GenomeCov19 IgM/IgG Test Kit

Store at 2 - 30°C

Cat. No.	Description	Quantity
G630	GenomeCov19 IgM/IgG Test Kit	25 Tests/Kit

For in vitro diagnostic use only. For professional use only.

Intended Use

The GenomeCov19 IgM/IgG Test Kit is a lateral flow immunoassay (Colloidal Gold Method) for the rapid detection of Human IgM and IgG antibodies against COVID-19/ SARS-CoV-2 virus in human whole blood, serum and plasma samples. The test is intended to either aid in the diagnosis of patients with active infections or help screen for asymptomatic carriers and patients who have recovered from infection. The test provides preliminary test results. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions.

Principle

The GenomeCov19 IgM/IgG Test Kit is a chromatographic immunoassay for the detection of antibodies against SARS-CoV-2. Each test strip has a conjugate pad containing SARS-CoV-2 recombinant antigens conjugated to colloidal gold and a test region on the nitrocellulose membrane coated with anti-human IgM and IgG. If anti-SARS-CoV-2 virus IgM or IgG is present in the specimen, it will react with the SARS-CoV-2 conjugates and the immunocomplex will be captured by the anti-human IgM or IgG in the test line region, resulting in a dark pink band. If the specimen does not contain any SARS-CoV-2 antibodies, no colored line will appear in either of the test line regions, indicating a negative result. As a procedural control, a colored line should appear in the control line region regardless of the color development in any of the other test lines.

Kit Components

Product Component	Quantity
COVID-19 Testing Strip (Individually packaged)	25
Sample Buffer	1
Transfer Pipet	25

Storage

Upon receipt, store the kit components at room temperature (2 - 30°C) for up to 18 months. DO NOT FREEZE. Do not store the test kit in direct sunlight.

Sample Preparation

The test can be performed with whole blood, serum or plasma samples.

For Whole Blood

Drops of whole blood can be obtained by venipuncture. Do not use hemolyzed blood for testing. Whole blood specimens should be stored at 2 - 8°C if not tested immediately. Whole blood specimens must be tested within 24 hours of collection.

For Plasma

Collect blood specimen by venipuncture into a collection tube containing EDTA or citrate. Separate the plasma by centrifugation, then carefully withdraw the plasma into a new pre-labelled tube.

For Serum

Collect blood specimen by venipuncture into a collection tube without anticoagulants. Allow the blood to clot before separating the serum by centrifugation. Carefully withdraw the serum into a new pre-labelled tube.

It is recommended to test specimens immediately after collection. Store plasma and serum specimens at 2 - 8°C for up to 5 days if not tested immediately. For long term storage, the specimens should be frozen at -20°C.

Protocol

1. If fresh specimens are being tested, proceed to step 2. If the specimen has been frozen, bring the specimen to room temperature slowly and mix well prior to use.
2. Open the sealed pouch containing the COVID-19 Testing Strip and place it on a clean, flat surface. Label the test strip with the specimen ID clearly.
3. Using a transfer pipet (included in the kit), transfer 1 drop of the whole blood, plasma or serum specimen to the circular sample well (refer to image below).
4. Add 2 - 3 drops of the Sample Buffer to the square buffer well on the test strip (refer to image below).
5. The results can be interpreted in 10 minutes.

   Note: Results must be interpreted within 15 minutes after specimen has been added to the sample well otherwise the test results should be considered invalid and the procedure should be repeated.

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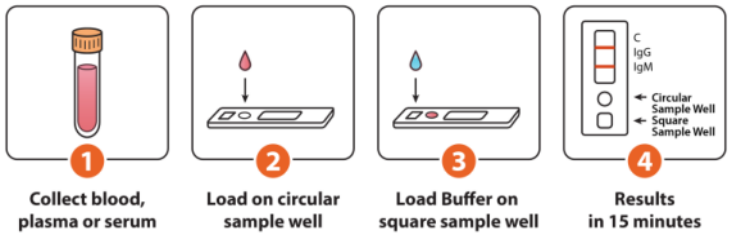
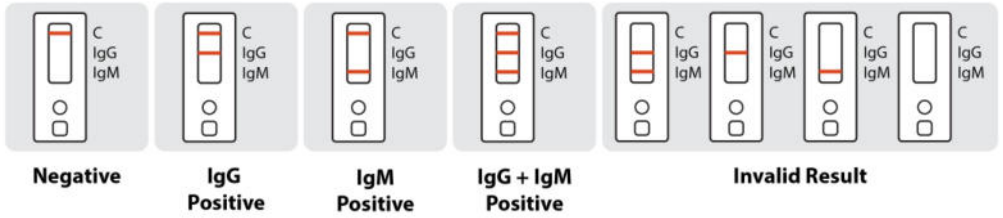


Test Result Interpretation



Negative: Only control line "C" shows a dark pink band.

Positive: Both the control line "C" and one of, or both of, "IgM" and "IgG" shows a dark pink band.

Inconclusive: The control line "C" shows a dark pink band and "IgM" and/or "IgG" shows a light pink band. It is recommended to repeat the test.

Invalid: If no band appears in the control line "C", the test result is invalid regardless of the presence or absence of band(s) in the "IgM" and "IgG" lines. It is recommended to repeat the test.

Performance Characteristics

Clinical performance: A total of 300 clinical specimens (100 positive and 200 negative specimens) were tested. Results showed 91.0% Sensitivity (91/100 positive results) and 99.0% Specificity (198/200 negative results).

Cross-Reactivity: The cross-reactivity was evaluated using serum or plasma specimen samples known to contain antibodies to HCoV-SARS, HCoV-OC43, HCoV-HKU1, influenza A and B virus, adenovirus, *Staphylococcus aureus*, or *Klebsiella pneumoniae*. No cross-reactivity was observed.

Precision: CV < 5% (Between and within batches).

Precautions

1. Do not open or remove test strips from their individually sealed pouches until immediately before use. As the test strip is very sensitive to humidity, it may affect the detection result.
2. Do not use sample buffer that is not provided with the kit.
3. Do not use tap water, purified water or distilled water for negative control.
4. Do not reuse test strips.
5. Do not use the reagents beyond the stated expiration date marked on the label.
6. The specimens to be tested should be regarded as infectious, and the specimen handling procedures should comply with the operation specifications of an infectious disease laboratory.
7. The presence of too many heterophilic antibodies or rheumatoid factors in blood samples may affect the test results.

Index of Symbol

IVD	*In Vitro* Diagnostic Use		See Instruction for Use		Caution
	Store between 2~30°C		Keep Dry		Keep away from Sunlight
REF	Catalog Number		Manufacturing Date	LOT	Lot Number
	Expiry Date		Number of Tests		Do not reuse
	Manufacturer	CE	CE Marking	EC REP	European Authorized Representative

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Revision Issue Date: Mar 20, 2020

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CERTIFICATE OF IVD NOTIFICATION

Ref. No.: GF 9078-2020

Order No.: GF 9018-2020

BELGIUM

Date: 23/04/2020

THIS IS TO CERTIFY THAT, ACCORDING TO THE COUNCIL DIRECTIVE 98/79/EC, OBELIS S.A. (O.E.A.R.C.) PERFORMED ALL NOTIFICATION DUTIES AND RESPONSIBILITIES AS THE EUROPEAN AUTHORIZED REPRESENTATIVE (EC REP) OF:

NAME: APPLIED BIOLOGICAL MATERIALS INC.

ADDRESS: #1-3671 VIKING WAY, RICHMOND, BC V6V 2J5 CANADA

AS STIPULATED AND DEMANDED BY THE AFOREMENTIONED DIRECTIVE.

The Manufacturer declares that the IVD devices comply with the Directive including all essential requirements.

The Manufacturer has provided Obelis s.a. (O.E.A.R.C.) with all the appropriate declarations according to the 98/79/EC Directive – article 10 requirements including the EC Declaration of Conformity confirming that his In-Vitro Diagnostics medical devices, as stipulated here above, are fulfilling the applicable requirements of the European Council Directive 98/79/EC

The notification of the following In-Vitro Diagnostic medical devices has been completed by Obelis s.a. (O.E.A.R.C.) on the 22/04/2020 in compliance with the European Council Directive 98/79/EC - article 10 requirements.

IN-VITRO DIAGNOSTIC MEDICAL DEVICES: PLEASE SEE ANNEX A - LIST OF DEVICES (1 PAGE, 3 DEVICES)

As of the 23/04/2020, and as long as the manufacturer will continue complying with the hereabove mentioned requirements* he therefore:

- Is required to affix the CE marking on these devices;

- Place these devices in the Territory of Belgium and/or the other EEA Member States (excluding territories not in alignment with Decision 2010/227/EU).

Obelis s.a. O.E.A.R.C.
Registered Address
Bld Général Wahis 53
1030 Bruxelles

Mr. G. Elkayam CEO
Obelis sa

Obelis European Authorized Representative Center is a member of the European Association of Authorized Representatives (E.A.A.R.), ISO 9001 : 2015 and ISO 13485 : 2016 certified in accordance to the profession of a European Authorized Representative.

* This is not a CE mark and is only provided as a template for informational purposes.

** This Certificate will be automatically void if the notification is rejected by the EU Authorities or upon termination of the EAR agreement.

Registered Address: Bd. Général Wahis 53 - 1030 Brussels I Registered Office Address: Bd Brand Whitlock 30, B–1200 Brussels - Belgium
T: + 32 (0) 2 732 5954 I F: + 32 (0) 2 732 6003 I Email: mail@obelis.net I Website: www.obelis.net
V3 – ID: 00454716 – 22/02/2019

Order No.: GF 9018-2020
Ref No.: GF 9078-2020

Annex A - List of Devices

(Recital 29 of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices)

#	Catalogue reference number	Commercial Name	Generic Device Term	Short description and intended use	GMDN/ EDMS Code	Class
1.	G628	GenomeCov19 Detection Kit	SARS-CoV-2 nucleic acid IVD, kit, nucleic acid technique (NAT)	This kit is used for the qualitative detection of nucleic acid from SARS-CoV-2 in human respiratory tract specimens by real time PCR systems. This test is used to aid the diagnosis of COVID-19 infection.	64747	Others
2.	G631	Sample Collection and Viral Transport Solution	Sample collection and transport solution	For safe collection, transport, and preservation of virus samples collected from naso/oropharyngeal swabs. Recommended for use with GenomeCov19 Detection Kit (G628).	52521	Others
3.	G630	GenomeCov19 IgM/IgG Test Kit	SARS-CoV-2 immunoglobulin G (IgG)/IgM antibody IVD, kit, immunochromatographic test (ICT), rapid	This kit is used for the qualitative detection of IgM and IgG antibodies against SARS-CoV-2 in human whole blood, serum and plasma samples, using a lateral flow immunoassay (Colloidal Gold Method). This test is used to aid the diagnosis of COVID-19 infection.	64756	Others

* Annex A is part of the Agreement.

** The here above product list classification is based on the classification claim of the manufacturer and under its sole responsibility (IVD 98/79/EC).

Obelis s.a.

Signature: G. ELKAYAM C.E.O

Stamp:
Obelis s.a. - O.E.A.R.C.
Registered Address :
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1030 Bruxelles
Tél. +32 2 732 59 54 - Fax +32 2 732 60 03