

To whom it may concern

CERTEST BIOTEC S.L., a company duly incorporated under the laws of Spain, specialised in the Research, Development and manufacturing of "In Vitro" products for the Clinical Diagnostic, located in Pol. Ind. Río Gállego II, calle J, nº 1, 50840 San Mateo de Gállego, Zaragoza (SPAIN).

States that:

Due to the identification of new variants of SARS-CoV-2, several analysis of the different SARS-CoV-2 variants applicable to the rapid test products for SARS-CoV-2 (*) detection in nasopharyngeal/nasal samples has been carried out at Certest Biotec S.L.

Catalogue references (*):	SC820001PC SC720001PC SZ882001PC (strip A: SARS-CoV-2) SS872001PC (strip A: SARS-CoV-2) SV862001PC (strip A: SARS-CoV-2)
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CerTest SARS-CoV-2 products (*) detects SARS-CoV-2 nucleoprotein (N).

This protein (N protein) has 419 amino acids. CerTest SARS-CoV-2 test (*) detects the C-terminal end of this protein (specifically AA247-364).

1. IN SILICO ANALYSIS

Alpha variant **SARS-CoV-2 VUI 202012/01** (year 2020, month 12, variant 01) founded in the **United Kingdom (UK)**.

This strain is a mutation mainly in spike proteins (S) but some mutations in zone N have been found. Mutations in N protein: Position 3 (D3L) and position 235 (S235F). These mutations are outside of our detection zone of the N protein: (AA247-364).

Conclusions: There should be no detection problems.

Beta variant **501Y.V2 (South Africa)**.

Mutations in N protein: Position 205 (T205I). These mutations are outside of our detection zone of the N protein: (AA247-364).

Conclusions: There should be no detection problems.

Gamma variant GR/501Y.V3 (B.1.1.28) (Brazilian).

Mutations in N protein: Position 80 (P80R), position 203 (R203K) and position 204 (G204R).

These mutations are outside of our detection zone of the N protein: (AA247-364).

Conclusions: There should be no detection problems.

Delta variant SARS-CoV-2 VUI-21APR-01, (Variant under investigation, year 2021, month 04, variant 01) founded in the India or (B.1.617.2) (Indian).

Mutations in N protein: Position 63 (D63G), position 203 (R203M) and position 377 (D377Y).

These mutations are outside of our detection zone of the N protein: (AA247-364) .

Conclusions: There should be no detection problems.

GH/452R.V1 (B.1.429)

Mutations in N protein: Position 205 (T205I). These mutations are outside of our detection zone of the N protein: (AA247-364).

Conclusions: There should be no detection problems.

Omicron variant GR/484A.V2 (B.1.1.529) (South Africa).

Mutations in N protein: Position 13 (P13L), Position 203 (R203K) and Position 204 (G204R) with three deletions in 31 ,32 and 33 (E, R and S deletion). These mutations or deletions are outside of our detection zone of the N protein: (AA247-364).

Conclusions: There should be no detection problems.

2. IN VITRO ANALYSIS USING RECOMBINANT PROTEINS FROM DIFFERENT VARIANTS.

Materials and Results:

MATERIALS:

- a) Certest SARS-CoV-2 immunochromatographic rapid tests assayed.

SARS-CoV-2 Lots	SC-019
Expiry date	2022-11

- b) Sample diluent.

Sample diluent Lot	DIL10-548
Expiry date	2025-12

- c) Recombinant SARS-CoV-2 nucleoproteins analysed (produced by CerTest Biotec).

Variant	Reference & Lot number	
Alpha	UK (175UK)	C19NP.UK-C001
Beta	South African (231NP)	C19NP.SA-C001
Gamma	Brazilian (232NP)	C19NP.BR-C001
Delta	Indian (250NP)	C19NP.IN-C001

RESULTS:

All the different recombinant nucleoproteins from different SARS-CoV-2 variants analysed conduct to similar analytical sensitivity (close to 1 ng/mL), which confirms the capability of the test for detecting all them at high level.

3. CLINICAL ANALYSIS

External and internal evaluations performed with samples from patients with identified SARS-CoV-2 variants have demonstrated the capability of Certest SARS-CoV-2 Test for detecting the variants Alpha and Delta of SARS-CoV-2. The Beta and Gamma variants have been checked with spiked samples.

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4. CONCLUSIONS

Our preliminary conclusions (considering the mutations in the various SARS-CoV-2 variants studied in this statement) have been confirmed from the tests performed.

Certest SARS-CoV-2 Test recognizes the recombinant nucleoproteins of all the different variants analysed, as expected according to *in silico* analysis of the recognition zone.

These results have been confirmed with real or spiked samples, always that this has been possible.

San Mateo de Gállego, Zaragoza (Spain) December 02nd, 2021

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2. Tegally H et al. Emergence and rapid spread of a new severe acute respiratory syndrome-related coronavirus 2 (SARS-CoV-2) lineage with multiple spike mutations in South Africa. medRxiv 2020. F01: 10.1101/2020.12.21.20248640.

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