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The Lepu antigen test is registered in the “COVID-19 In Vitro Diagnostic Devices and Test Methods Database” of the European Commission.

The objective of the JRC COVID-19 In Vitro Diagnostic Devices and Test Methods Database is to collect in a single place all publicly available information on performance of CE-marked in vitro diagnostic medical devices (IVDs) as well as in-house laboratory-developed devices and related test methods for COVID-19. (<https://covid-19-diagnostics.jrc.ec.europa.eu/>)

Of the 494 registered antigen tests with CE markings, only 16 are both on the HSC Common List and on the HSC Mutual Recognition List. Among those is the Lepu antigen test.

Below please find the information listed about the Lepu antigen test:

19/03/2021 COVID-19 In Vitro Diagnostic Medical Devices | COVID-19 In Vitro Diagnostic Devices and Test Methods Database
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COVID-19 In Vitro Diagnostic Devices and Test Methods Database

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COVID-19 In Vitro Diagnostic Medical Devices

16 records found Download as [JSON](#) or [XML](#)

CE Marking	Manufacturer	Commercial Name	Method	Target	Format	
Yes	Abbott Rapid Diagnostics	Panbio COVID-19 Ag Test	Immunoassay	Antigen	Near POC / POC	>
Yes	AMEDA Labordiagnostik GmbH	AMP Rapid Test SARS-CoV-2 Ag	Immunochematography	Antigen	Near POC / POC	>
Yes	Becton Dickinson	Veritor System Rapid Detection of SARS-CoV-2	Immunoassay	Antigen	Near POC / POC	>
Yes	Beijing Lepu Medical Technology Co., Ltd	SARS-CoV-2 Antigen Rapid Test Kit	Immunoassay	Antigen	Near POC / POC	>
Yes	BIOSYNEX SWISS SA	BIOSYNEX COVID-19 Ag BSS	Immunochematography	Antigen	Near POC / POC	>
Yes	CerTest Biotec, S.L.	CerTest SARS-CoV-2 Card test	Immunoassay	Antigen	Near POC / POC	>
Yes	Hangzhou Clongene Biotech Co., Ltd	Covid-19 Antigen Rapid Test Kit	Immunochematography	Antigen	Near POC / POC	>
Yes	Healgen Scientific Limited Liability Company	Coronavirus Ag Rapid Test Cassette	Immunochematography	Antigen	Near POC / POC	>
Yes	LumiraDX UK Ltd	LumiraDX SARS-CoV-2 Ag Test	Immunoassay	Antigen	Near POC / POC	>
Yes	Nai von minden GmbH	NADAL COVID-19 Ag Test	Chromatography	Antigen	Near POC / POC	>
Yes	Quidel Corporation	Sofia SARS Antigen FIA	Immunoassay	Antigen	Near POC / POC	>
Yes	SD BIOSENSOR Inc	STANDARD F COVID-19 Ag FIA	Immunoassay	Antigen	Near POC / POC	>
Yes	SD BIOSENSOR Inc	STANDARD Q COVID-19 Ag Test	Immunochematography	Antigen	Near POC / POC	>
Yes	Siemens Healthineers	CLINITEST Rapid Covid-19 Antigen Test	Immunochematography	Antigen	Near POC / POC	>
Yes	Xiamen Boson Biotech Co. Ltd	Rapid SARS-CoV-2 Antigen Test Card	Immunochematography	Antigen	Near POC / POC	>
Yes	Zhejiang Orient Gene Biotech	Coronavirus Ag Rapid Test Cassette (Swab)	Immunoassay	Antigen	Near POC / POC	>

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.
[Acknowledgements](#)

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COVID-19 In Vitro Diagnostic Medical Device - detail | COVID-19 In Vitro Diagnostic Devices and Test Methods Database

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COVID-19 In Vitro Diagnostic Medical Device - detail

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SARS-CoV-2 Antigen Rapid Test Kit

Manufactured by Beijing Lepu Medical Technology
Co., Ltd - <https://en.lepumedical.com/> 

Device

identification

number

1331

CE Marking ✔ Yes

HSC ✔ Yes

common list

HSC mutual ✔ Yes

recognition

Format Near POC / POC

Physical Card

Support

Target Antigen

<https://covid-19-diagnostics.jrc.ec.europa.eu/devices/detail/1331>

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COVID-19 In Vitro Diagnostic Medical Device - detail | COVID-19 In Vitro Diagnostic Devices and Test Methods Database

Specimen	Nasal swab
Commercial Status	Commercialised
Last Update	03/03/2021 12:08

Detection Principle	Immuno-Antigen
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Rapid Diagnostic	Yes
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Reader Required	No
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Method	Immunoassay
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Measurement Qualitative	
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Time	15 minutes
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Subclass	Colloidal gold
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Accuracy	96.67 %
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Clinical Sensitivity	92 %
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