

## Performance results for the detection of SARS-CoV-2 in comparison with the standard technique of the CNR



Name of the PCR kit: *SmartAmp Covid-19 (Lamp system)*

Manufacturer/Supplier: *EMG/MSE*

Extraction/Detection: *LifeCase (portable minilab)*

### Investigating laboratory

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### AIMS

The aim of this evaluation is to test the **analytical sensitivity** of the test mentioned above, for the detection of SARS-CoV-2 in two conditions: the **SmartAmp Covid-19 kit + LifeCase**, and the **SmartAmp Covid-19 kit + LightCycler480**. These conditions were compared with the standard technique used by the CNR at the Pasteur Institute, and were tested on the following samples:

- RNA extracted with **LifeCase** from a pool of SARS-CoV-2 positive respiratory samples, covering a large range of Ct, up to the limit of detection (pools 1, 2, 3, 4, 5, 6, 7, 8 and 9)
- RNA extracted with **LifeCase** from a pool of SARS-CoV-2 negative respiratory samples (Pool neg)

**Specificity of the kit and cross-reactions with other variants of coronavirus are not evaluated in this study**

## **MATERIAL AND METHODS**

### **Selection of samples**

Nine pools of nasopharyngeal (respiratory) samples from patients presenting similar Ct values (in each pool), including one composed of negative serum only. Most concentrated pools (1, 3 and 4) are tested only once. Less concentrated pools (5, 6, 7, 8 and 9) are tested in triplicates.

### **Standard technique at the CNR**

RNA extraction with the extraction kit NucleoSpin Dx Virus (Ref. Macherey Nagel 740895.50)

SuperScript™ III Platinum® One-Step Quantitative RT-PCR System (Ref. Invitrogen 1732-020)

Two targets: IP2 and IP4

Sampling volume: 5 µl

### **Tested technique, according to instructions provided by supplier**

Sampling volume: 10 µl of the RNA extracted with **LifeCase**

Amplification on LightCycler480 and **LifeCase**

## RESULTS

Sample ID	Ct from std CNR technique*		Results (+/total) with LifeCase		Results (+/total) with Roche lightCycler480	
	IP2	IP4	SARS-CoV-2	Comments	SARS-CoV-2	Comments
Pool 1	14.99	15.13	1/1		1/1	
Pool 3	19.05	19.12	1/1		1/1	
Pool 4	22.48	22.60	1/1		1/1	
Pool 5	25.51	25.52	3/3		3/3	
Pool 6	30.23	30.55	3/3		3/3	
Pool 7	32.93	33.36	3/3		3/3	
Pool 8	34.39	35.13	3/3		3/3	
Pool 9	38.35	38.82	ND	Weak signal	ND	
Pool neg	ND	ND	ND		ND	
Water	ND	ND	ND		ND	

ND: not detected

\* [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](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)

The standard CNR technique detects viral RNA from SARS-CoV-2:

- Up to pool 9 for both target sequences IP2 and IP4

The **SmartAmp Covid-19** kit detects pools 1 to 8 regardless of the amplification method, whether LifeCase or LightCycler480. For the pool of samples least concentrated in viral RNA (pool 9), detection was not validated by the kit due to the weakness of signal (however it is visible) and because it neared the end of the amplification run.

The **SmartAmp Covid-19** kit presents:

- A sensitivity very slightly inferior to that of the standard CNR technique

Note: a step of sample dilution has been included to the protocol for this evaluation. Sensitivity of SmartAmp Covid-19 + LifeCase is very acceptable for a system performing both sample extraction and amplification.

## CONCLUSIONS

The National Reference Centre of Viral Respiratory Infections (including the flu) considers that the **SmartAmp Covid-19 (+LifeCase)** kit **has** an **acceptable** sensitivity for the detection of SARS-CoV-2.

**Specificity of the kit has not been tested.**