SZABO SCANDIC

Part of Europa Biosite

Produktinformation

- Forschungsprodukte & Biochemikalien
- Zellkultur & Verbrauchsmaterial
- Diagnostik & molekulare Diagnostik
- Laborgeräte & Service

Weitere Information auf den folgenden Seiten!
See the following pages for more information!

Lieferung & Zahlungsart

siehe unsere Liefer- und Versandbedingungen

Zuschläge

- Mindermengenzuschlag
- Trockeneiszuschlag
- Gefahrgutzuschlag
- Expressversand

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savyonDIAGNOSTICS
Member of the Gamida Diagnostics Division

QuickStripe™ SARS CoV-2 IgG/IgM

NEW

Rapid - results within 15 min

Versatile - to be used with serum, plasma or whole blood

Simple - to perform and interpret results

Accurate - high sensitivity and specificity

Informative – differentiation of early IgM antibodies and long-term IgG antibodies

CE IVD

www.savyondx.com

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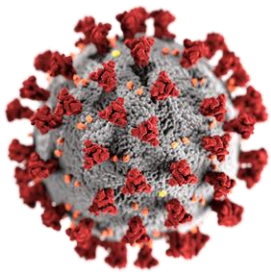
Member of the gamida diagnostics division



Intended Use:

QuickStripe™ SARS CoV-2 IgG/IgM is intended for the qualitative detection of IgG and IgM antibody content against SARS CoV-2 in clinical samples (serum/ plasma/ whole blood)

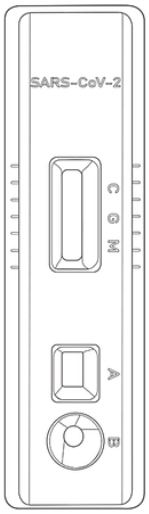
FOR PROFFESIONAL IN VITRO USE

Quick and Easy Operation:

STEP 1: Add 20ul of whole blood or 10ul of serum/plasma to **well A**

STEP 2: Add 2 drops of sample diluent to **well B**

STEP 3: Read the results within 15 min



Simple Interpretation:

Agreement with Reference Serology:

		IgM	IgG
REFERENCE SEROLOGY	**Positive Agreement**	97%	100%
	Negative Agreement	100%	99%

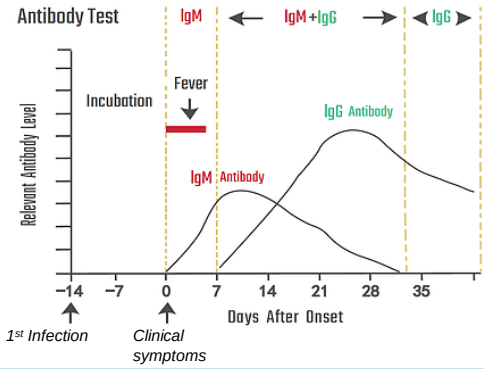
Serology Testing at the COVID-19 Pandemic:

According to guidelines published by the American Society of Microbiology (ASM) and the US Food and Drug administration (FDA), serological testing should be performed:

(1) For the identification of individuals who have previously been infected with SARS CoV-2. This knowledge can be used to guide epidemiology and seroprevalence studies, as well as to facilitate contact tracing

(2) To identify potential convalescent plasma donors and to evaluate the immune response to candidate vaccines

(3) To aid in the diagnosis of COVID-19 in RT-PCR negative patients who later present symptoms during disease course



Agreement with RT-PCR:

Samples for serology were taken on the same day as nasopharyngeal swab samples for RT-PCR ***(Day 0)***

		IgM	IgG	IgM+IgG
RT-PCR On Day 0	**Positive Agreement**	87.5%	68.8%	87.5%
	Negative Agreement	94%*	94%	94%

(*) *samples negative by RT-PCR were confirmed as positive for IgM and IgG by other serological tests*

Ordering Information:

Test Name	Tests/kit	Catalog No.
QuickStripe™ SARS CoV-2 IgG/IgM	20	41226

3557 01-07/20

CE IVD

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CE

QuickStripe™ SARS CoV-2 IgG/IgM

A rapid test for the qualitative detection of antibody content against SARS-CoV-2 in clinical samples (serum/plasma/whole blood).

Instruction Manual

Test kit for 20 determinations

(Catalog No. 41226)

For professional in vitro diagnostic use only
Store at 4-30°C. **Do Not Freeze**

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Intended Use

The product is intended for the qualitative detection of antibody content against SARS-CoV-2 in clinical samples (serum/plasma/whole blood).
For professional in vitro use only.

Summary and Explanation

Coronavirus, as a large virus family, is a single positive stranded RNA virus with envelope. The virus is known to cause major illnesses such as colds, Middle East Respiratory Syndrome (MERS), and Severe Acute Respiratory Syndrome (SARS). The novel virus, now known as SARS-CoV-2, was discovered in Wuhan virus pneumonia cases in 2019, and was officially named by the World Health Organization on January 12, 2020. The core protein of SARS-CoV-2 is the N protein (nucleocapsid), which is a protein component located inside the virus. It is relatively conserved among β-coronaviruses and is often used as a tool for the diagnosis of coronaviruses. ACE2, as a key receptor for SARS-CoV-2 to enter cells, is of great significance for the research of the viral infection mechanism.

Measurement Principle

This product is based on the principle of antigen-antibody reaction and immunoassay technique. The test device contains colloidal gold-labeled SARS-CoV-2 recombinant protein, mouse-anti human IgG antibody immobilized in the G test area, mouse-anti human IgM antibody immobilized in the M test area and the corresponding antibody in the quality control area (C).
During the test, when the SARS-CoV-2 IgM antibody level in the sample is at or above the limit of detection of the test, the SARS-CoV-2 IgM antibody in the sample binds to the colloidal gold-labeled SARS-CoV-2 recombinant protein, which is pre-coated on a gold label pad. The conjugates migrate upward through capillary effect and are captured by mouse-anti human IgM antibody immobilized in the M test area subsequently and this produces a colored line, which appears in the M test area. When the SARS-CoV-2 IgG antibody level in the sample is at or above the limit of detection of the test, the SARS-CoV-2 IgG antibody in the sample binds to the colloidal gold-labeled SARS-CoV-2 recombinant protein, which is pre-coated on a gold label pad. The conjugates migrate upward through capillary effect and are captured by the mouse-anti human IgG antibody immobilized in the G test area subsequently and this produces a colored line, which appears in the G test area. If it is a negative sample, no colored line will appear in the M and G test area. Regardless of the presence or absence of the SARS-CoV-2 antibody in the sample, a colored line will appear in the quality control area (C). The colored line in the quality control area (C) is a criterion for judging whether there is enough sample and whether the chromatography process is normal. It also serves as the internal control standard for reagents.

Components

Devices	Droppers	Instructions for User	Sample Dilution
20	20	1	1*2.5ml
Each Cassette is packed in an aluminum pouch with desiccant			

Storage and Stability

The product should be stored at 4℃~ 30℃, be kept dry and away from sunlight. The shelf life is 12 months.

Each device should be used within 1 hour after unsealing.

Production Date and Expiration date are shown on the package label.

Sample Requirements

The test can be performed on either serum, plasma or whole blood. The sample should be collected by professional medical staff. Be advised that it is preferable for detection to use serum or plasma. However, under emergency conditions or special conditions, the whole blood of patients can be used for rapid testing.

The sample should be tested immediately after collection.

The sample should not be kept at room temperature for long periods. Whole blood samples that cannot be tested immediately can be kept for 24 hours in a refrigerator between 2-8℃. Serum or plasma samples can be preserved for 3 days in a refrigerator at a temperature of between 2-8℃. For longer storage, samples should be frozen and stored at -20℃. Avoid repeated freeze-thaw cycles.
Before testing, the sample must be defrosted to room temperature and will be ready for testing only after homogeneity. The sample should be mixed before testing.

Do not use samples from patients with severe hemolysis, severe lipids, and/or jaundice.

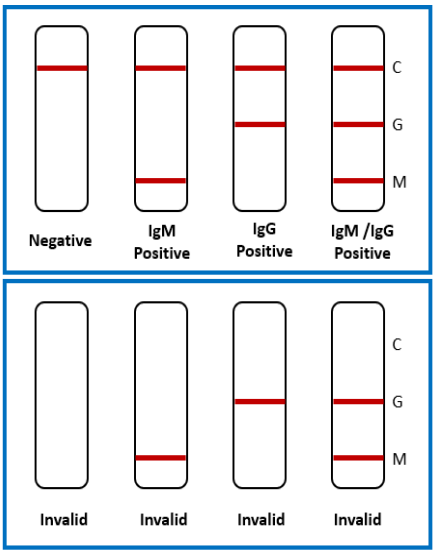
Test Method

Please read the instructions for use carefully before performing the test. Before testing, bring the reagents and blood samples to room temperature.

1. Remove the test cassette from the reagent bag and use it within 1 hour, especially in an environment with a room temperature higher than 30°C or in high humidity.
2. Place the kit on a clean platform.
   - Serum or plasma sample: Add one drop (about 10 uL) of the serum or plasma sample to well A, with a dropper, and then add two drops (about 80 uL) of the sample dilution to well B, and start timing.
   - Whole blood sample: Add two drops (about 20 uL) of the whole blood sample to sample well A with a dropper, and then add two drops (about 80 uL) of the sample dilution to sample well B, and start timing.
3. Wait for the colored line to appear. The test results should be read at 15 minute. Do not read the results after 20 minutes.

The Explanation of the Testing Results

- **Positive:** colored line should appear in both the quality control area and either area M or G.
- **Negative:** The colored line should appear only in the quality control area (C).
- **Invalid:** There is no colored line in the quality control area (C), indicating incorrect operating procedures or that the test strip has already deteriorated. Under these conditions, read the instructions for use again carefully, and then use a new test strip to test again. If the problem still exists, stop using this lot number immediately and contact your local supplier.



C: Quality Control Line **M**: IgM Detection line **G**: IgG Detection line

Limitation of Procedure

1. The test results of this product should be comprehensively interpreted by a physician in combination with other clinical information, and should not be used as the only criterion.
2. The product should be used to test for the SARS CoV-2 antibody of the tested sample.

Product Performance

Cross reactivity

This test device has no cross reactivity with endemic human coronavirus OC43 antibody, influenza A virus antibody, influenza B virus antibody, respiratory syncytial virus antibody, adenovirus antibody, EB virus antibody, measles virus antibody, cytomegalovirus antibody, rotavirus antibody, norovirus antibody, mumps virus antibody, varicella-zoster virus antibody, and mycoplasma pneumonia antibody.

Interfering substances

There is no interference in the test results by the substances below, in the following concentrations:
Bilirubin concentration ≤ 250 μ mol/l; triglycerides concentration ≤15 m mol/l; hemoglobin concentration ≤10 g/dL; rheumatoid factor concentration ≤80RU/ml; anti-mitochondrial antibody concentration ≤ 80 U/mL; antinuclear antibody concentration ≤80U/mL; the total IgG concentration ≤14g/L.
The test results are not influenced by the following substances: α-interferon, zanamivir, ribavirin, oseltamivir, and paramivir, Lopinavir, ritonavir, abidol, levofloxacin, azithromycin, ceftriaxone, meropenem, tobramycin, histamine hydrochloride, phenylephrine, oxymetazoline, sodium chloride (containing Preservatives), beclomethasone, dexamethasone, flunisolide, triamcinolone, budesonide, mometasone and fluticasone.

Clinical Performance

IgM performance data

Method		**Other Rapid Test**		Total Results
QuickStrip SARS-Cov-2 IgG/IgM	Results	Positive	Negative	
	Positive	71	0	71
	Negative	2	147	149
Total Results		73	147	220

Sensitivity – 97% (95% CI: 95%-97.92%)
Specificity – 100%

IgG performance data

Method		**Other Rapid Test**		Total Results
QuickStrip SARS-Cov-2 IgG/IgM	Results	Positive	Negative	
	Positive	92	1	93
	Negative	0	127	127
Total Results		92	128	220

Sensitivity – 100 %
Specificity – 99.2 % (95% CI: 98%-99%)

Precautions

1. The test is only suitable for professional *in vitro* auxiliary diagnosis. Do not use expired products.
2. Do not freeze or use after the expiration date (see the packaging for the expiration date).
3. Avoid excessive temperature and humidity in the experimental environment. The reaction temperature should be between 15-30°C and the humidity should be below 70%.
4. The package bag contains desiccant, and it should not be ingested.
5. It is recommended to use fresh blood for the sample collection. It is not recommended to use blood from patients with high lipid content, jaundice, and high rheumatoid factor samples. Do not use hemolyzed samples.
6. When testing, please wear protective clothing, medical mask, gloves and goggles.
7. Do not use the test card if broken, or with unclear marks, or past the expiration date.
8. Dispose of used specimens, test cards and other waste in accordance with relevant local laws and regulations.

Explanation of Symbols

Symbols for IVD components and Reagents			
	Manufacturer	IVD	For i*n vitro* diagnostic use only
EC REP	Authorized representative		Consult instructions for use
	Contains sufficient for <n> tests		Keep dry
REF	Catalogue Code		Temperature limitation
LOT	Lot Number		Use by
DIL	Sample diluent		

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