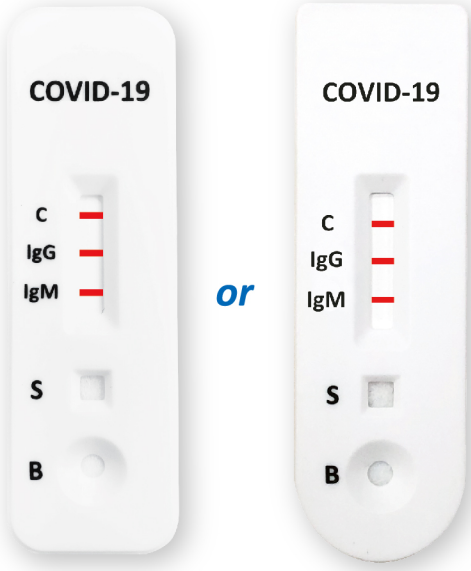
CORONACHEK™

For Emergency Authorization Use (EUA) only
For in vitro diagnostic use only
For prescription use only





CoronaCHEK COVID-19 IgG/IgM Rapid Test Cassette

The CoronaCHEK COVID-19 IgG/IgM Rapid Test Cassette is a rapid lateral flow chromatographic immunoassay intended for the qualitative detection and differentiation of IgM and IgG antibodies to SARS-CoV-2 in human venous whole blood (sodium heparin, potassium EDTA, and sodium citrate), serum or plasma (sodium heparin, potassium EDTA and sodium citrate), and fingerstick whole blood.

REFER TO FDA GUIDANCE DOCUMENT DATED 12/21/2020

CLIAwaived™ Inc.

EC REP Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany

Hangzhou Biotest Biotech Co., Ltd.
No.17, Futai Road, Zhongtai Street, Yuhang District, Hangzhou, -311121, P.R. China

CoronaCHEK

COVID-19 IgG/IgM Rapid Test Cassette

Accurate Results*

POSITIVE AGREEMENT:

	Site	Days post symptom onset	# PCR positive at any time	RightSign COVID-19 IgG/IgM Rapid Test Cassette		
				# positive results	PPA	95%CI
IgM	A & B-2 (Serum)	≤7	9	6	66.67%	(35.42% -87.94%)
		8-14	83	77	96.25%	(89.55% - 98.72%)
		≥15	158	150	94.94%	(90.33% - 97.41%)
IgG	A & B-2 (Serum)	≤7	9	6	66.67%	(35.42% - 87.94%)
		8-14	83	76	91.57%	(83.60% - 95.85%)
		≥15	158	152	96.20%	(91.96% - 98.25%)

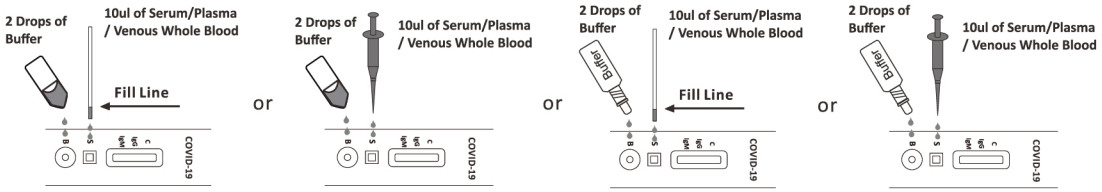
NEGATIVE AGREEMENT:

	Site	# PCR negative	RightSign COVID-19 IgG/IgM Rapid Test Cassette		
			# negative results	NPA	95%CI
IgM	Sites combined	210	206	98.10%	(95.12% - 99.26%)
IgG		210	209	99.52%	(97.38% - 99.99%)

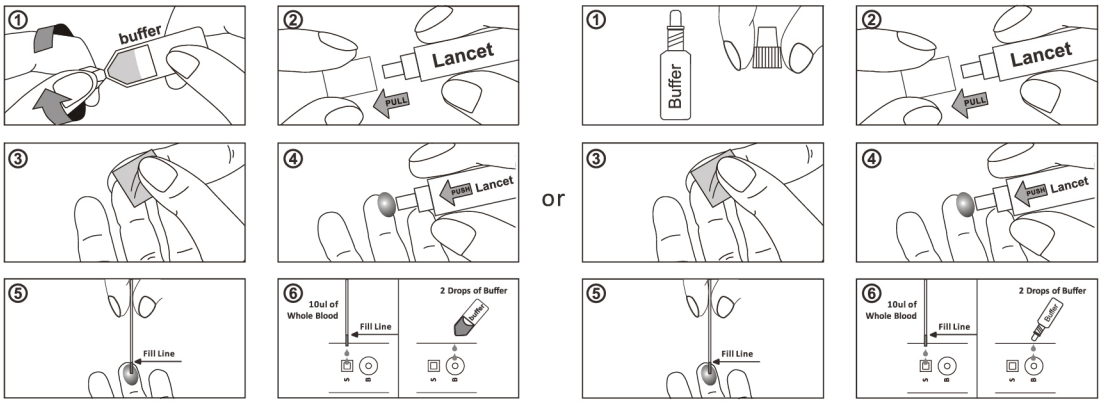
*For detailed clinical data, please refer to the package insert.

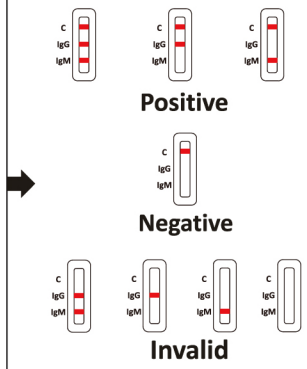
Convenient Procedure

- **for Serum, Plasma or Venous Whole Blood**



- **for Fingerstick Whole Blood**





Ordering Information

Cat.No.	Product	Specimen	Format	Pack
INGM-MC42-CC	CoronaCHEK COVID-19 IgG/IgM Rapid Test Cassette	WB/S/P	Cassette	20T

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