



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

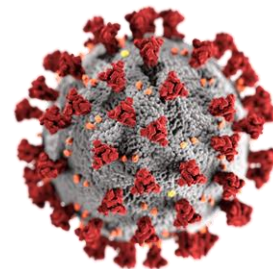
Simple - to perform and interpret results

Accurate - high sensitivity and specificity

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



CE IVD



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)

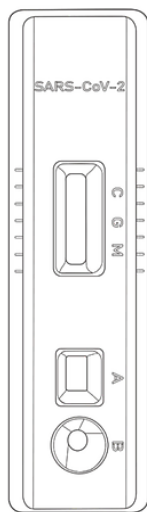
FOR PROFESSIONAL IN VITRO USE

Quick and Easy Operation:

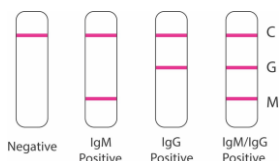
STEP 1: Add 20ul of whole blood or 10ul of serum/plasma to **well A**

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:

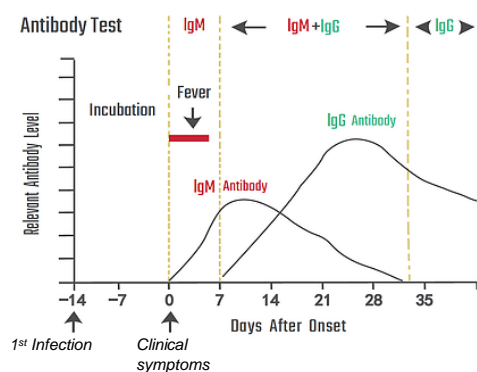
	IgM	IgG
Positive Agreement	97%	100%
Negative Agreement	100%	99%

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