

COVID-19 In Vitro Diagnostic Devices and Test Methods Database

[Home](#) > [COVID-19 In Vitro Diagnostic Medical Devices](#) > [COVID-19 In Vitro Diagnostic Medical Device - detail](#)




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[< Previous](#)

[Next >](#)

CHIL COVID-19 Antigen Rapid Test (Nasopharyngeal / Oropharyngeal Swab-Cassette)

Manufactured by Chil Tibbi Malzeme Sanayi ve Ticaret Limited Şirketi

Device identification number	1691
CE Marking	 Yes
HSC common list	 No
HSC mutual recognition	 No
Format	Near POC / POC
Physical Support	Cassette
Target	Antigen
Specimen	Nasopharyngeal swab, Oropharyngeal swab
Pathogens detected	SARS-CoV
Commercial Status	Commercialised
Last Update	2021-08-06 08:23:13 CET
Comments	The CHIL® COVID-19 antigen rapid test is an immunochromatographic in-vitro test for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct nasopharyngeal and oropharyngeal swabs directly from people. This instruction for use (IFU) must be read and followed carefully prior to use. The reliability of assay results cannot be guaranteed in case of any discrepancies from the instructions for use. This product is intended exclusively for professional use in the laboratory and at the point of care.

Assay Type	Immuno-Antigen
Rapid Diagnostic	Yes
Reader Required	No
Subcategory	Other
Method	Immunoassay
Measurement	Qualitative
Time	15 minutes
Subclass	Sandwich
LOD	30 %
Calibration	evaluated
Crossreactivity	evaluated
Fp	0.49 % (2 False Positives out of 405)
Fn	0.85 % (4 False Negatives out of 466)
Precision	evaluated
Accuracy	99.54 %
Reproducibility	evaluated
Robustness	evaluated
Clinical Sensitivity	99.01 %
Clinical Specificity	99.57 %
Type of antigen	nucleoprotein

The database contains publicly available In Vitro Diagnostic Medical Devices for COVID-19 and it is being updated periodically. Please note that additional performance (as retrieved from manufacturers web pages) is provided only for devices commercially available with CE-IVD mark.

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