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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

## COVID-19 In Vitro Diagnostic Medical Device - detail

### SPESERA Covid-19 Antibody IgG-IgM Rapid Test Cassette

Manufactured by SPESERA SAĞLIK ÜRÜNLERİ İÇ VE DIŞ LTD. ŞTİ.,  
Turkey - [www.spesera.com.tr](http://www.spesera.com.tr)

Device identification number	2616
CE Marking	Yes
HSC common list	No
HSC mutual recognition	No
Format	Near POC / POC
Physical Support	Cassette
Target	Antibody, IgG, IgM
Specimen	Plasma, Serum, Whole blood, Whole blood with anti-coagulants

Commercial Status	Commercialised
Last Update	2021-09-09 09:47:37 CET
Comments	<a href="http://www.spesera.com.tr">www.spesera.com.tr</a>

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Assay Type	Immuno-Antibody
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	5.04 % (17/337)
Fn	5.22 % (29/555)
Precision	Evaluated
Accuracy	95.09 %
Reproducibility	Evaluated
Robustness	Evaluated
Clinical Sensitivity	95.19 %
Clinical Specificity	95.03 %
Type of antigen	Other

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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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