Want to know more about Novacyt's Near-Patient Testing System?

Novacyt's Near-Patient Test System (NPTS) for COVID-19

Introduction

The value of testing for COVID-19 is well documented not only in the UK, but globally as we reflect on how the disease has spread and impacted countries differently. Whilst testing is widely accepted as the greatest weapon we currently have against the SARS-CoV-2 virus, implementation has not been without its challenges as various issues have limited healthcare systems in being able to reach their targets for desired testing output, as well as question the eventual performance of the test. These challenges include high demand and restricted supply of necessary consumables and reagents for testing, particularly for closed-instrumentation systems, confusion on what the most appropriate test method is within the scientific community (rapid, ELISA, molecular or sequencing), and the perceived value of each diagnostic marker of the disease as our understanding of COVID-19 developed (antigen, antibody, genetic elements). On 14 February 2020, Primerdesign (a subsidiary of the Novacyt Group) announced the launch of one of the world's first CE Marked *in vitro* diagnostic (CE-IVD) polymerase chain reaction (PCR) tests for COVID-19. The success of this product became apparent quickly through its market-leading performance, as demonstrated by various global regulatory accreditations and the unfortunate scale of the pandemic's impact on the need for testing. As testing capacity increased globally, limitations of centralised laboratory-based testing, including getting samples to laboratories, complex testing protocols and a high-level of instrumentation required for testing, to support patient management in certain remote or isolated areas also become more evident. It has been well documented that testing of vulnerable patients for COVID-19, including patients with existing chronic health conditions or elderly patients, as quickly as possible supports the management of care. As we reflect on the lessons learned since the outbreak of COVID-19, and continue to be prepared for subsequent spikes in infection rates, it is clear that accurate testing remains our strongest weapon against further spread of disease, but also the application of frequent and rapid testing in the areas that need it most will be crucial in reducing the social and economic impact of the virus.

What is NPTS?

Primerdesign's team of scientists have been working on two main objectives since the initial launch of the genesig® COVID-19 test; 1) evolution of the test to accommodate higher throughput testing scenarios and 2) evolution of the test to accommodate deployment in specific areas where the throughput is lower, but the test-to-result is more time-critical. The latter encompasses several challenges that include:

- An environment for the safe handling of potentially infected samples (this is typically a pathology laboratory)
- A protocol that is easy to follow and with fewer variables to limit any opportunity for error
- A simplified process for RNA extraction, which is a pre-analytical phase of testing that requires dedicated reagents, consumables and sometimes instrumentation to isolate the genetic material within a sample necessary for giving a test result
- Certain conditions (mainly time and temperature) to enable scientific limitations of the chemistry involved to offer a result that is consistently accurate

The complete workflow solution designed and implemented for Novacyt's NPTS brings together the Company's innovative development of various diagnostic reagents, in combination with its **genesig® COVID-19** test, into a format that is able to address these challenges, making its application viable in remote settings, as well as increasing rapid testing capacity for laboratories. Specifically, the NPTS includes our **exsig™ COVID-19 Direct** product, a combination of our original **genesig® COVID-19** PCR product and exsig™ direct-to-PCR sample preparation technology, onto our own platform, the **genesig® q16** instrument, within a dedicated and proven workflow that delivers results in under 60 minutes. This solution takes into consideration all the safety precautions

necessary in sample handling (including viral inactivation) and brings all the benefits of molecular accuracy into a rapid-PCR package.

Where Can NPTS Be Used?

As an initial focus for the NPTS, Novacyt is working to continue to support the NHS in its ongoing need to manage potentially infected patients with COVID-19. By segmenting the need for testing into specific application areas, we have identified potential conditions where we believe we can support optimal and timely patient management. These include:

- **A&E Departments** – to facilitate an immediate testing capacity for urgent patients, as well as protecting healthcare workers that operate in this environment
- **Imaging Suites** – following the suspension of routine surgeries and imaging appointments as a result of the impact of COVID-19, adoption of the NPTS could support many of these care pathways return to "normality", including regular operating schedules and earliest detection of cancer
- **Transplant Centres** – as one of the most time sensitive areas of medicine, speedy confirmation of infection status prior to surgery commencement is the optimal way of ensuring patient and healthcare workers' safety
- **Respiratory Clinics** – as services designed to treat and manage patients infected with some of the most infectious illnesses that exist, effective management and appropriate congregation of individuals within these dedicated centres is vital in minimising the spread of COVID-19 within this vulnerable population group
- **Care Homes** – support either centralised testing for care home residents and their respective care workers for areas with a high density of homes, or provide dedicated on-site testing within a designated and appropriate space
- **GP Surgeries** – many surgeries have a process in place to send samples to their local general hospital pathology services to carry out testing for them. However, for those in remote locations and at significant distance from their nearest hospital, this process becomes longer than necessary. Deployment of the NPTS in these settings could eliminate this problem

We are also looking to expand the application of the NPTS further into remote settings, such as on cruise ships, on small islands without the infrastructure to support large testing capacities, airport testing for traveller screening and military deployment.

Who Can Use the NPTS?

As a CE-IVD, the NPTS remains a designated product for professional use only. However, the focus on development has been to simplify the workflow as much as possible to make the widespread deployment easy to manage and support.

Where Is the NPTS Currently Being Used?

In addition to the clinical data generated to support the launch of the NPTS, there are two large clinical studies currently ongoing to support the potential deployment of NPTS for specific areas of care. These include:

- Queen Mary University of London – a 2,000 patient clinical trial using the NPTS in London care homes to investigate whether daily COVID-19 testing reduces the infection rate, morbidity and mortality in this high-risk population
- A London Hospital Trust – a clinical trial to support the return to regular surgery scheduling for heart surgeries and imaging appointments

A number of NHS hospitals have already adopted the NPTS to supplement their existing COVID-19 capacity. We believe the completion of these clinical trials will further support the use of Novacyt's NPTS within NHS hospitals, as well as provide evidence to support testing capacity for the elderly and vulnerable population group in care homes. **exsig™ COVID-19 Direct and genesig® COVID-19 are available to purchase as standalone items now. Contact our customer care team at enquiries@primerdesign.co.uk for same day dispatch on all orders submitted before 13:00 BST.**