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COVID-19 In Vitro Diagnostic Devices and Test Methods Database

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COVID-19 In Vitro Diagnostic Medical Device - detail

SPESERA Covid-19 Antibody Neutralizing Rapid Test Cassette

Manufactured by SPESERA SAĞLIK ÜRÜNLERİ İÇ VE DIŞ LTD. ŞTİ.,
Turkey - www.spesera.com.tr

Device identification number	2615
CE Marking	Yes
HSC common list	No
HSC mutual recognition	No
Format	Near POC / POC
Physical Support	Cassette
Target	Antibody, IgG
Specimen	Plasma, Serum, Whole blood, Whole blood with anti-coagulants

Pathogens detected	SARS-CoV
Commercial Status	Commercialised
Last Update	2021-09-09 09:43:20 CET
Comments	www.spesera.com.tr

Assay Type	Immuno-Antibody
Self Test	Yes
Subcategory	Extraction kit
Method	Immunochromatography
Measurement	Qualitative
Time	15 minutes
Subclass	Neutralization Antibody (NAb)
LOD	580 TCID50/ml
Calibration	Evaluated
Crossreactivity	Evaluated
Fp	1.19 % (4/335)
Fn	0.81 % (3/366)
Precision	Evaluated
Accuracy	99.01 %
Reproducibility	Evaluated
Robustness	Evaluated
Clinical Sensitivity	98.2 %
Clinical Specificity	99.17 %
Type of antigen	Other

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](#)

COVID-19 Test Methods and Devices

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