Participating Institutions

Istituto Superiore di Sanità (ISS)

ISS is a public government institution representing the technical-scientific arm of the Italian National Health Service. Its main activities include research, disease and healthcare control, documentation and training in the field of public health. The Institute is also a source of information on public health issues.

University Hospital of Basel

The University Hospital of Basel is a Swiss public institution. Its Department of Biomedicine (DBM) unites the entire research laboratories of the Faculty of Medicine. Oncology, Immunology, Neurobiology and Stem Cells and Regenerative Medicine are the key research areas of the DBM.

University Hospital Tor Vergata

The University Hospital Tor Vergata has been designated by the Lazio Region as a COVID-19 Hospital because it hosts a level II Department of emergency assistance with adapted medical and surgical wards and consultants. It is currently devoted to the management of patients with Severe Acute Respiratory Syndrome caused by SARS-CoV-2.

The NATO Science for Peace and Security Programme

The **NATO Science for Peace and Security (SPS) Programme** is an integral part of the NATO Emerging Security Challenges (ESC) Division. The SPS Programme develops and implements practical cooperation and enhances dialogue between NATO nations and Partner countries through capacity-building and security-related civil science, technology and innovation. All SPS activities contribute towards the Alliance's Strategic Objectives, have a clear link to security and respond to at least one of the SPS Key Priorities.

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NATO OTAN

Emerging Security Challenges Division

New and validated tools for the diagnosis and follow-up of

SARS-CoV-2 infected individuals

Science for Peace and Security (SPS) Programme

Project description

The COVID-19 pandemic has exposed the importance of rapid and accurate diagnosis of viruses. A correct diagnosis of SARS-CoV-2 infection is fundamental for the appropriate treatment of patients, but it is also required for the efficient isolation of contacts, as well as for large screening programs aimed at reducing the viral spread.

This SPS Multi-Year Project proposes to use immuno-diagnostic methods to provide rapid and accurate diagnosis of the SARS-CoV-2 infection. The objective is to produce recombinant structural proteins coded by SARS-CoV-2, and monoclonal antibodies (mAbs) specifically able to recognize these proteins. These reagents will be used to develop robust COVID-19 diagnostic tests.

Goals

The aim of this project is not only to produce immunodiagnostic tools specific for SARS-CoV-2 antigens in sera of patients or contacts, but also to detect viral particles or viral-released proteins in biologic fluids of infected individuals for a rapid diagnosis based on the detection of antigens. The detection of antigens as a measure of individuals' infectivity has already been applied to the diagnosis of active tuberculosis, for which the differential diagnosis is crucial in order to plan therapies and restriction measures.

Deliverables

- Synthesis of SARS-CoV-2 recombinant proteins;

- Production of mAbs specific for SARS-CoV-2 proteins;

- Development and validation of methods to reveal SARS-CoV-2 antigens and specific anti-SARS-CoV-2 human immunoglobulin G (IgG) and immunoglobulin M (IgM) antibodies in bio-fluids from patients affected or not affected by COVID-19;

- Development and validation of lateral flow immunoassays;

- Development of a novel, portable, specific, and sensitive tool for the fast detection of SARS-CoV-2 antigens and specific anti-SARS-CoV-2 human IgG and IgM in bio-fluids from patients affected or not affected by COVID-19.

Impact

This project will contribute to limiting the SARS-CoV-2 diffusion by providing new tools for rapid diagnosis that can be used in large-scale settings. It will develop a new generation of specific, rapid, accurate and sensitive immuno diagnostic methods.

The current laboratory diagnosis of COVID-19 requires specialized laboratories with expensive equipment and trained technicians. These limitations make the procedure unsuitable for rapid and simple diagnoses and screening of patients, which hinders outbreak containment efforts.

The developed diagnostic kits will allow for faster detection of SARS-Cov-2 released in environmental and human body fluids, and a more accurate identification of the immune response (IgG and IgM) to SARS-CoV-2 structural antigens. The innovative aspects of this project include, but are not limited to, the possibility to measure both serum antibodies of IgM and IgG class, specific for structural SARS-CoV-2 virus and viral antigens in biofluids.

The immunization procedure that will be used to generate monoclonal antibodies will also provide an immunogenicity preclinical model of a COVID-19 preventing vaccine. The identification of virus-neutralizing antibodies could represent a first step in the development of immuno therapeutics based on the administration of antibodies to treat infected patients.