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Information about our SARS-CoV2 (COVID-19) PCR testing

Introduction:

Over the past several years, the development and application of molecular diagnostic techniques have initiated a revolution in the diagnosis and monitoring of infectious diseases and cancer and genetics.

Techniques used in molecular diagnostic include core molecular biology methods such as nucleic acid isolation and quantification, PCR amplification, sequencing, and STR analysis.

PCR (Polymerase chain reaction) tests require multiple liquid pipetting, mixing and transferring steps. **If the PCR process is performed manually it provides non-standardized, less reliable test results, and in the worst case, it leads to false negative, false positive, or invalid test results.**

The RNA/DNA extraction step is a critical part of the PCR process. It is the bottle-neck, too. For this reason the use of an automated extraction process is highly recommended instead of relying on manual extraction processes / pipetting by a lab technician.

Advanced molecular diagnostic techniques have been developed and turned into a wide range of fully automated PCR systems, providing standardized results by minimizing the manual pipetting and transferring steps and, thus, human errors.

The PCR systems used in our facility:

Our PCR Laboratory is accredited and certified by the Ministry of Public Health of Afghanistan and by WHO representatives and hold a valid operation license.

We use two different PCR systems, both semi-automated, minimizing human error and allowing us **to provide standardized PCR test results according to international standards and quality requirements.** *Despite much higher investment and running costs, we are able to offer our semi-automated PCR tests at competitive prices as compared to facilities performing only manual PCR tests.*

Another great benefit of our systems is the use of freeze-dried reagent cartridges which are temperature stable and can be transported and stored at room temperature.

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Manual and many other conventional PCR reagent kits have to be transported on dry-ice and stored in dedicated PCR freezers, requiring an uninterrupted cool chain, a most challenging task in Afghanistan!

The test performance and 'features' of our both PCR systems:

Test feature:	Boditech SARS-CoV-2	Cepheid Xpert® Xpress SARS-CoV-2
Automated RNA/DNA extraction	YES	YES
Minimal "hands-on" / manual work by Lab. Technician required	YES	YES
Reagents are transported and stored at room temperature	YES	YES
PCR Test kits are CE or FDA approved and is in vitro diagnostic (IVD) certified.	CE YES	CE, FDA YES
PCR Kits detect at least two target gene of SARS-CoV2 virus	YES - E gene - RdRp gene	YES - N2 gene - E gene
Test systems are listed on FIND (Foundation for Innovative New Diagnostics (FIND)	YES	YES
Sample collection with sterile swabs and Viral transport medium.	YES	YES
Nasopharyngeal and oropharyngeal swab collection (2 swab used).	YES	YES
SOP followed for correct sample collection	YES	YES

The Boditech PCR and the Cepheid GeneExpert Xpress SARS-CoV2 tests have demonstrated a 100% accuracy in an independent study, facilitated through the World Health Organization (WHO) and the Foundation for Innovative Diagnostics (FIND) collective.

Detailed test performance data can be found via this link:

<https://www.finddx.org/covid-19/sarscov2-eval-molecular/molecular-eval-results/>

We are able to offer site visit services for clients unable to pass by our facility on Kolula Pushta road. We provide a dedicated email address and phone number to book an appointment.

Our swab sampling processes include taking two swabs (nasopharyngeal / oropharyngeal). This is for quality assurance purposes and to provide higher screening sensitivity which cannot be achieved by use of a single swab only.

We follow strict swab sampling standard operating procedures (SOPs) recommended by the CDC and the WHO. This is to assure the highest standard of safety for our valued customers and clients. In addition to very strict, regular sampling equipment and sampling room disinfection, we also perform UVC light disinfection of the sampling rooms.



We will furthermore provide a short but comprehensive information sheet for each client explaining the swab sampling process and our security and hygiene measures, as well as all required contact details and operation hours to provide a fast, reliable and comfortable screening process.

With best regards,



Christian Diering
General Manager



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