

THE CLINICAL PATHOLOGY AND LABORATORY MEDICINE IN THE DIAGNOSIS OF COVID-19

HRPLabs (Hato Rey Pathology) is a distinctly Puerto Rican institution that provides laboratory services to the entire Island and that over the years has remained at the forefront of its services according to the medical need of the population. That is why since April 1, 2020, thanks to Dr. Luis Ferrer, a clinical pathologist specialized in Immunopathology together with his technical and support team, we began to carry out molecular tests for the detection of SARS-CoV-2, better known as the coronavirus disease or COVID-19 serving as a reference laboratory to hospitals and also in a space with a tent in front of our clinical laboratory for the safety of our patients. In turn, Dr. Keila Rivera Roman, also a clinical pathologist with a subspecialty in molecular genetics, completed the validation of our team, which doubled the number of tests we could perform daily. Dr. Rivera Román also validated the serological test for the detection of antibodies and development of immunity.

Laboratory tests are vital for the diagnosis, screening of patients and therefore, to control the public health situation that we live today. We can say that the clinic that each patient reflects in relation to COVID-19 can be ambiguous and can be identified with the previously mentioned common symptoms; But in the same way, it can be a completely asymptomatic patient and be a source of involuntary contagion for other loved ones or people with whom it has contact. Laboratory tests are our resource to be able to identify if the patient is positive for COVID-19 or any other acute infection of the upper respiratory tract such as the Influenza virus or bacterial infection caused by *Mycoplasma*, among others.

HRPLabs has a wide medical faculty of pathologists, thus covering multiple subspecialties, making it a very useful resource for the medical community in the country where quality is paramount. A subspecialty pathologist in immunohistochemistry, genetics and molecular is highly trained to obtain the specific sequences of the coronavirus (SARS-CoV-2). The genome of the virus is made of ribonucleic acid (RNA), this genetic material through laboratory processes is extracted, purified and mixed with other reagents to later be analyzed by a team that uses the methodology of the polymerase chain in real time (RT-PCR). Once any sample from the upper respiratory tract with suspicion of the virus is received, it goes through all these regulated processes in which diagnostic quality is guaranteed. If the patient sample contains the viral genetic material that we wish to detect, the material will be amplified and indicate a positive value. Our pathologists are highly accessible to the physician managing the patient; This is an added value since the clinical correlation with the history of each patient is required to determine the status of the infection and how to proceed with the treatment of the patient, safeguarding her life at all times. A positive result is indicative that the patient has SARS-CoV-2 RNA present, but does not rule out co-infections with other pathogens. The direct service of anatomical and clinical pathology for hospitals is of fundamental relevance for the optimal management of the patient.

Now, let's talk about the tests that have to be developed quickly and even that are acquired commercially in the face of medical need and public health surveillance. There are extremely important characteristics that every professional who provides health services must know when

deciding to provide them to their patients; Within these, sensitivity, specificity and we cannot leave behind the diagnostic precision, in turn, the time to receive the results reports. It is vital to know the patient's history to identify which test will be the best to perform. Within the tests we have heard about the molecular methodology for the detection and diagnosis of the virus, and serological tests (better known as rapid tests).

Rapid tests are often helpful in detecting whether the patient's body has created immunity to the virus; In other words, to create immunity, the patient had to be exposed to viral particles and, consequently, this or was infected with the disease. The biological sample collection is by venipuncture in which blood is extracted from the patient and it is processed. The result is obtained quickly, in just minutes.

There is very little information related to the precision of these tests regarding the immune response of patients and how it changes. Typically, the body develops immunity within five (5) to seven (7) days after exposure. A positive serology result must be confirmed with the molecular test; In this way, we will validate whether the patient has an active viral infection, being a potential vector of contagion for others or not.

The molecular methodology test uses the real-time polymerase chain reaction (PCR) and is of vital utility for the detection of active coronavirus; In other words, it is useful for diagnosing the coronavirus. The collection of this biological sample is through a nasopharynx or oropharynx swab in which genetic information is extracted for the detection of the virus. This molecular test is used as a confirmatory test. Results delivery time is 24 to 48 hours.

The community and the entire health system depend on accessibility to tests, reports of reliable results in the optimal period of time to promote good patient management and minimize the public health situation that afflicts us worldwide. Achieving this is an effort of multiple health professionals, laboratory medicine, subspecialties in the field of health and even other professional disciplines that, even if they are not related to direct patient care, contribute greatly to this pandemic. Strength is in the union and this is everyone's responsibility as a population. At HRPLabs our commitment to patients is invaluable; For this reason we offer them continuous support and the uninterrupted availability of our health services in the face of this public health situation; Our priority is the health of each patient.

We thank everyone as they are part of this great effort to safeguard the health of our population; We urge you to continue with prevention and protection measures.