

## **VALIDATION REPORT OF COMMERCIAL SYSTEM qCOVID-19® BY GENOMICA SAU FOR THE DETECTION OF THE NEW CORONAVIRUS SARS-CoV2 IN RESPIRATORY SAMPLES**

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### **Objective.**

Validation of the commercial system qCOVID-19®, based in a real time PCR-based technic, designed by GENOMICA SAU for the detection of coronavirus SARS-CoV2 in respiratory samples.

### **Methods.**

The system was tested with a panel of 80 clinical samples (naso-pharyngeal exudates) from the biobank of the Spanish National Center for Microbiology. The panel included 26 positive samples and 54 negative samples previously characterized using reference procedures recommended by WHO and implemented by the Spanish National Center for Microbiology. The reference methodology consisted in two different real time PCR-based techniques with extraction and amplification procedures according to reference 1.

### **Results.**

Results obtained with the system qCOVID-19® (batch number 1.3.20-1, PCR MIX1) (Table 1) showed 26 positive samples and 54 negative samples, with a sensitivity of 100% and specificity of 100%.

Comparative results for the commercial testing and the reference procedures are displayed in Table 1.

### **Conclusions**

The system qCOVID-19® showed a high diagnostic performance with both sensitivity and specificity of 100% for the detection of viral nucleic acid of SARS-CoV2 in respiratory samples.

### **References**

1. Corman VM, Landt O, Kaiser M, et al. Detection of 2019 novel coronavirus (2019-nCoV) by real-time RT-PCR. Euro Surveill. 2020 Jan;25(3). PMID: 31992387.

**Table 1.** Results obtained in the validation of the system qCOVID-19®.

<b>CODE</b>	<b>RESULT BY REFERENCE PROCEDURE</b>	<b>RESULT BY qCOVID-19 MIX1</b>	<b>VALIDATION qCOVID-19 MIX1</b>
#01	NEG	NEG	OK
#02	NEG	NEG	OK
#03	NEG	NEG	OK
#04	NEG	NEG	OK
#05	NEG	NEG	OK
#06	NEG	NEG	OK
#07	NEG	NEG	OK
#08	NEG	NEG	OK
#09	NEG	NEG	OK
#10	NEG	NEG	OK
#11	NEG	NEG	OK
#12	NEG	NEG	OK
#13	NEG	NEG	OK
#14	NEG	NEG	OK
#15	POS	POS	OK
#16	NEG	NEG	OK
#17	NEG	NEG	OK
#18	POS	POS	OK
#19	POS	POS	OK
#20	NEG	NEG	OK
#21	NEG	NEG	OK
#22	POS	POS	OK
#23	POS	POS	OK
#24	NEG	NEG	OK
#25	NEG	NEG	OK
#26	POS	POS	OK
#27	NEG	NEG	OK
#28	NEG	NEG	OK
#29	NEG	NEG	OK
#30	NEG	NEG	OK
#31	NEG	NEG	OK
#32	POS	POS	OK
#33	POS	POS	OK
#34	POS	POS	OK
#35	POS	POS	OK
#36	NEG	NEG	OK
#37	POS	POS	OK
#38	NEG	NEG	OK
#39	NEG	NEG	OK
#40	POS	POS	OK

#41	NEG	NEG	OK
#42	NEG	NEG	OK
#43	NEG	NEG	OK
#44	NEG	NEG	OK
#45	NEG	NEG	OK
#46	NEG	NEG	OK
#47	POS	POS	OK
#48	POS	POS	OK
#49	POS	POS	OK
#50	NEG	NEG	OK
#51	NEG	NEG	OK
#52	POS	POS	OK
#53	NEG	NEG	OK
#54	POS	POS	OK
#55	NEG	NEG	OK
#56	POS	POS	OK
#57	NEG	NEG	OK
#58	NEG	NEG	OK
#59	NEG	NEG	OK
#60	NEG	NEG	OK
#61	POS	POS	OK
#62	NEG	NEG	OK
#63	NEG	NEG	OK
#64	NEG	NEG	OK
#65	NEG	NEG	OK
#66	POS	POS	OK
#67	NEG	NEG	OK
#68	NEG	NEG	OK
#69	POS	POS	OK
#70	POS	POS	OK
#71	POS	POS	OK
#72	NEG	NEG	OK
#73	NEG	NEG	OK
#74	POS	POS	OK
#75	NEG	NEG	OK
#76	NEG	NEG	OK
#77	NEG	NEG	OK
#78	NEG	NEG	OK
#79	POS	POS	OK
#80	POS	POS	OK

**Head of the Spanish National Center for Microbiology**

**Jesús Oteo Iglesias**