SUMMARY OF CLINICAL EVALUATION

Testing dates: 28.01.2021– 18.03.2021
Report assembled by: Sabina Żołędowska, CQO
The tested medical device for in vitro diagnostic use: SAVD

SAVD clinical evaluation was carried out in Service Laboratories in Warsaw and Gdansk (Poland). Anonymized patient samples were collected by a nurse or a doctor (professional healthcare worker).

Total number of samples: 366 (270 positives and 96 negatives). In this samples there were 140 throat swab samples, 40 throat + nose swab samples and 185 nasopharyngeal samples.

Total number of samples subjected to analysis: 349.

Clinical efficacy of SAVD in comparison to RT-PCR (Primer Design):

- Warsaw results

		RT-PCR	
		Positive	Negative
SAVD	Positive	42	0
	Negative	2	96

- Gdansk results

		RT-PCR	
		Positive	Negative
SAVD	Positive	209	N/A
	Negative	N/A	N/A

- **TOTAL:**

		RT-PCR	
		Positive	Negative
SAVD	Positive	251	0
	Negative	2	96

SPECIFICITY = (TN / TN + FP) × 100

A 100% diagnostic specificity for SAVD was determined for this panel (95% CI 94,04% - 100,00%).

SENSITIVITY [%] = (TP / TP + FN) × 100

A 99% diagnostic sensitivity for SAVD was determined for this panel (95% CI 88,47% - 99,59%).

Approved for external release by Sabina Żołędowska, CQO

Date of approval: 22.03.2021

Signature: