

PRODUCT DATASHEET MEDSYS

Novel Coronavirus (SARS-CoV-2) Antigen Rapid Detection Kit (100 Stück – AT 770/21)



Bundesinstitut
für Arzneimittel
und Medizinprodukte



Paul-Ehrlich-Institut



RiLiBÄK



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Antigen-Tests auf SARS-CoV-2 zur professionellen Anwendung

die Gegenstand des Anspruchs nach §1 Satz 1 Coronavirus-Testverordnung (TestV) sind („Schnelltests“)

Test-ID	Handelsname	Evaluierung PEI	Omkron-Erkennung entsprechend der Brüdigung-Prüfung des PEI	Hersteller			Europäischer Bevollmächtigter			Sensitivität		Spezifität		Gebrauchs-anweisung	
				Name	Stadt	Land	Name	Stadt	Land	Testort*	%	95%iges Vertrauensintervall	%		95%iges Vertrauensintervall
AT770(21)	Novel Coronavirus (SARS-CoV-2) Antigen Rapid Detection Kit	Ja	Ja	Jiangxi Province Jinkuan Medical Instrument Co., LTD.	Nanchang	CN	SUNGO Europe BV	Amsterdam	NL	POC (ohne Gerät)	96,00	92,16 - 99,84	99,70	98,53 - 100	Link ...

Product number: 364215376135191 / REG: **AT 770/21**

Link: <https://antigentest.bfarm.de/ords/antigen/r/antigentest/liste-der-antigentests>



MEDSYS / Novel Coronavirus SARS-CoV-2 Antigen Test (Colloidal Gold)

Pack/VE: 100 Stück

Characteristics

- Test results after 15 minutes
- Sensitivity: 96,00 %
- Specificity: 99,70 %
- Medical product: CE & IVD

Application

This kit is used for in vitro qualitative determination of novel coronavirus antigen in human nasal swabs or throat swabs. It is used as rapid investigation for suspected cases of novel coronavirus, can also be used as a reconfirmation method for nucleic acid detection in discharged cases. The test impresses with its ease of use and is handy and mobile. NO additional instruments are required.



Content (DE/EN)

- 100 x Novel Coronavirus Antigen Test Cassette
- 100 x Sample extraction buffer
- 100 x Disposable virus sampling swab
- 1 x Positive/Negative Control Set
- 1 x batch controle (according to RiliBäk DE)
- Instructions for use (1 x DE / 1 x EN)

Approved users

Professional healthcare, only for professional use

CONTACT

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Limit of detection (LoD)

2,5 x10^{2,2} TCID₅₀/ml

Category: Rapid test

Technical Data Sheet

Instruction for use

Art-No. / REF: 364215376135191

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