

INTRODUCTION

Rapid increase in COVID-19 cases is due to new phylogenetic cluster including UK-variant VUI202012/01 defined by multiple spike protein mutations (deletion 69-70, deletion 144, N501Y, A570D, D614G, P681H, T617I, S982A, D1118H). Often Δ69-70 has not been detected by RT-PCR causing false negative. Avoiding it is possible thanks to molecular assay developed by Bioside: **qualyfast®SARS-CoV-2 UK-Variant qPCR (quantitative Polymerase-Chain-Reaction) assay** which allows to specifically identify the UK-variant.

AIM

Validate the performance of new **Bioside qualyfast®SARS-CoV-2 UK-Variant qPCR assay** for the concurrent discrimination of SARS-CoV-2 UK-Variant in clinical samples

- S-gene target;
- screening phase facilitation: reduction of sequencing work and detection times for promptly infection identification;
- reduction of false negative.

METHOD

qualyfast®SARS-CoV-2 UK-Variant freeze-dried innovative assay developed by:

- **proprietary** Bioside technology;
- **lyophilized form**: solid cake stabilized at room temperature;
- simple to use;
- detection **at the same time** both SARS-CoV-2 UK-Variant (Δ69-70 in S-gene) and Sarbecovirus (E-gene) from clinical samples.

54 nasopharyngeal swabs were analyzed; the genomic extraction was performed using both silica-based columns and magnetic beads and the RNA was analyzed with qualyfast®SARS-CoV-2 UK-Variant obtaining results in two hours.



RESULTS

qualyfast®SARS-CoV-2 UK-Variant allows **simultaneous discrimination of SARS-CoV-2 UK-Variant from not-UK-Variant in positive samples** (see Figure 1).

The assay shows **100% specificity and 96% sensitivity** for SARS-CoV-2 UK-Variant (see Table 1)

No cross-reaction with other SARS-CoV-2 Variant. This proves that primers and probes were optimized, analytical specificity and sensitivity maximized.



positive	total positive	Specificity
27	27	100%
negative	total negative	Sensitivity
26	27	96%

Table1: Assay sensitivity and specificity on 223 samples.

Figure1: qPCR discrimination between SARS-CoV-2 UK-Variant and Sarbecovirus in positive samples.

CONCLUSIONS

Bioside has developed **qualyfast® SARS-CoV-2 UK-Variant, a One Step RT qPCR assay** by a proprietary **freeze-drying technology**.

- ✓ Lyophilized and multiplexing Bioside technology accurately detected positive samples for SARS-CoV-2 discriminating simultaneously UK-Variant with higher specificity to improve patient prognosis.
- ✓ Assay in lyophilized form stable at room temperature for 12 months is really easy to use, permitting virological analysis within 2 hours for rapid monitoring of infection in order to guarantee a large-scale population molecular tracing.
- ✓ Bioside multiplexing assay also reduces analytical costs and time of analysis, enables Point-of-Care tests and labor saving.

Our mission is to detect and isolate quickly new Sars-CoV-2 UK-Variant by integrating standard laboratory molecular tests in order to guarantee a massive screening of the population. Our work continued and focused on identifying different variants of SARS-CoV-2 targeting the relevant mutations of each. We then validated **qualyfast® SARS-CoV-2 Variant Multiplex assays** which allows to discriminate:

UK	Δ69-70, Δ144, N501Y
South Africa	Δ241-243, N501Y, E484K
Brazil/Japan P.1	H655Y, N501Y, E484K
Indian	L452R, P681R
Indian B.1.617.2-B.1.617.3	Δ 157-158, L452R, P681R
Niger	Δ144, E484K
Brazil P.2	E484K
Philippines and Columbia	E484K, N501Y

Bioside lyophilized assays can detect: Δ69-70, Δ144, N501Y, E484K, L452R, P681R, Δ157-158, Δ241-243, H655Y to immediately select the most popular SARS-CoV-2 Variants.

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