

## Detection of SARS-CoV-2 variants of concern (VOC) with COVID-19 Ag K-Set

### First study

#### 1 Objective:

To verify the ability of detection of the nucleoprotein (NP) of SARS-CoV-2 variant of concern (VOC) by COVID-19 Ag K-Set.

#### 2 Protocol:

##### Material:

- COVID-19 Ag K-Set Batch GP210101
- Sample extraction buffer: Batch GP210101
- SARS-CoV-2 NP (A) from bacterial extract Batch B2119
- SARS-CoV-2 NP **Alpha** (B.1.1.7) from bacterial extract Batch B2119
- SARS-CoV-2 NP **Beta** (B.1.351) from bacterial extract Batch B2119
- SARS-CoV-2 NP **Gamma** (P.1) from bacterial extract Batch B2119
- Reference Scale card Coris\_Or\_V3 ID 9 (RSC) Batch B2004

The experiment was performed by the R&D department of Coris BioConcept and register in the laboratory book: "D2101\_D2102 - 1 - Variants SARS-CoV-2 NP Prototype vs Coris".

Each NP is diluted 2x, 10x, 100x, 1000x, 10.000x, 100.000x and 1000.000x

For each concentration, the recombinant proteins are diluted in sample extraction buffer (batch GP210101P) and 100ul of each mixture are placed on the COVID-19 Ag K-Set

The migration is performed during 15 minutes.

The test is performed in simplicate.

**Acceptance criteria:** All NP from the different variant of SARS-CoV-2 shall be detected: score on the Reference Scale Card Coris  $\geq 3$ .

#### 3 Results:

Table below shows the results for different NP from SARS-CoV-2 variants (Score based on the reference scale card coris\_Or\_V3 ID 9)

Dilutions	SARS-CoV-2_NP (A)	SARS-CoV-2_NP Alpha	SARS-CoV-2_NP Beta	SARS-CoV-2_NP Gamma
2x	> 11	> 11	> 11	> 11
10x	> 11	> 11	> 11	> 11
100x	> 11	> 11	> 11	> 11
1000x	> 11	> 11	> 11	> 11
10000x	> 11	> 11	> 11	> 11
100000x	11	11	11	11
1000000x	8	8	7	7

All dilutions of the different NP are correctly detected. We observed only a slight variability of the signals between the different NP at the dilutions of 1000.000x

#### 4 Conclusions:

Based on these results, the COVID-19 Ag K-Set is able to detect the 3 VOC mentioned in this first study.

## Second study

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### 1 Objective:

To verify the ability of detection of SARS-CoV-2 variant of concern (VOC) by COVID-19 Ag K-SeT.

### 2 Protocol:

Study was performed at the microbiology laboratory of the Liege university hospital center from September 16<sup>th</sup> 2021 to September 17<sup>th</sup> 2021.

#### Material:

- COVID-19 Ag K-Set Kit Prototype Batch 45900I2103
- Samples:
  - o 7 SARS-CoV-2 Delta variant (B.1.617.2, AY.7.1, AY9 and AY12) positives sample
  - o 1 SARS-CoV-2 Alpha variant (B.1.1.7) positives sample
  - o 1 SARS-CoV-2 Beta variant (B.1.351) positives sample
  - o 1 SARS-CoV-2 Gamma variant (P.1) positives sample
  - o 1 SARS-CoV-2 Thêta variant (P3) positives sample

The COVID-19 Ag K-SeT test was used according to the manufacturer's recommendations (D-IFU-25 COVID-19 Ag K-SeT\_TB\_V1). Eleven positive nasopharyngeal samples were tested. Samples come from our laboratory or from subcontracting laboratories. The origin of the samples as well as the original Ct values are indicated. Five of them have been tested in duplicate.

The genotype of these 11 positive samples was previously determined according to the protocol described in the article by Artesi et al, JCM 2020 (A Recurrent Mutation at Position 26340 of SARS-CoV-2 Is Associated with Failure of the E Gene Quantitative RT-PCR Utilized in a Commercial Dual-Target Diagnostic Assay).

**Acceptance criteria:** All different variants of SARS-CoV-2 shall be detected as positive.

Reference	F-DND-10 Test Report (Template v1 – Edition 13/12/2017)	2/5
Record	S:\02-DND\Projet\05-V&V\R-DND-10 (Test item)_product_vX	



Test Report

R-DND-10 Report\_VOC of SARS-CoV-2\_COVID-19 Ag K-SeT\_v3

### 3 Results:

Internal ID	Sampling date	Sample tube	Storage	PCR date	PCR method	PCR result (Ct)	Clade	Lineage	Test date	Test result
13-210701-5397	01/07/2021	VST*	-80°C	01/07/2021	Cobas 6800	18.9	Alpha	B.1.1.7	16/09/2021	+
									17/09/2021	+
13-210630-5322	30/06/2021	VST*	-80°C	30/06/2021	Cobas 6800	21	Gamma	P.1	16/09/2021	+
									17/09/2021	+
13-210831-0031	10/08/2021	VPM**	4°C	11/08/2021	Thermofisher	12.9	Delta	AY.12	16/09/2021	+
									17/09/2021	+
13-210827-5478	27/08/2021	VST*	-80°C	27/08/2021	Cobas 6800	21.86	Delta	AY.7.1	17/09/2021	+
13-210903-5639	03/09/2021	VST*	-80°C	06/09/2021	Alinity m	24	Delta	AY.7.1	17/09/2021	+
13-210901-0059	30/08/2021	VPM**	4°C	31/08/2021	Thermofisher	12.5	Delta	AY.9	16/09/2021	Inclusive***
									17/09/2021	+
13-210823-5642	23/08/2021	VST*	-80°C	23/08/2021	Alinity m	13.7	Delta	AY.9	17/09/2021	+
13-210820-0073	18/08/2021	VPM**	4°C	18/08/2021	Thermofisher	11.9	Delta	AY.9	17/09/2021	+
13-210810-5644	10/08/2021	VST*	-80°C	11/08/2021	Alinity m	17.18	Delta	B.1.617.2	17/09/2021	+
13-210702-5732	02/07/2021	VST*	-80°C	03/07/2021	Alinity m	23.5	Thêta	P.3	16/09/2021	+
									17/09/2021	+
13-210316-0089	13/03/2021	VST*	-80°C	13/03/2021	Thermofisher	8.6	Beta	B1.351	17/09/2021	+

\*VST = Vacuette (Virus Stabilization Tube) (Greiner)

\*\*VPM = Virus preservation medium (Kang Jian)

\*\*\* A single sample 13-210901-0059, Delta variant AY.9 obtained an inconclusive result. The sample was retested the next day and the result obtained was positive

Reference	F-DND-10 Test Report (Template v1 – Edition 13/12/2017)	3/5
Record	S:\02-DND\Projet\05-V&VR-DND-10 (Test item)_product_vX	

## 4 Conclusions

All positive samples for the strains tested, namely strains of SARS-COV-2 variants Alpha (B1.1.7), Beta (B1.351), Gamma (P.1), Delta (B1.617.2, AY.7.1 , AY9 and AY12) and Theta (P.3) are detected by the COVID-19 Ag K-SeT test (CORIS BioConcept) within the sensitivity of this test.

In conclusion, all the variants mentioned in this report are correctly detected with the COVID-19 Ag K-SeT.

## Third study

### 1 Objective:

To verify the ability of detection of the nucleoprotein (NP) of SARS-CoV-2 Omicron variant by COVID-19 Ag K-SeT.

### 2 Protocol:

#### Material:

- COVID-19 Ag K-Set Batch GP2200402
- Sample extraction buffer: Batch GP210101
- SARS-CoV-2 NP **Omicron** (B.1.1.529) from bacterial extract Batch L2117
- Reference Scale card Coris\_Or\_V3 ID 9 (RSC) Batch B2004

The experiment was performed by the R&D department of Coris BioConcept and register in the laboratory book: "L2117 - 1 - Détection variant Omicron SARS-CoV-2 NP.xls".

The NP is diluted 2x, 10x, 100x, 1000x, 10.000x, 100.000x and 1000.000x. For each concentration, the recombinant proteins are diluted in sample extraction buffer (batch GP210101) and 100ul of each mixture are placed on the COVID-19 Ag K-Set.

The migration is performed during 15 minutes.

The test is performed in simplicate.

**Acceptance criteria:** All NP from the different variant of SARS-CoV-2 shall be detected: score on the Reference Scale Card Coris  $\geq 3$ .

### 3 Results:

Table below shows the results for different NP from SARS-CoV-2 variants (Score based on the reference scale card coris\_Or\_V3 ID 9)

Dilutions	SARS-CoV-2_NP Omicron
2x	> 11
10x	> 11
100x	> 11
1.000x	> 11
10.000x	> 11
100.000x	11
1.000.000x	8

## 4 Conclusions

All dilutions of the NP of SARS-COV-2 variants Omicron (B1.1.529) are correctly detected by the COVID-19 Ag K-SeT test (CORIS BioConcept) within the sensitivity of this test. We observed only a slight decrease of the signals at the dilutions of 1.000.000x, similarly to what was observed with other VOC (see study 1 above)

In conclusion, all the variants mentioned in this report are correctly detected with the COVID-19 Ag K-SeT.

### Change history

Version	Date	Name	Description
01	07/07/2021	GuY	Initial
02	27/09/2021	GuY	Update of tested variants of Sars-Cov-2 (second study)
03	17/12/2021	GuY	Update of omicron variants of Sars-Cov-2 (third study)