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Creation of the Puerto Rico Diagnostic Tests Evaluation Commission (PRoDTEC) for SARS-CoV [1]

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By:

Departamento de Salud de Puerto Rico

The Department of Health and the Puerto Rico Science Trust collaborated to obtain the FDA Consent to grant emergency use authorizations (EUA) for tests that detect SARS-CoV-2 in laboratories, giving scientific autonomy to Puerto Rico during the emergency of COVID-19

September 23, 2020. San Juan, Puerto Rico - Given the need to increase in Puerto Rico the capacity to diagnose COVID-19, the Department of Health of Puerto Rico (DOHPR) and the Puerto Rico Science, Technology and Research Trust (PRSTRT) have collaborated in the creation of the Puerto Rico Diagnostic Test Evaluation Commission (PRoDTEC). The PRoDTEC is a panel of experts that will review and approve with greater agility the use of diagnostic tests on the Island for the detection of the SARS-CoV-2 virus, which causes the COVID-19 disease.

“The Commission will be responsible for evaluating the validity as well as stimulating the development of new COVID-19 diagnostic methodologies and tests for the detection of the

new coronavirus during the public health emergency in Puerto Rico. The creation of the PRoDTEC gives Puerto Rico the ability - in collaboration with the United States Food and Drug Administration (FDA) - to carry out evaluations to do tests with agility while maintaining scientific rigor. This is a cutting-edge initiative necessary to respond to the emergency with the best scientific knowledge. Puerto Rico has the scientific capacity to do so, and at the Department of Health, we want to leverage those talents and knowledge for the benefit of our people," said Dr. Lorenzo González, secretary of the DSPR. "The PRoDTEC aims to help Puerto Rico overcome the emergency we face by advancing the availability of COVID-19 diagnoses that help save lives and prevent infections. The structure of PRoDTEC is also an important step for Puerto Rico, beyond the pandemic, because it serves as a basis to speed up the implementation of new science-based diagnostic methods for other emerging infectious diseases in the future," he said.

Earlier in the year, the secretary of HHS (Health and Human Services) declared a public health emergency in the United States and its territories due to the COVID-19 virus. As a result of this statement, in March, the FDA, under a Memorandum issued by the President of the United States, allowed states and territories of the United States that so requested, the power to evaluate and authorize the use of tests for COVID-19 in state or jurisdiction clinical laboratories.

Lucy Crespo, Chief Executive Officer of the PRSTRT, said: "What this represents for the people is the ability to continue increasing the number of diagnostic tests in our battle against this virus with an agile process and a Commission with prominent scientists in Puerto Rico. In the month of July, Puerto Rico managed to achieve about 6,000 daily tests, then that number was reduced to about 4,000 daily tests. With the creation of the PRoDTEC, it is expected to streamline the authorization process so that more laboratories can participate and thus the potential of daily tests in Puerto Rico can be maximized," she concluded.

Under this state consent, it is not necessary to send validation evidence of the SARS-CoV-2 test to the FDA; instead, the state or territory assumes the responsibility of reviewing this evidence and authorizing the COVID-19 tests performed by local laboratories that meet the criteria. The FDA emergency use authorization process can typically take months.

With this step, Puerto Rico joins a few pioneering states that have chosen to take advantage of this opportunity, including Connecticut, Maryland, Mississippi, Nevada, New Jersey, New York, and Washington.

"This is an important collaboration between the Department of Health and the Puerto Rico Science Trust that will result in significant health benefits for the country, for this pandemic, and for future epidemics," explained Dr. Daniel Colón-Ramos, trustee of the PRSTRT and President of the Scientific Committee appointed to manage the creation of the PRoDTEC. "The Secretary of Health, Dr. Lorenzo González, delegated us without restrictions, but with the clear task of using rigorous criteria in the selection of candidates to form part of the Commission. The Scientific Committee of Trustees reviewed half a dozen competing nominations; and we unanimously selected as members of the PRoDTEC Dr. Marcos López Casillas, PRPHT research manager; Agnes Rodríguez Soto, Senior Quality Systems Consultant (Business Excellence Consulting) and Dr. Federico Goodsaid Zalduondo, CEO of

MBQ Pharma. This is an important achievement for science and for Puerto Rico," he concluded. It is worth mentioning that the group of experts should have capacities in the fields of biochemistry, molecular biology, clinical laboratory sciences, virology, pathology, or epidemiology, among others.

PRoDTEC will first submit a protocol for expedited evaluation of COVID-19 diagnostic tests for approval by the Department of Health. Then, it will collaborate with the COVID-19 Clinical Laboratory Working Group to establish said protocol in laboratories certified under CLIA (Clinical Laboratory Improvement) that meet the regulatory requirements to perform highly complex tests.

For more information about PRoDTEC visit https://www.prodtec.org [2]

About the Puerto Rico Science, Technology and Research Trust

The Puerto Rico Science, Technology and Research Trust, as described in Public Law 214, is a non-profit organization created in 2004 to promote the participation and creation of jobs on the Island in the global knowledge economy by promoting investment and financing of research and development of science and technology. It invests, facilitates, and develops the capacities that continuously advance the economy of Puerto Rico and the well-being of its citizens, through companies based on innovation, science and technology and its industrial base. With the goal that by 2022, Puerto Rico will be a center of global recognition that develops and retains scientists, companies, and entrepreneurs of world excellence, to boost our competitiveness and creativity. It is also responsible for Puerto Rico's public policy for science, technology, research and development, and public health. For more information: www.prsciencetrust.org [3]

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