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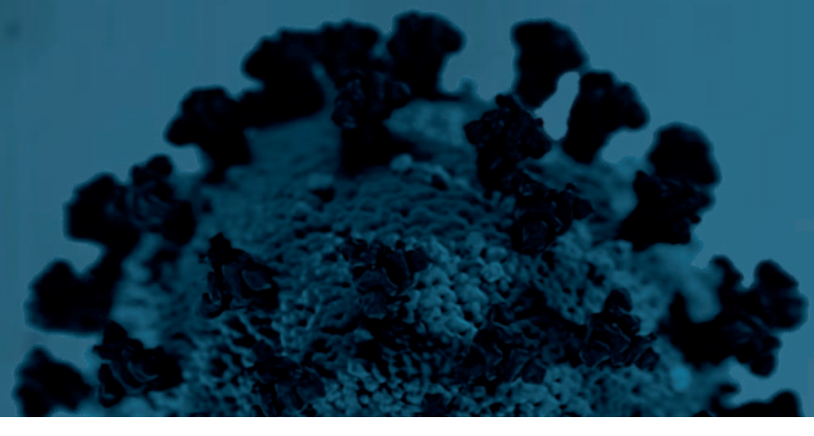
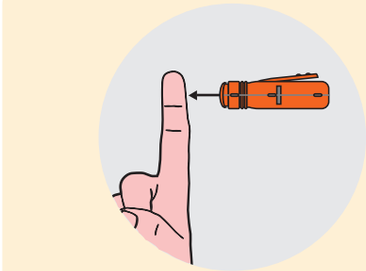
COVID-19 IgG/IgM Rapid Test

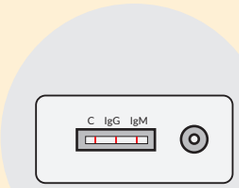


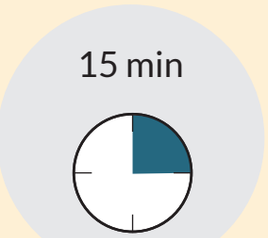
The **COVID-19 rapid test** is a **qualitative diagnostic test** that uses the technology of **lateral flow immunochromatography** for the specific detection of **human antibodies IgG and IgM anti SARS-CoV-2**, it allows the detection of **these antibodies in plasma or whole blood samples**. This test can be used in the screening and diagnosis of **SARS-CoV-2 virus infection**.

Test characteristics

- Detection of antibodies IgG/IgM anti SARS-CoV-2
- Quick test 15 min
- Easy to use
- Simple the interpretation of the results
- Safe: Less risk of contamination during the sampling
- Reliable:
  - Sensitivity: 91.80% - 96.40% in hospitalized patients. Able to detect cases of COVID-19 with false negatives with test RT-PCR. Confirmed in Spain.
  - Specificity: 97% - 100%.
- Low cost

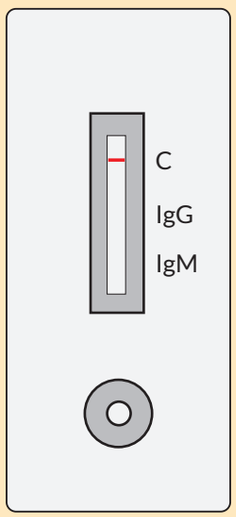






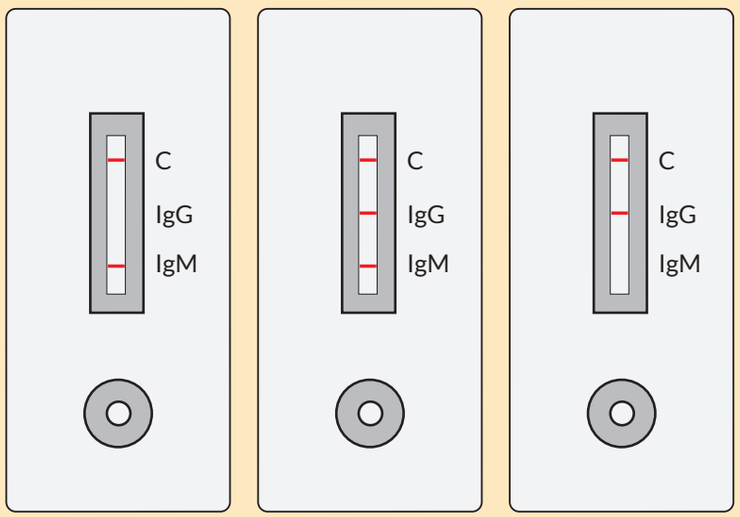
Interpretation of results

Negative Results



IgM-/IgG-
Without infection or not detectable

Positive Results

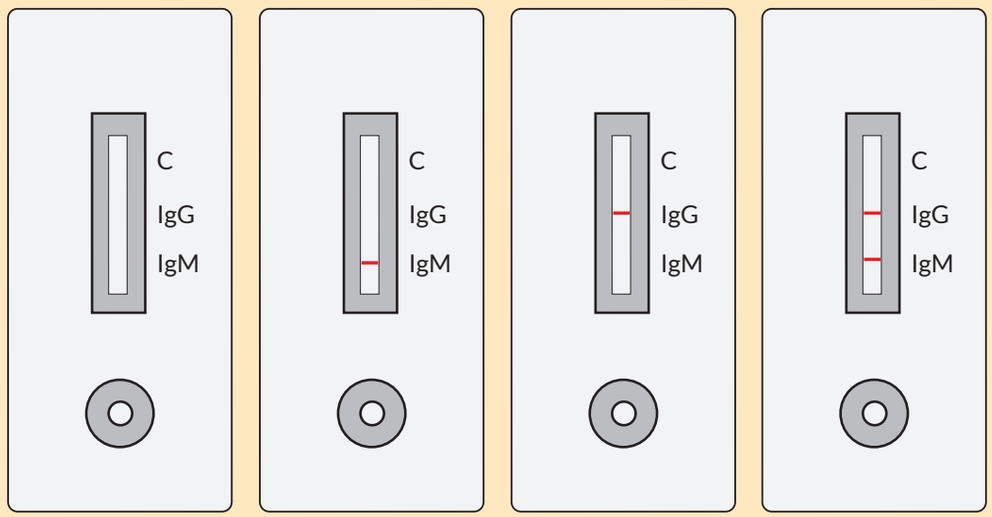


IgM+/IgG-
Very recent infection

IgM+/IgG+
Recent infection

IgM-/IgG+
No recent infection

Invalid Results



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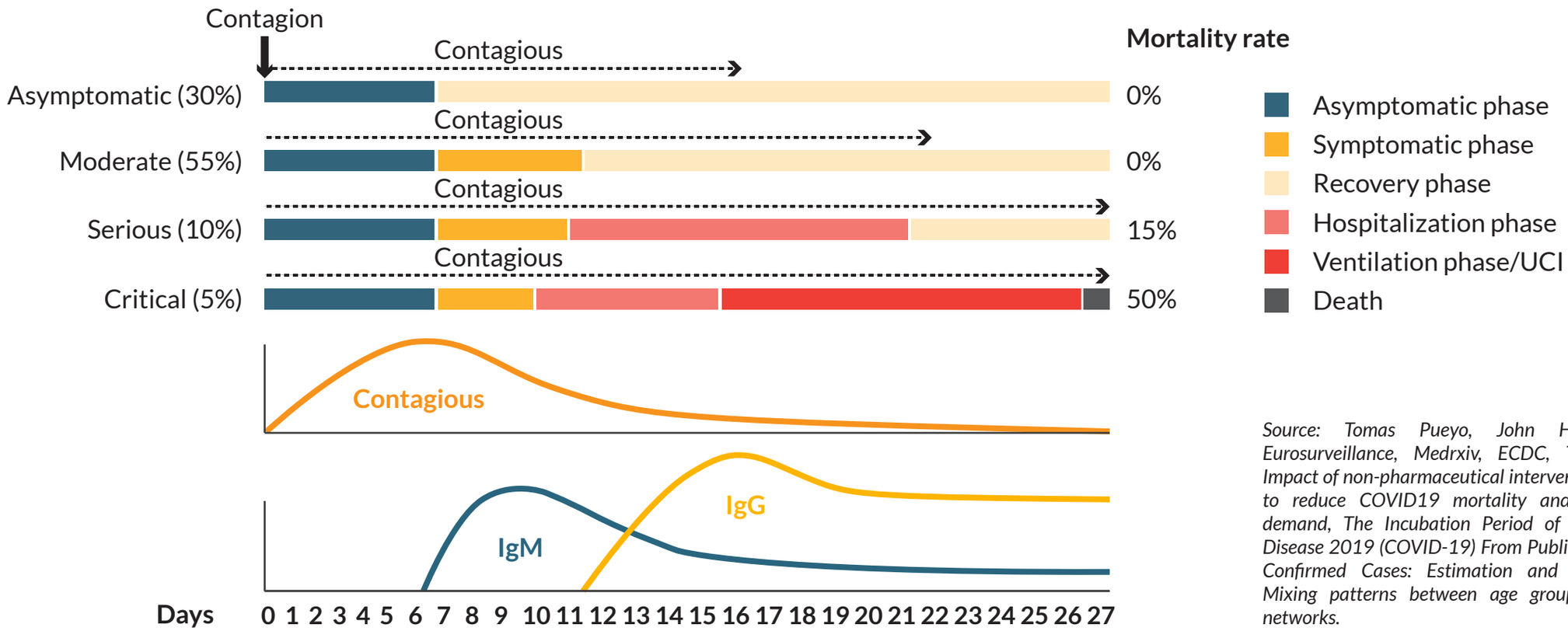
Recommendations of the Ministry for the application of methods

There are published studies that describe the immune response in humans indicating an increased sensitivity of detection of these in the course of infection which is >90% after two weeks from the initiation of the infection.

Figure 1: Average periods of transmissibility according to the severity of COVID-19 cases and periods detection of RNA of SARS-CoV-2 through PCR and of antibodies by serological methods.



Source: Tomas Pueyo, John Hsu, WHO, Eurosurveillance, Medrxiv, ECDC, The Lancet, Impact of non-pharmaceutical interventions (NPIS) to reduce COVID19 mortality and healthcare demand, The Incubation Period of Coronavirus Disease 2019 (COVID-19) From Publicly Reported Confirmed Cases: Estimation and Application, Mixing patterns between age groups in social networks.

Result analysis

PCR	Ag	IgM	IgG	Interpretation
+	-	-	-	Pre symptomatic phase
+	+/-[a]	+/-	+/-	Initial phase (approx. 1-7 days)
+/-[b]	-	+	+/-	2ª Phase (8-14 days)
+/-[c]	-	++	++	3ª Phase >15 days
-	-	+/-[d]	++	Past infection (immune)

Source: Ministerio de Sanidad. (2020). Interpretación De Las Pruebas Diagnósticas Frente a SARS-Cov-2 (2ª ed., p. 5).

[a]The detection of Ag (with current diagnostic kits) only occurs at high viral loads so rarely a PCR(-) result found with Ag +.
[b]In this clinical phase of 8-14 days, there are cases of patients with PCR (-) who have antibodies.
[c]There are cases of patients who have passed the infection have antibodies and continue to give a positive PCR result.
[d]It seems that IgM can last over time.

Advantages of using the COVID-19 IgG / IgM Rapid Test

	COVID-19 Rapid Test	RT-PCR
Equipment	No equipment required	Thermocycle
Execution time	15 minutes	4-5 hours
Sample	One or two drops of **blood /serum**. Low risk of contamination of the sanitary staff.	**Nasopharyngeal exudate.** Very invasive, high risk of sanitary staff contamination.
Storage temperature	Ambient	4 °C / -20 °C
Test execution	Simple. No highly qualified person is needed.	Require a qualified person with technical experience.
Sensitivity in persons	>90% (from 7 days after the appearance of symptoms)	58%-98%
Work areas	Health centers, ambulances, emergency triage, home of the patient.	Requires clinical laboratory with adequate equipment.

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Main applications of COVID-19 IgG/IgM Rapid Test

- Screening of patients in the triage area who come with symptoms with more than five days from the onset.
- Confirmation of infection in patients with symptoms and suspected false negative in PCR.
- Identification of immunized sanitary staff (presence of IgG) with more than 15 days in the absence of symptoms or with negative RT-PCR.
- Obtaining epidemiological data from COVID-19.
- Identification of immunized population for clinical or other applications
- Screening of the immunized population. Data that can be useful in taking certain decisions.

Clinical Validation in the Hospital Virgen de las Nieves

Purpose of the study:

Evaluate the clinical efficacy of rapid tests for detection of IgG/IgM antibodies brand Biotime for the determination of coronavirus infection with respect to the RT-PCR method in patients with symptoms (in days).

Study design:

45 patients were selected, who had previously undergone RT-PCR test, of which:

- 38 (84.4%) had strong COVID-19 symptoms (fever, cough, migraines, and dyspnea).
- 7 (15.6%) healthy individuals (or with other pathologies).

The sampling was carried out at different times:

- Most of the samples for PCR were taken in the first 7 days after presenting symptoms.
- The samples for the rapid diagnostic tests were taken between 9-25 days after presenting symptoms.

Clinical Validation in the Hospital Virgen de las Nieves

Results:

		Results validation H.V.N	
	Manufacturer data	Biotime test	RT-PCR
Sensitivity	96,40%	89,50%	71,10%
Specificity	100%	100%	100%

Significant results p<0,05
The data provided by the manufacturer comes from studies led in Chinese hospitals.

In this data analysis, positive cases are patients who present the clinical picture of COVID-19 disease:

- Symptoms: Fever, cough, dyspnea and migraines.
- Radiological pattern with diffuse or patchy bilateral interstitial pneumonia.
- Compatible analytical abnormalities (high levels of lactate dehydrogenase, ferritin, reactive protein C , D-dimer and lymphopenia).

Clinical Validation in the Hospital Virgen de las Nieves

Study remarks:

- Samples that have positive RT-PCR in patients with COVID-19 were taken before (6.04 ± 2.92 days) than those with a negative result (9 ± 2.93).
- The concordance between RT-PCR and the antibody test is not very high (60.5%), although both were agreed with the clinical diagnosis.
- Carrying out the rapid test included in this study allowed confirmation of the diagnosis in all patients with a negative RT-PCR result (n = 11, 100%). In ten of the patients with negative RT-PCR (data not shown), the test was repeated following the recommendations, with just a conversion into a bronchial aspirate (a better-quality sample).

Detection of IgM/IgG antibodies by the Biotime rapid method showed a higher sensitivity to detect SARS-CoV2 infection than genetic detection by RT-PCR, among 9 and 25 days after the onset of symptoms (90% vs. 71%).

Both methods showed 100% specificity in this study.

Clinical Validation in the Hospital Virgen de las Nieves

Purpose of the study:

Evaluate the clinical efficacy of rapid tests for detection of IgG/IgM antibodies brand SingClean for the determination of coronavirus infection with respect to the RT-PCR method in patients with symptoms (in days).

Study design:

45 patients were selected, who had previously undergone RT-PCR test, of which:

- 38 (84.4%) had strong COVID-19 symptoms (fever, cough, migraines, and dyspnea).
- 7 (15.6%) healthy individuals (or with other pathologies).

The sampling was carried out at different times:

- Most of the samples for PCR were taken in the first 7 days after presenting symptoms.
- The samples for the rapid diagnostic tests were taken between 9-25 days after presenting symptoms.

Clinical Validation in the Hospital Virgen de las Nieves

Results:

		Results validation H.V.N	
	Manufacturer data	SingClean test	RT-PCR
Sensitivity	91,80%	87,50%	71,10%
Specificity	97%	100%	100%

Significant results p<0,05
The data provided by the manufacturer comes from studies led in Chinese hospitals.

In this data analysis, positive cases are patients who present the clinical picture of COVID-19 disease:

- Symptoms: Fever, cough, dyspnea and migraines.
- Radiological pattern with diffuse or patchy bilateral interstitial pneumonia.
- Compatible analytical abnormalities (high levels of lactate dehydrogenase, ferritin, reactive protein C , D-dimer and lymphopenia).

Clinical Validation in the Hospital Virgen de las Nieves

Study remarks:

- Samples that have positive RT-PCR in patients with COVID-19 were taken before (6.04 ± 2.92 days) than those with a negative result (9 ± 2.93).
- The concordance between RT-PCR and the antibody test is not very high (62.5%), although both were agreed with the clinical diagnosis.
- Carrying out the rapid test included in this study allowed confirmation of the diagnosis in all patients with a negative RT-PCR result (n = 11, 100%). In ten of the patients with negative RT-PCR (data not shown), the test was repeated following the recommendations, with just a conversion into a bronchial aspirate (a better-quality sample).

Detection of IgM/IgG antibodies by the Singclean rapid method showed a higher sensitivity to detect SARS-CoV2 infection than genetic detection by RT-PCR, among 9 and 25 days after the onset of symptoms (88% vs. 71%).

Both methods showed 100% specificity in this study.

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Biomedal works under the quality standards of ISO 9001 and 13485

Please, for more information contact us or visit our website.

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