SARS-CoV-2 Antigen Rapid Test Kit

(Fluorescence Immunochromatography)

Clinical Evaluation Report

30 November 2020

Objective

The objective of this study was to evaluate the diagnostic performances of SARS-CoV-2 Antigen Rapid Test Kit (fluorescence immunochromatography) produced by Biohit Healthcare (Hefei) Co., Ltd. (sensitivity, specificity and positive and negative predictive values from pre-specified prevalence assumptions) carried out on nasopharyngeal and oropharyngeal swab samples collected.

Material and methods

This was a retrospective study carried out using nasopharyngeal and oropharyngeal swab samples, from 119 patients with COVID-19 infection confirmed by PCR. Negative samples were collected from 250 patients with confirmed PCR negative results.

Samples tested included:

- 119 nasopharyngeal and oropharyngeal swab samples from German laboratory in 3ml Nacl or 3ml PBS, tested positive for SARS-CoV-2 by PCR (RT-PCR by Roche Cobas system), tested in November, 2020. The time span of the samples is from beginning of the pandemic to November 2020. The nasopharyngeal and oropharyngeal swabs samples were collected on the day of confirmed diagnosis of COVID-19 infection (the day of PCR test result is positive).
- 250 nasopharyngeal and oropharyngeal swab samples in 3ml Nacl or 3ml PBS from the same sources, tested negative for SARS-CoV-2 by PCR (RT-PCR by Roche Cobas system), tested in November 2020.

Reagent and Instrument：

- SARS-CoV-2 Antigen Rapid Test Kit (fluorescence immunochromatography) Manufacturer：Biohit Healthcare (Hefei) Co., Ltd.; Batch number: SA200903.
- Ultraviolet flashlight：TANK007 (365nm wavelength)
  Manufacturer：Shenzhen Zhong Dao Electronics Co., Ltd.

Results

The Biohit results are shown below table:

1) **Sensitivity** (Se, percentage of positive RAPID results among the cases identified as positive by PCR [i.e., true positives / (true positives + false negatives)]);
2) **Specificity** (Sp, percentage of negative RAPID results among the cases identified as negative [i.e., true negatives / (true negatives + false positives)]);
3) **Positive predictive values** (PPV: probability that a positive test is a true positive in PCR, defined by the formula Se * P / (Se * P + (1-P) * (1-Sp)) [with P = prevalence]); calculated for pre-specified prevalence of infection in the tested population of 1% and 5%.
4) **Negative predictive values** (NPV: probability that a negative test is a true negative in PCR, defined by the formula Sp * (1-P) / (Sp * (1-P) + P * (1-Se)) [with P =

prevalence]); calculated for pre-specified prevalence of infection in the tested population of 1% and 5%.

Specificity				Sensitivity				PPV		NPN	
N	%Negative	IC 95%		N	%Positive	IC 95%		P=1%	P=5%	P=1%	P=5%
250	99.6%	97.79%	99.99%	119	78.15%	69.65%	85.20%	66.37%	91.14%	99.78%	99.77%
CT Value				Number	Sensitivity	IC 95%					
CT≤20				8	100%	63.06%	100.00%	71.63%	92.94%	100.00%	100.00%
CT]20-25]				36	100%	90.26%	100.00%	71.63%	92.94%	100.00%	100.00%
CT]25-30]				46	84.78%	71.13%	93.66%	68.16%	91.77%	99.85%	99.84%
CT>30				29	34.48%	17.94%	54.33%	46.54%	81.94%	99.34%	99.31%
CT≤33				106	86.79%	78.83%	92.59%	68.67%	91.95%	99.87%	99.86%
CT≤30				90	92.22%	84.63%	96.82%	69.96%	92.39%	99.92%	99.92%
CT≤25				44	100%	91.96%	100.00%	71.63%	92.94%	100.00%	100.00%
Overall sensitivity versus PCR: 78.15% - Sensitivity for Ct ≤33: 86.79% - Specificity: 99.6%											

Comparison with other COVID- 19 antigenic TRODs

Source：Diagnostic performance evaluation of covid-19 rapid diagnostic localization test(*https://www.aphp.fr/contenu/evaluation-de-la-performance-diagnostique-des-tests- rapides-dorientation-diagnostique*)

This was a retrospective study carried out using nasopharyngeal samples collected prospectively. Samples tested included **297 aliquots** of nasopharyngeal samples in commercial viral transport medium (Cepheid® or Deltalab®) or physiological serum, **tested positive for SARS-CoV-2 by PCR, and 337 aliquots** of nasopharyngeal samples in commercial viral transport medium (Cepheid®), **tested negative for SARS-CoV-2** because they were taken before the virus circulating period, i.e., between April and August 2019. Six COVID-19 antigenic TRODs were verified, **the ABBOTT, BIOSYNEX and AAZ tests were the most efficient.**

1) Test ABBOTT

ABBOTT											
Spécificité					Sensibilité				VI P		VP N	
	N témoins	Témoins négatifs	IC 95%		N cas	% C as positifs	IC 95%		Prévalence 1%	Prévalence 5%	Prévalence 1%	Prévalence 5%
G lo bal	337	100,0%	98,9%	100,0%	295	55,3%	49,4%	61,0%	100,0%	100,0%	99,6%	97,7%
Par sous groupes	Délai d'apparition des symptômes											
	Délai 0-3j				97	79,4%	70,0%	86,9%	100,0%	100,0%	99,8%	98,9%
	Délai 4-7j				103	52,4%	42,4%	62,4%	100,0%	100,0%	99,5%	97,6%
	Délai 8-11j				63	33,3%	22,0%	46,3%	100,0%	100,0%	99,3%	96,6%
	Délai ⩾12j				24	37,5%	18,8%	59,4%	100,0%	100,0%	99,4%	96,8%
	Délai ⩽7j				200	65,5%	58,5%	72,1%	100,0%	100,0%	99,7%	98,2%
	Ct value											
	Ct ⩽20				40	95,5%	83,1%	99,4%	100,0%	100,0%	99,9%	99,7%
	Ct]20-25]				90	83,3%	74,0%	90,4%	100,0%	100,0%	99,8%	99,1%
	Ct]25-30]				73	57,5%	45,4%	69,0%	100,0%	100,0%	99,6%	97,8%
	Ct >30				88	8,0%	3,3%	15,7%	100,0%	100,0%	99,1%	95,4%
	Ct ⩽33				245	65,7%	59,4%	71,6%	100,0%	100,0%	99,7%	98,2%
	Ct ⩽25				130	86,9%	79,9%	92,2%	100,0%	100,0%	99,9%	99,3%
	Ct ⩽23				96	94,8%	88,3%	98,3%	100,0%	100,0%	99,9%	99,7%
	Sévérité											
	Bénin				202	58,4%	51,3%	65,3%	100,0%	100,0%	99,6%	97,9%
	Sévère				92	47,8%	37,3%	58,5%	100,0%	100,0%	99,5%	97,3%

Sensibilité globale versus PCR : 55,3% - Sensibilité pour Ct ⩽33 : 65,7% - Spécificité : 100%

NB : Résultats invalides : 2 positifs en PCR

Overall sensitivity versus PCR: 55.3% - Sensitivity for Ct ⩽33: 65.7% - Specificity: 100%

NB: Invalid results: 2 positive in PCR

2) BIOSYNEX

BIOSYNEX												
Spécificité					Sensibilité				VI P		VP N	
	N témoins	Témoins négatifs	IC 95%		N cas	% C as positifs	IC 95%		Prévalence 1%	Prévalence 5%	Prévalence 1%	Prévalence 5%
G lo bal	337	98,5%	96,6%	99,9%	297	59,6%	53,8%	65,2%	28,6%	67,6%	99,6%	97,9%
Par sous groupes	Délai d'apparition des symptômes											
	Délai 0-3j				97	81,4%	72,3%	88,6%	35,4%	74,1%	99,8%	99,0%
	Délai 4-7j				103	56,3%	46,2%	66,1%	27,5%	66,4%	99,6%	97,7%
	Délai 8-11j				63	42,9%	30,5%	56,0%	22,4%	60,1%	99,4%	97,0%
	Délai ⩾12j				26	42,3%	23,4%	63,1%	22,2%	59,8%	99,4%	97,0%
	Délai ⩽7j				200	68,5%	61,6%	74,9%	31,6%	70,6%	99,7%	98,3%
	Ct value											
	Ct ⩽20				40	97,5%	86,8%	99,9%	39,6%	77,4%	100,0%	99,9%
	Ct]20-25]				90	92,2%	84,6%	96,8%	38,3%	76,4%	99,9%	99,6%
	Ct]25-30]				74	63,5%	51,5%	74,4%	30,0%	69,0%	99,6%	98,1%
	Ct >30				89	9,0%	4,0%	16,0%	5,7%	24,0%	99,1%	95,4%
	Ct ⩽33				247	65,7%	65,2%	76,8%	32,4%	71,4%	99,7%	98,5%
	Ct ⩽25				130	86,9%	88,2%	97,3%	38,7%	76,7%	99,9%	99,7%
	Ct ⩽23				96	94,8%	91,1%	99,4%	39,5%	77,3%	100,0%	99,8%
	Sévérité											
	Bénin				202	60,4%	53,3%	67,2%	28,9%	67,9%	99,6%	97,9%
	Sévère				94	58,5%	47,9%	68,6%	28,3%	67,2%	99,6%	97,8%

Sensibilité globale versus PCR : 59,6% - Sensibilité pour Ct ⩽33 : 71,3% - Spécificité : 98,5%

NB : Résultats invalides : aucun

Overall sensitivity versus PCR: 59.6% - Sensitivity for Ct ⩽33: 71.3% - Specificity: 98.5%

NB: Invalid results: none

3) AAZ

AZZ												
Spécificité					Sensibilité				VI P		VP N	
	N témoins	Témoins négatifs	IC 95%		N cas	% C as positifs	IC 95%		Pré valence 1%	Prévalence 5%	Prévalence 1%	Prévalence 5%
G lo bal	337	100,0%	98,9%	100,0%	295	61,7%	55,9%	67,3%	100,0%	100,0%	99,6%	98,0%
Par sous groupes	Délai d'apparition des symptômes											
	Délai 0-3j				97	81,4%	72,3%	88,6%	100,0%	100,0%	99,8%	99,0%
	Délai 4-7j				103	61,2%	51,1%	62,4%	100,0%	100,0%	99,6%	98,0%
	Délai 8-11j				63	42,9%	30,5%	59,0%	100,0%	100,0%	99,4%	97,1%
	Délai ⩾12j				24	37,5%	18,8%	59,4%	100,0%	100,0%	99,4%	96,8%
	Délai ⩽7j				200	71,0%	64,2%	77,2%	100,0%	100,0%	99,7%	98,5%
	Ct value											
	Ct ⩽20				40	100,0%	91,2%	100,0%	100,0%	100,0%	100,0%	100,0%
	Ct]20-25]				90	94,4%	87,5%	98,2%	100,0%	100,0%	99,9%	99,7%
	Ct]25-30]				73	65,8%	53,7%	76,5%	100,0%	100,0%	99,7%	98,2%
	Ct >30				88	9,1%	4,0%	17,1%	100,0%	100,0%	99,1%	95,4%
	Ct ⩽33				245	73,5%	67,5%	78,9%	100,0%	100,0%	99,7%	98,6%
	Ct ⩽25				130	96,2%	91,3%	98,7%	100,0%	100,0%	100,0%	99,8%
	Ct ⩽23				96	97,9%	92,7%	99,7%	100,0%	100,0%	100,0%	99,9%
	Sévérité											
	Bénin				202	62,4%	55,3%	69,1%	100,0%	100,0%	99,6%	98,1%
	Sévère				92	59,8%	49,0%	69,9%	100,0%	100,0%	99,6%	97,9%

Sensibilité globale versus PCR : 61,7% - Sensibilité pour Ct ⩽33 : 73,5% - Spécificité : 100%
NB : Résultats invalides : 2 positifs en PCR
Overall sensitivity versus PCR: 61.7% - Sensitivity for Ct ⩽33: 73.5% - Specificity: 100%
NB: Invalid results: 2 positive in PCR

Conclusion

Based on the above research, Biohit SARS-CoV-2 Antigen Rapid Test Kit (fluorescence immunochromatography) is most effective in diagnostic performances of COVID-19.