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COVID-19
IgG/IgM
RAPID TEST KIT

Dyed Microspheres

CE

Approved by
CE CERTIFICATION

IgM-IgG Antibody Rapid Test Kit for COVID-19
(Dyed microspheres)

TECHNICAL COMPARISON
of COVID-19 ANTIBODY TESTING REAGENT PRODUCTS IN THE MARKET

Methodological principles	DYED MICROSPHERES	COLLOIDAL GOLD METHOD
Color	Sapphire blue is easy to read	Hemolysis sample is difficult to read
Sensitivity	Excellent	Normal
Stability	Excellent	Normal
Period of Testing	< 8 min	15 - 30 min
Marking method	Stable chemical cross-linking	Unstable physical absorption
Positive coincidence rate	High sensitivity, low false negative rate	Low sensitivity, high false negative rate
Negative coincidence rate	Low false positive rate, high coincidence rate	High false positive rate, low coincidence rate
Consistency	Good	Normal

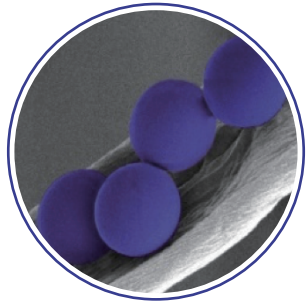
CONTACT

Fangzhou Jia | +86 138 1606 4000
Fangzhou@topmedlab.com

中文咨询

王璐瑶 | +86 010 6362 1810

ROFI Brand by
TOPMEDLAB®
鼎 实 医 疗 科 技



HIGH SENSITIVITY
LOW FALSE POSITIVE

25 µL

FINGERTIPS BLOOD

Whole Venous Blood
Serum Or Plasma Only

8 min

ONE CARD DUAL TESTS

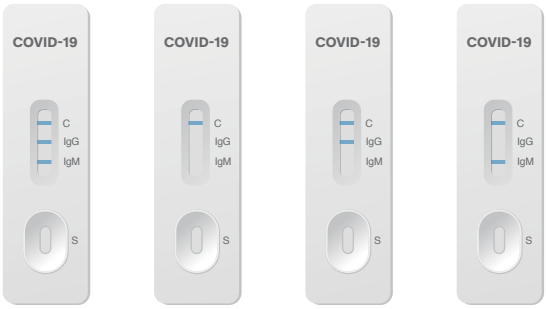
Two results will be displayed
in 8 minutes

ADVANCED DYED MICROSPHERES TECHNOLOGY

Hydrophilic surface, rich in group and higher protein bonding capacity.
Internal dyeing process, full color, chemical coupling perfectly substitute for physical adsorption.
High sensitivity, good stability, bright color and easy to read,
serving as an ideal substitute for colloidal gold

Product Name	IgM-IgG Antibody Rapid Test Kit for COVID-19 (Dyed microspheres)
Specimen Type	25ul fingertips blood, whole venous blood, serum or plasma
Period of Testing	8 minutes
Detecting Principles	Novel coronavirus (COVID-19) IgG/IgM antibodies in blood samples were detected by immune chromatographic Dyed microspheres

TEST RESULT INTERPRETATION



Positive | Negative | IgG Positive | IgM Positive

CE CERTIFICATE

Technical Document No.: DS-TCF-01

EC Declaration of Conformity

Manufacturer:

Suzhou Topmedlab Medical Science and Technology Co.,Ltd.
8 Jinfeng Rd.North 1st Floor.No.12 Building, Suzhou, Jiangsu Province,China

whose single Authorized EU-Representative:

MedPath GmbH
Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany
DIMID code: DE/0000047823
Tel: + 49 (0) 89 189174474
Mail: info@medpath.pro

We, the manufacturer, herewith declare that the products:

(COVID-19)IgG/IgM Rapid test kit (dyed microspheres)
Model: 25Tests/box

meet the provisions of 98/79/EC (IVDD) (In vitro diagnostic medical devices) which apply to them.

The medical device has been assigned to Others according to Annex II of the 98/79/EC. It bears the mark

CE

following the conformity assessment procedures relating to the EC Declaration of Conformity set out in Annex III of 98/79/EC.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration.

The product identified above complies with the essential requirements of the above EC Directives by meeting the following standards:

EN 13641:2002; EN13612:2002+AC:2002; EN ISO 23640:2015; EN ISO 17511:2003; EN ISO 13485: 2016; EN ISO 14971:2012; EN ISO 15223-1:2016; EN ISO 18113-1:2011; EN ISO 18113-2:2011; EN 13975: 2003

The above mentioned declaration of conformity is exclusively under the responsibility of

Suzhou Topmedlab Medical Science and Technology Co.,Ltd.
8 Jinfeng Rd.North 1st Floor.No.12 Building, Suzhou, Jiangsu Province,China

2020.05.16
Place, date

Legally binding signature, Function