Mariya GABRIEL
Commissioner for Innovation, Research,
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Brussels, 30/09/2020
vdl-ca-12.cab staff.dir(2020)4662876

Dear Ms Carvalho, Ms Pereira, Ms Monteiro de Aguiar, Mr Rangel, Mr Fernandes and Mr Amaro,

Thank you very much for your letter and your interest in Research and Innovation (R&I) on diagnostic tools and testing for COVID-19. Testing is a key component of how EU Member States are managing the COVID-19 pandemic as well as their strategy for a return to normal life. Rapid diagnostic tests, especially point-of-care, are an essential tool to handle this return as well as to reduce the risk of further spread of the virus. Recognising this issue, diagnostics is an area that we have supported in many of our R&I initiatives, from the very beginning with a first emergency call for Expression of Interest launched in January 2020.
Up until September 2020, the European Union has allocated EUR 440.6 million to 103 projects targeted specifically to the COVID-19 pandemic. These projects address the development of diagnostics, treatments, vaccines, epidemiology, preparedness and response to outbreaks, socioeconomics, production and digital technologies, as well as the infrastructures and data resources that enable this research. Out of these 103 projects, 25 address directly diagnosis. I am pleased to share with you additional details on all these projects in the annex to this letter.
I would like to particularly flag the success of one of the first 18 research and innovation projects funded by the EU to tackle the coronavirus. Researchers involved in the "HG nCoV19 test" project, selected for funding from the EU research and innovation programme Horizon 2020 under the first emergency call launched in January, have obtained approval to put a new rapid point-of-care diagnostic for COVID-19 on the market. The project developed a new portable diagnostic system to detect viral infection that gives accurate and reliable results in 30 minutes.
I would like to emphasise that the European Commission (EC) activities related to diagnostics have not been limited to funding research and innovation projects. Let me give you some examples:

- *Within the activities of the ERAvsCorona Action Plan, the EC services together with experts of Member States elaborated a document on the Research and Innovation priorities for COVID-19 testing that has been shared with Member States in July 2020.*

- *The lack of positive control materials was one of the top three challenges faced by laboratories for the reliable implementation of coronavirus tests. To respond to this, scientists from the EC's Joint Research Centre designed and produce since April 2020 control material that laboratories can use to check the correct functioning of their coronavirus tests and to avoid false negatives.*
- *In April 2020, as part of the European Roadmap towards lifting coronavirus containment measures, the Commission presented guidelines on coronavirus testing methodologies. It aims to support Member States in effectively using testing tools in the context of their national strategies and during the different stages of the pandemic, including when phasing out confinement measures.*

Allow me to reassure you that we remain fully committed to ensure that the EC's support to research and innovation are oriented to support and reinforce our Member States public health sectors and mitigate the socio-economic impact in the European Union.

Yours sincerely,

Mariya Gabriel

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Annex : EU funded R&I projects

1st Horizon 2020 call for expression of interest (March 2020)

In January 2020, the Commission launched an emergency call, through which EUR 48.2 million were awarded to 18 research projects. The projects, are working on improving epidemiology and public health, including preparedness and response to outbreaks, diagnostic tests, new treatments and new vaccines. Among these, 3 projects are receiving a total of EUR 6.4 million to develop effective, rapid point-of-care diagnostics:

- **CoNVat:** Combating 2019-nCoV: Advanced Nanobiosensing platforms for POC (Point-of-Care) global diagnostics and surveillance. The project will develop a rapid point-of-care diagnosis and monitoring, and also monitor the evolution of viruses in animals and help prevent future outbreaks. Led by Fundacio Institut Catala de Nanociencia i Nanotecnologia (ES).
- **CoronaDX:** Three Rapid Diagnostic tests (Point-of-Care) for COVID-19 Coronavirus, improving epidemic preparedness, public health and socio-economic benefits that can be used with minimal training. Led by Danmarks Tekniske Universitet (DK).
- **HG nCoV19 test:** Development and validation of rapid molecular diagnostic test for nCoV19, that does not require virus extraction chemistry, with a particular focus on early stage disease diagnosis. Led by Hibergene Diagnostics (IE). Researchers involved in the EU-funded HG nCoV19 test project developed a new portable diagnostic system to detect viral infection that gives accurate and reliable results in 30 minutes.

Special Innovative Medicines Initiative call (May 2020)

On 3 March 2020, the Innovative Medicines Initiative (IMI) supported through the European Commission's Horizon 2020 Framework Programme for Research and Innovation, launched a special fast-track call for the "Development of therapeutics and diagnostics combatting coronavirus infections" with an EU contribution of EUR 45 million, which was subsequently increased to EUR 72 million. On 12 May 2020, following the independent evaluation of proposals, it was announced that 8 projects were short-listed for funding, including on 5 projects receiving EUR 28 million in EU grants to develop rapid diagnostics:

- **COVID-RED** - COVID-19 infections: remote early detection. The project will combine expertise in clinical epidemiology with digital devices (such as wearables and mobile apps) to rapidly and reliably detect cases, so that patients can be prioritised for testing. Led by Universitair Medisch Centrum Utrecht (NL)

- **DECISION** - A miniaturised disposable molecular diagnostics platform for combatting coronavirus infections. This low-cost, diagnostic system that will make it possible to test patients with laboratory quality performance almost anywhere in 15 minutes or less. Led by GNA Biosolutions (DE)

- **DRAGON** - Rapid and secure AI imaging based diagnosis, stratification, follow-up, and preparedness for coronavirus pandemics.
  The project aims to deliver a decision support system for improved and more rapid diagnosis and prognosis. Citizens and patients will be involved in the development of the system. Led by Oncoradiomics (BE)

- **KRONO** - Evaluation of a production ready portable, point-of-need platform, direct from nasal swab test for the molecular diagnostic detection of COVID-19 infection. The project aims to develop a simple test with results in just 40 minutes and create the capacity to rapidly deploying new tests in response to future outbreaks. Led by BG Research (UK).

- **RAPID-COVID** - Robust automation and point of care identification of COVID for a diagnostic test that can simultaneously detect SARS-CoV-2, as well as 30 other common respiratory bacteria and viruses, to ensure patients are quickly isolated and that all patients receive the right treatment. Led by GeneFirst (UK)

EIC Accelerator (June 2020)

In mid-March 2020, the European Innovation Council (EIC) launched a call for innovative companies to apply for EIC Accelerator funding. Following a record number of applications selected, 36 projects dealing with Covid-19 were selected, of which 3 focus on testing with a total funding of EUR 11,1 million.

The 3 companies working on testing aim to develop devices that can be used anywhere and will deliver results very quickly, enabling front-line health workers to make a fast and accurate diagnosis, in turn reducing the risk of further spread of the virus.

- **Aidence Holding BV** (NL): Software for the automated detection of Covid-19 infection on chest
- **Somaprobes, S.L.** (ES) Rapid and easy- test for Coronavirus infections
- **XSENSIO SA** (CH): Wearable diagnostic for inflammation tracking for personalised patient care among at-risk patients

EIT health rapid response program (April 2020)

As part of its Rapid Response initiative in the fight against COVID-19 pandemic, EIT-Health (European Institute of Innovation and Technology) is supporting 15 short-term projects that focus on immediate and impactful solutions for a total of almost EUR 7 million, with the participation of 41 partners. Among these, 8 projects are receiving EUR 4.25 million to develop efficient and early diagnostic methods:

- **CoViproteHCt:** The project aims to identify the true markers of protective immunity. The research team will compare blood content of healthcare personnel who have tested positive for SARS CoV-2 with their health status over six months Led by Technische Universität München (DE).
- **FastRAi:** FastRAi are looking to support over-burdened hospitals and radiologists dealing with COVID-19. They are developing an AI algorithm that can project x-rays onto CT images and build up data on the progression of lung disease. Led by Technische Universität München (DE).
- **NanoDx COVID-19:** This project will provide a more sensitive means of diagnosing COVID-19. It combines innovations in two technologies: nanoporous silicon and an immuno protemic, or protein-based test, to help diagnose low concentrations of viral infection. Led by INSERM (FR).
- **PlasmonDetect:** PlasmonDetect is developing a novel molecular diagnostic technology called “plasmonic strand-displacement amplification assay” for rapid detection of COVID-19. The process allows for fast and specific detection of viral RNA and could be valuable in on-site testing. Led by Technical University of Denmark (DK).

- **ProCop:** The project aims to develop and validate a new blood-based score for COVID-19 to help determine the severity of a patient's condition, their prognosis and their likelihood of developing a drug-induced-liver-injury due to COVID-19 medication. Led by Assistance Publique – Hôpitaux de Paris (FR).
- **QwikZyme:** The team is developing a diagnostic device to detect ultra-low concentrations of the SARS-CoV-2 virus that causes COVID-19. The testing should enable earlier diagnosis and can also be used on people without symptoms. Led by Imperial College London (UK).
- **SDx SARS-CoV-2:** The test aims to detect the RNA of the SARS-CoV-2 virus before antibodies and symptoms occur. Coupled with serological tests to detect SARS-CoV-2 specific antibodies, it could be leveraged by health authorities to develop strategies, minimising economic disruption. Led by University of Tartu (EE).
- **Certify.health:** Certify.health is developing a COVID-19 status certificate – telling whether a person is infected, free of infection or immune. With this, it should be possible to trace contacts, validate diagnostic tests and confirm authorisations – with privacy protected. Led by Hospital Clinic de Barcelona (ES).