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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 AG/Influenza A&B Combo Rapid Test Cassette

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

Device identification number	2617
CE Marking	Yes
HSC common list	No
HSC mutual recognition	No
Format	Near POC / POC
Physical Support	Cassette
Target	Antigen

Specimen	Anterior nasal swab, Nasal swab, Nasopharyngeal swab, Oropharyngeal swab, Throat swab
Pathogens detected	Alpha Coronavirus 229E (HCoV-229E), Alpha Coronavirus NI63 (HCoV-NI63), Beta Coronavirus HKU1 (HCoV-HKU1), Beta Coronavirus OC43 (HCoV-OC43), Coronaviruses (HCoV), Influenza A, Influenza B
Commercial Status	Commercialised
Last Update	2021-09-09 09:50:42 CET
Comments	www.spesera.com.tr

Assay Type	Immuno-Antigen
Self Test	Yes
Subcategory	Extraction kit
Method	Immunochromatography
Measurement	Qualitative
Time	15 minutes
Subclass	Membrane-based
LOD	580 TCID50/ml
Calibration	Evaluated
Crossreactivity	Evaluated
Fp	0 % 0/39
Fn	5.17 % (6/116)
Precision	Evaluated
Accuracy	96.3 %
Reproducibility	Evaluated
Robustness	Evaluated

Clinical Sensitivity	86.7 %
Clinical Specificity	100 %
Type of antigen	Nonstructural protein NS3

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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