SARS-CoV-2 Antigen Rapid Test Kit

(Fluorescence Immunochromatography)

Clinical Evaluation Report

30 November 2020

Collaboration:

Wiesbaden Germany，Microbiology Institute of German Armed Forces

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 samples collected.

Material and methods

This was a retrospective study carried out using nasopharyngeal 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 samples frozen at -80 ° C 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 **70** samples from **Labor Dr. Riegel in Wiesbaden Germany**, and **49** samples from **Microbiology Institute of German Armed Forces**. The nasopharyngeal swab samples were collected on the day of confirmed diagnosis of COVID-19 infection (the day of PCR test result is positive).
- **250** nasopharyngeal samples frozen at -80 ° C 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.

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 frozen at -80 ° C 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 frozen at -80 ° C in commercial viral transport medium (Cepheid®) **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				VPP		VPN	
	N témoins	Témoins négatifs	IC 95%		N cas	% Cas positifs	IC 95%		Prévalence 1%	Prévalence 5%	Prévalence 1%	Prévalence 5%
Global	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	95,0%	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				VPP		VPN	
	N témoins	Témoins négatifs	IC 95%		N cas	% Cas positifs	IC 95%		Prévalence 1%	Prévalence 5%	Prévalence 1%	Prévalence 5%
Global	337	98,5%	96,6%	99,5%	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%	16,9%	5,7%	24,0%	99,1%	95,4%
	Ct ≤33				247	71,3%	65,2%	76,8%	32,4%	71,4%	99,7%	98,5%
	Ct ≤25				130	93,8%	88,2%	97,3%	38,7%	76,7%	99,9%	99,7%
	Ct ≤23				96	96,9%	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

AAZ											
	Spécificité				Sensibilité				VPP		VPN	
	N témoins	Témoins négatifs	IC95%		N cas	% Cas positifs	IC95%		Prévalence 1%	Prévalence 5%	Prévalence 1%	Prévalence 5%
Global	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%	70,6%	100,0%	100,0%	99,6%	98,0%
	Délai 8-11j				63	42,9%	30,5%	56,0%	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.