

## Validation of AMP Rapid Test SARS-CoV-2 Ag

<b>Product description:</b>	Rapid Test for detection of SARS-CoV-2 Antigen
<b>Clinical value:</b>	Pre-testing of patients For faster transfer or initiation of therapy, less floating beds for patients without COVID-symptoms or with negative antigen test Screening of employees Finding asymptomatic, infectious employees
<b>Manufacturer:</b>	AMEDA Labordiagnostik GmbH, Krenngasse 12, 8010 Graz
<b>Scientific literature edited by:</b>	Dr. A Voill-Glaninger

### PRE-ANALYTICS

<b>Sample material required:</b>	Nasopharyngeal swab
<b>Sample preparation:</b>	According to instructions for use
<b>Pre-analytical peculiarities:</b>	Correct pre-analytics is very important to promote sensitivity (deep smear, exact sample preparation in the extraction buffer)
<b>Patient preparation:</b>	None

### EVALUATION

Responsible for Evaluation:

**Laboratory specialist:** Dr. A Voill-Glaninger, Dr. René Zadnikar

**BA (execution):** Nursing team in central emergency room

Evaluation:

**Number of patient samples:** 200

**Reference method:** PCR Test

**Evaluation started:** 02.11.2020                      **Final report:** 02.12.2020

Created by:  
Team (Coord.)

Approved by :  
Management

Results:

<b>Assessment of sensitivity:</b>	with averaged ct - values, if 2 available		
	Viral load	100.000	ct 26,2: 100%
	Viral load	50.000	ct 28,0: 100%
	Viral load	10.000	ct 30,0: 90%
	Viral load	5.000	ct 31,0: 90%
<b>Assessment of specificity:</b>	100% (0 FP of 59 confirmed by PCR)		
<b>Duration of investigation:</b>	appr. 20 minutes incl. collection of swab sample		
<b>Practicability:</b>	as usual for rapid tests		

**Assessment of results by laboratory specialist and biomedical analyst:**

AMP Rapid Test SARS-CoV-2 Ag shows significantly better sensitivity and specificity, especially in the range of relevant viral load, than three antigen tests from mayor international suppliers, which were also evaluated by WiGev (one alternative antigen test evaluated in-house and in Clinic Favoriten, two others evaluated Clinic Favoriten and Clinic Hitzing [data inspected]). Furthermore, the test is also offered as a combined test together with Influenza A/B and, as a product from an Austrian manufacturer, offers a high level of security in respect to availability and delivery time.

**Conclusion:**

**Approval for pre-testing of patients and screening of employees with immediate effect and for preferred use.**

Doz. Dr. Astrid Voill-Glaninger

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Management