PERFORMANCE EVALUATION RESULTS
FOR DETECTION OF SARS-CoV-2 BY
COMPARISON WITH THE REFERENCE TECHNIQUE OF CNR

Kit Name: ANDiS SARS-CoV-2 and Influenza A&B RT-qPCR Detection Kit
Supplier: Wiratech
Detection: 2 targets (SARS-CoV-2) + 1 endogenous control
Influenza A and B

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OBJECTIVES

The objective of the evaluation is to test the analytical sensitivity of the test mentioned above, for the detection of SARS-CoV-2 by comparison with the reference technique used at the CNR of the Pasteur Institute, from:

- RNA extracted from mixtures of respiratory samples positive for SARS-CoV-2 and covering a wide range of Ct up to the detection limit (pools 1, 3, 4, 5, 6, 7, 8 and 9).
- An RNA extracted from mixtures of negative respiratory samples for SARS-CoV- 2 (pool Neg).
- RNA extracted from respiratory samples positive for influenza virus type A (Flu A) and type B (Flu B).

The specificity of the kit and in particular the cross-reactions with other strains of coronavirus are not evaluated by this test.

MATERIALS AND METHODS

Panel of tested samples

- Nine mixtures of patient nasopharyngeal respiratory samples with similar Ct values, one of which is negative sera. The most concentrated mixtures (pools 1, 3 and 4) are tested only once. The least concentrated mixtures (pools 5, 6, 7, 8 and 9) and the negative are tested in triplicates.
- RNA extracted from a supernatant of viral culture diluted to 10ooe serving as positive control.
- Two nasopharyngeal respiratory samples from patients positive for influenza A and influenza B respectively. These samples are only tested once.

CNR reference technique

Extraction with the NucleoSpin Dx Virus Extraction kit (Ref. Macherey Nagel 740895.50).
Superscript ™ Ill Platinum® One-Step Quantitative RT-PCR System (Ref. Lnvitrogen 1732-020).
Two targets: IP2 and IP4
Test sample: 5 µL

Technique evaluated according to the supplier's instructions

12.5 µL test sample.
Amplification on ABI 7500

RESULTS

Numéro échantillon	Ct de la technique de référence *		Ct du kit ANDiS SARS-CoV-2 et Grippe A/B par RT-qPCR					
	IP2	IP4	N gene	ORF1ab gene	Grippe A	Grippe B	Contrôle interne	Commentaires
Pool 1	15,0	15,1	13,62	15,02	ND	ND	ND	
Pool 3	19,1	19,1	17,86	18,67	ND	ND	19,18	
Pool 4	22,5	22,6	21,63	22,55	ND	ND	16,39	
Pool 5	25,5	25,5	23,80	24,66	ND	ND	18,56	
Pool 6	30,2	30,6	26,71	27,86	ND	ND	20,32	
Pool 7	32,9	33,3	29,92	32,03	ND	ND	28,21	
Pool 8	34,4	35,1	33,15	34,19	ND	ND	31,77	
Pool 9	38,4	38,1	35,22	37,4	ND	ND	32,51	2/3 pour ORF1ab gene
Pool Neg	ND	ND	ND	ND	ND	ND	30,43	
ARN viral	32,03	28,82	25,50	30,17	ND	ND	NA	
Contrôle positif kit	NA	NA	35,82	34,60	36,31	32,66	35,21	
Grippe A			ND	ND	23,30	ND	NA	
Grippe B			ND	ND	ND	31,51	NA	

ND : non détecté ; NA : non applicable
* : https://www.who.int/docs/default-source/coronaviruse/real-time-rt-pcr-assays-for-the-detection-of-sars-cov-2-institut-pasteur-paris.pdf?sfvrsn=3662fcb6_2

Paris, le 3/06/2020.
Pr. Sylvie van der WERF

The CNR reference technique detects the viral RNA of SARS-CoV-2

- Up to pool 9 with IP2 and IP4 targets

The **ANDiS SARS-CoV-2 and Influenza A&B RT-qPCR Detection Kit** detects the viral RNA from SARS-CoV-2 to pool 9, the most diluted of the panel.
The **ANDiS SARS-CoV-2 and Influenza A&B RT-qPCR Detection Kit** presents:

- a sensitivity identical to that of the CNR reference technique on the two targets
- absence of internal control detection for pool 1.
  This is likely related to interference due to the high concentration of target RNA. The detection of the internal control is essential to make a negative result but it is not useful to make a positive result all the same.

CONCLUSIONS

The National Reference Center for Respiratory Infections Viruses (including influenza) considers **ANDiS SARS-CoV-2 and Influenza A&B RT-qPCR Detection Kit** to have an acceptable sensitivity for detection of SARS-CoV-2.

The specificity of the kit has not been evaluated.