Presse Release

A new rapid test of Covid-19 ends with all limitations of Nasopharingeal Antigen

- ***The studies, endorsed by the Universities of Paris and Cologne, show that the new test has a sensitivity of 100% and a specificity of 98.9% during the first 10 days of the disease, even in asymptomatic people.***

- ***Obtaining the sample to measure the presence of viral antigen in blood is what guarantees the reliability and what makes the difference with the rest of the detection methods existing in the market, in which a nose or throat swab is used.***

- ***The new test puts an end to the difficulty in collecting these samples correctly in the case of PCR tests and nasopharyngeal antigens. This difficulty translates into a burden for their reliability, which results in up to 50% false negatives.***

- ***"Thanks to its low cost and reliability, the SARS-CoV-2 serological antigen rapid test facilitates frequent testing for improved control of the pandemic".***

Madrid, November 5, 2020- The misuse of antigen tests, which results in recurrent false negatives, as well as their low effectiveness during the first days of infection and in people who are asymptomatic or have smaller amounts of virus, has put Spanish experts in epidemiology and public health on alert.

In this respect, the beginning of the commercialization in Spain of the rapid test SARS-CoV-2 serological antigen developed by the Finnish-Chinese company BIOHIT Healthcare, specialized in biomedicine and in the development and application of in vitro diagnostic technology, is of special importance. This is a new rapid diagnostic kit for coronavirus through blood samples that is the most reliable on the market, with 100% effectiveness between days 0 and 7 after infection and 100% sensitivity and specificity of 98.9% during the first 10 days of the disease even in asymptomatic people, where the tests used to date are showing their greatest limitations.

The effectiveness of these tests has recently been endorsed by the French National Institute for Health and Medical Research (INSERM) and by the laboratory 'Infection, Antimicrobials, Modelling, Evolution' (IAME) of the University of Paris, as well as by the collaboration between the Institute of Innate Immunity of the University of Cologne (Germany) and Quanterix Biotechnology Corporation of Massachusetts (USA). In addition, the test is currently in the process of being certified by the American FDA.

In order to obtain the samples, and unlike the antigen and PCR tests currently used, in the case of the BIOHIT rapid serological antigen test, a simple puncture is enough to extract about five drops of blood (0.2ml to 0.3ml). This method of obtaining the sample to measure the presence of viral antigen in serum or plasma is what makes the difference with the rest of the detection methods available in the market, in which a nose or throat swab is used, which requires a correct sampling of the nasopharynx, which is very unpleasant for some patients.

According to several studies, the difficulty in collecting these samples correctly would reduce the detection of positive PCR or nasopharyngeal antigen tests to 63% in the case of nasal smear collection and 32% when the collection is from the throat. An average of only 50% reliability, which means that, for example, every second PCR test results in a false negative.

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 SARS-CoV-2 rapid serological antigen test, in addition to those already mentioned, the new system has multiple other advantages over PCR and nasopharyngeal antigen tests. Among them are "its affordable price and also eliminates the need to repeat the test in case of positive thanks to its 100% reliability, which also leads to time and cost savings; 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, facilitates frequent testing to improve control of the pandemic".

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 it permanently in 2018, thus further improving the industrial chain and laying the foundation 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 consultancy services for importing products into Europe; as well as for the sale and marketing of specialized diagnostic products in Europe.

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