation was carried out using this kit with the lot number of BY202108331 and the expiry date was Aug.30 2022.

Instrument Used

NA

Type of sample used

Nasopharyngeal swab & Oropharyngeal swab samples in VTM

Reagent and Sample Preparation. Result Interpretation

Kindly refer to product package insert tn the attachment

Sample Used

Known Positive Sample = 50
Known Negative Sample = 50
Total samples used for analysis = 100

Performance Analysis

Test	Tested Kit Assay		Interpretation
	Positive	Negative	
SARS-COV2 Positive (COVID-19)	45	5	Sensitvity= 90%
SARS-CoV2 Negative (COVID-19)	0	50	Specificity = 100%

Comments

Positive panels were selected among the samples that had been tested positive using our RT-PCR teat system and Ihe CT values were ranged from to 30 As the negative panels had been tested negative using our RT-PCR test system.

Clinical trial from Thailand

		RT-PCR Confirmed Cases		
		Positive	Negative	Total
SARS-CoV-2Antigen Assay Kit(Colloidal Gold Method)	Positive 55	53	0	53
	Negative 100	2	100	102
	Total	55	100	155

- Sensitivity =A/(A+C)×100%
  =53/(53+2)×100%
  =96.36%
- Positive Predictive value(%) =A/(A+B)×100%
  =53/(53+0)×100%
  =100%
- Specificity =D/(B+D)×100%
  =100/(0+100)×100%
  =100%
- Negative Predictive value(%) =D/(C+D)×100%
  =100/(2+100)×100%
  =98.04%

In house LOD research & comparison

Manu-facturers	N protein (pg/mL)	Inactivated Virus Culture(IVC) Titer			
		IVC 1	IVC 2	IVC 3	IVC 4
BALLYA A	10	40,000	200,000	100,000	200,000
BALLYA B	10	40,000	200,000	50,000	200,000
SD	25	2,500	100,000	25,000	25,000
BS	50	2,500	50,000	50,000	<50,000
AB	50	<2,500	100,000	50,000	100,000
WF	>100	<2,500	<50,000	100,000	<50,000
FP	50	2,500	50,000	100,000	<50,000

Conclusion

Uncut sheets LOD equal to CT value <30, 100% detection ratio; CT values 30, >98% detection ratio; CT values 31-35, from 67% - 85% ratio. TCIDso/ml (100 - 200).
The datas just only for reference, because the controls are big different between manufacturers, or from positive patients in each countries, or virus variation or mutation may cause different performance.