

COVID-19: the alliance between Diesse and TLS produces the diagnostic kit used in clinical trials on monoclonal antibody therapy

The kit developed by Diesse on the basis of the TLS Foundation MAD Lab's experience on monoclonal antibodies will support diagnosis and monitoring activities during the recently-initiated clinical phases

Siena, 9th March 2021 – The joint commitment of DIESSSE R&D and the TLS research group managed by Dr Rappuoli has led to the development of a **specific diagnostic kit for the quantitative determination of the medicinal product in patients' serum**. The kit **will be used in the clinical trials that were recently undertaken** by Toscana Life Sciences Sviluppo. The clinical trials will make it possible to assess the safety and efficacy of the human monoclonal antibody therapy developed by TLS for the treatment of SARS-CoV-2 infection.

DIESSSE, an IVD sector leader, **has developed a kit based on the wide range of monoclonal antibodies that the TLS research group** (headed by Dr Rappuoli) extracted and selected from the blood of patients who were convalescing or had recovered from COVID-19. More specifically, **the diagnostic kit is based on the therapeutic monoclonal antibody J08, which is used to monitor therapy**. The test boasts the advantage of being able to provide **diagnostic data during the volunteer enrolment phase** and guarantee **close monitoring throughout the entire follow-up period** (for example, in order to analyse therapeutic dose levels), thus making it possible to accurately characterise the concentration of antibodies that are present before and after administration of the therapy.

Throughout the trial, **at least 3,500 specimens will be acquired for analysis by a team of Diesse researchers** at Toscana Life Sciences Foundation.

"The research conducted on human monoclonal antibodies has huge potential, as testified to by the results of their many applications on the diagnostic, therapeutic and preventative fronts", explains Rino Rappuoli, scientific supervisor of the TLS Foundation MAD Lab. "This is where the TLS ecosystem proves its worth, allowing us to pool expertise and experience to develop diagnostic and therapeutic devices that improve our response to the current emergency. From this point of view, the collaboration with Diesse was exceptional".

The diagnostic kit is available on the Chorus system, where it is already possible to run 6 tests for the treatment of SARS-COV-2, thereby guaranteeing a user-friendly, automated and flexible workflow.

"We are proud to be able to provide this important clinical trial with what we believe to be the best COVID diagnostic kit that we have developed over the past few months. Not only does the test use as a matrix the native virus, which has been inactivated by using a method that we patented, but it also uses the labelled therapeutic antibody to afford unparalleled specificity," explains Diesse CEO, Dr Massimiliano Boggetti.

Far more than a strategic alliance and a licensing agreement, the venture is a high-value partnership that will result in a joint development project.

Clinical trials on the anti SARS-COV2 monoclonal antibody therapy started on March 1st. Phase I clinical trial involves the Spallanzani Institute in Rome (IT) and the Clinical Research Centre in Verona (IT) and will enrol 30 healthy adult men and women overall. This phase I study aims to ascertain the safety of the monoclonal antibody, defined as absence of serious adverse events after treatment of the healthy volunteers participating in the study. Furthermore the study will describe the pharmacokinetics of the molecule.

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