

Press release

**COVID-19: THE MOST EFFECTIVE ANTIGEN RAPID TEST ON THE
MARKET ARRIVES IN SPAIN, ENDING ERRORS IN THE
SAMPLING OF PCR TESTS**

- *The SARS-CoV-2 Serological Antigen Rapid Test is characterized by extremely high sensitivity. Studies show that this is 100% as of the fourth day after COVID-19 symptoms, making it the most sensitive rapid test available on the market.*
- *The new test eliminates the difficulty for the correct taking of these samples in the case of PCR tests. This difficulty translates into a drag on its reliability, which results in false negatives in up to 50% of cases.*
- *"Thanks to its low cost and reliability, the rapid SARS-CoV-2 serological antigen test facilitates frequent tests to improve pandemic control."*
- *BIOHIT and Dialane AG already have on the market the rapid ANTIBODY SARS-CoV-2 IgM / IgG test, endorsed in a comparative study by the prestigious Yale University, with a sensitivity of 100% and a specificity of 99.7%.*

Madrid, September 29, 2020 - The Finnish-Chinese company BIOHIT Healthcare, specialized in biomedicine and in the development and application of in vitro diagnostic technology, has started to market its rapid SARS-CoV-2 serological antigen test in Spain. It is the most reliable coronavirus diagnostic kit on the market, with 100% efficiency between days 4 and 7 after infection, when most symptoms occur, and an average sensitivity of 95% during the first 14 days of illness.

To obtain the samples, and unlike what happens with the PCR tests used today, in the case of the BIOHIT rapid serological antigen test, a simple prick is enough to extract about five drops of blood. This method of obtaining the sample to measure the presence of viral antigen in serum or plasma is what makes the difference with respect to the rest of the detection methods on the market, in which a nose or throat swab is used, which require correct sampling of the nasopharynx, which is very unpleasant for some patients. According to [various studies](#), the difficulty in correctly taking these samples would reduce the sensitivity of PCR tests to 63% in the case of taking nasal smears and to 32% when taking throat smears. An average of just 50% sensitivity, which means that one in two PCR tests results in a false negative / positive.

According to Dr. Chris Mauracher, virologist, biochemist and CEO of Dialane AG, a Swiss company that has collaborated with BIOHIT in the development of the rapid SARS-CoV-2 serological antigen test, in addition to those already mentioned, the new system has many other advantages regarding the PCR and Nasopharyngeal Antigen tests. Among them, it stands out "its affordable

price and that also eliminates the need to repeat the test in the event of a positive result thanks to its 100% reliability, which also saves time and costs; the fact that it allows the detection of asymptomatic people, reducing the risk of spreading the virus; and that, thanks to its low cost and reliability, it facilitates frequent analysis to improve pandemic control ”.

Mauracher also wanted to highlight the potential and production capacity of BIOHIT and Dialane AG, which he explains are in a position to put 20 million diagnostic kits on the market without interruption per month: “BioHit tests are among the best on the market and our customers can trust 100% in the reliability and security of the deliveries requested ”.

Combination bet: antigen kits and antibody kits

The **SARS-CoV-2 serological antigen rapid test from BIOHIT** and Dialane AG joins the other product that both companies already had on the market: **the SARS-CoV-2 IgM / IgG ANTIBODY rapid test**, a rapid test that was one of the first two developed by a company based in the European Union that was CE certified and the first to be further certified by the US regulatory authorities through the US Food and Drug Administration (FDA). The SARS-CoV-2 IgM / IgG ANTIBODY rapid test has two independently published studies, one from Yale University and one from the [US Department of Health](#), which confirmed the extremely high reliability of the test.

Starting 14 days after infection, when the sensitivity of the antigen test falls below 20%, the rapid ANTIBODY SARS-CoV-2 IgM / IgG test guarantees an efficacy of 99.7% -100%. In this sense, the [study carried out and published by Yale University highlights](#) the "high levels of sensitivity and specificity" of the test and the fact that it maintains its performance "against various populations and patient matrices, as well as in the presence of numerous potentially interfering substances ”.

In the conclusions of the same independent study, the authors also point out that the rapid ANTIBODY SARS-CoV-2 IgM / IgG test shows "promise" for use as a "mobile diagnostic tool" and underline the "potential utility" of a test. “So simple and cost effective” to catalogue epidemiological data such as prevalence and past infection status.

The opinion is corroborated by Dr. Chris Mauracher, for whom the combined detection of Serological Antigen and Antibody in blood can be very useful to "verify each other different stages of the disease and provide complete evidence" for the diagnosis of COVID-19, which makes the combination "a very useful tool" to support public health strategies by having a global map of the evolution of the virus by zones and regions.

“It is extremely important that we can make both tests available to clinicians. Antigen testing helps experts confirm SARS-CoV-2 infection in the early stages, so that symptomatic and asymptomatic infected patients can be confirmed and isolated. The antibody test, meanwhile, can confirm a past infection that may not have been diagnosed, "concludes Dr. Mauracher.

About BIOHIT: Founded in November 2013, BIOHIT Healthcare (Hefei) Co., is a Finnish-Chinese company that has always been committed to the development and application of in vitro diagnostic technology. Since its inception, the Chinese company carried out a long-term strategic cooperation with BIOHIT Oyj, a leading biomedical company in Finland founded in the 1970s, which ended up acquiring definitively in 2018, thus further improving the chain industrial and laying the foundations for its opening to the global market.

About DIALANE AG: Dialane AG was founded in 2008 by Dr. Chris Mauracher (Virologist and Biochemist) to offer diagnostic companies consulting services for importing products to Europe; as well as for the sale and marketing of specialized diagnostic products in Europe.

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