



HYRIS  
GLOBAL DIAGNOSTICS

SARS-CoV-2  
Human Diagnostic

CE IVD

Hyris System

# SARS-CoV-2 emergency

The COVID-19 pandemic is causing a lot of problems to our lives, and improved testing is recognised as a key element to contain and mitigate adverse impacts. The nasopharyngeal swab has been the only recognized method - from both a diagnostic and a legal perspective – to offer a conclusive diagnosis. The samples collected with the swabs need to be assessed in a lab with a specific molecular analysis of the viral RNA performed on a real time-PCR instrument. Hyris products enable genetic testing of biological samples in any setting, at any time, with real time access to results. As transmission occurs either by exposure to micro droplets loaded with the virus or by contact with contaminated surfaces, Hyris has developed a diagnostic system that can test either individuals or surfaces, offering an innovative and comprehensive product range for COVID-19 test management.

## Human Test

The platform can be used as a POINT-OF-CARE test to detect the virus presence in individuals. The Hyris system has been shown in clinical trials to offer accurate, validated results even when used outside of hospitals and centralised laboratories. The Hyris System offers a unique combination of clinical-grade results and unparalleled speed and ease of use. A great tool to monitor and contain the spread of the novel coronavirus. The test for the detection of COVID-19 in human specimen provides an answer to the question “am I COVID-19 positive?” in less than two hours and is extremely easy to perform.

### Testing scenarios

#### Major reference centers

Hospitals and reference labs.

#### Satellite testing laboratories

Smaller labs located around the country.

#### Strategical productive field

Industrial plants, buildings, products.

#### On site testing

Doctors and medical professionals’ offices, emergency room, military sites, ships and moving labs, cruise ships and many more.

## Testing process in 2 steps

### 1. Sampling

Hyris can provide materials and instructions for the safe collection, transport and preservation of the samples. The swabs are based on commercially available technologies developed specifically for human testing.

DIRECT  
AMPLIFICATION  
WITHOUT  
SAMPLE  
PREPARATION

### 2. Analysis

The next step is the genetic analysis of the virus, with RT-PCR methods, using:

- bKIT for the detection of SARS-CoV-2
- RNase free cartridges
- bCUBE
- bAPP

## RESULTS

The Hyris System for human specimens has an integrated automatic data elaboration AI module which allows an immediate and simple interpretation of results on the Hyris web app software. The data generated are available and remotely accessible anywhere, anytime on the cloud.

# Hyris System

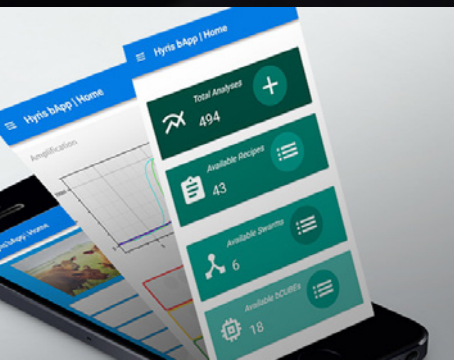
Hyris developed the Hyris System which, taking advantage of Hyris platform and its workflow, enables safe and accurate on-site testing of the SARS-CoV-2 presence in human specimens.



## bCUBE

*Miniaturized device for the analysis of nucleic acids.  
It allows users to run Real Time PCR analyses.*

- Portable
- Rapid DNA/RNA analysis
- Real-time PCR and isothermal protocols
- Performance comparable or better than other commercially available RT-PCR instruments
- No installation required



## bAPP

*Hyris web app software,  
working on all the major operating systems.*

- Start & monitor runs with few touches
- Intuitive
- No installation needed
- PC/Mac/Mobile
- Remote control of multiple bCUBEs
- Automatic results interpretation
- Cloud based support

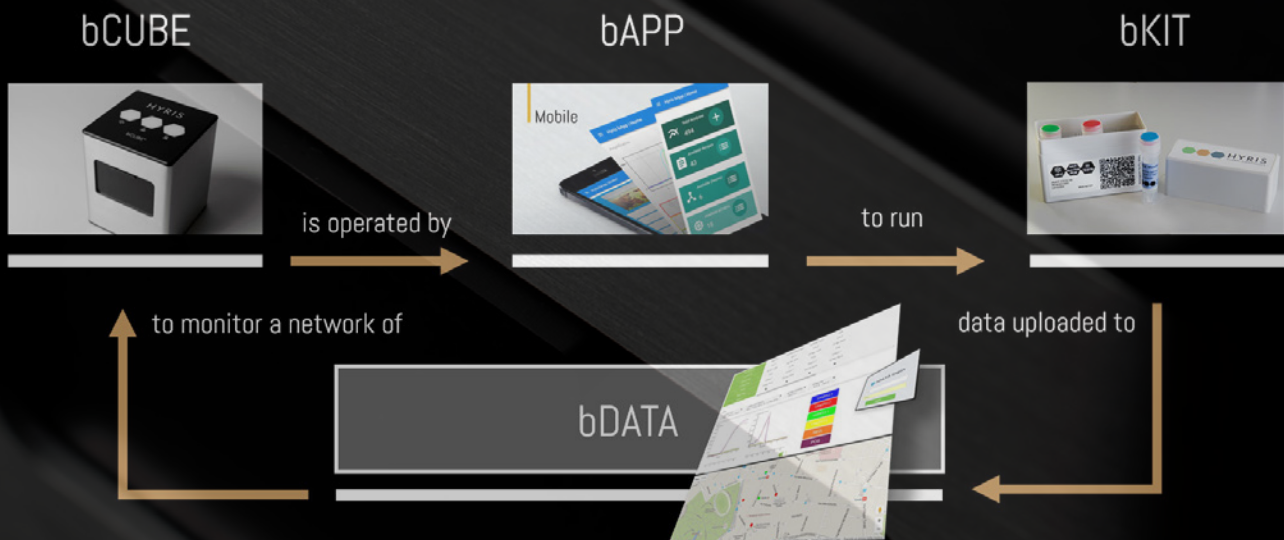


## bKIT

*Validated reagents  
for specific DNA/RNA recognition.*

- Ready to use
- Specific genetic recognition of Pathogens
- Automatic protocol setup with QR code
- Tested and validated

## Workflow



# bKIT

## Virus Finder COVID-19 bKIT - P/N bKTH-SCV2.02

Material reserved to the healthcare class

For SARS-CoV-2 Human testing: reagent set developed specifically to test human specimens, including all the required reagents to perform the test.

- Direct amplification with no need for sample extraction (showing comparable performance to other systems using extracted samples)
- Targets the viral Nucleocapsid gene (N gene)
- Up to 24 samples with 1 bKIT (soon up to 64 samples with a 36 wells cartridge and a new bKIT format)
- Up to 6 patient samples simultaneously (soon up to 16 patient samples with a 36 wells cartridge)
- Fast sample-to-answer process with positive sample results in less than an hour and negative in <2h
- Real Time PCR reaction, the gold standard for COVID19 diagnostic
- QR code to load the analysis protocol

Hyris Ltd manufactures a molecular test for the detection of SARS-CoV-2 in human specimens. The assay follows the specifications, including primer sequences, described and validated by the CDC and listed by WHO (links below).

## bKIT Reliability

- Validated on bCUBE by several clinical studies with a high sensitivity (>95%, CI 95%) and no false negatives reported [Miscio et al. J Transl Med (2020)]
- Positive and negative controls to validate the results
- Internal Control to avoid false negative results
- Clinical trials concluded with success (at Hospital Pascale/Federico II/Cotugno, IZSLER: Reference center for COVID-19 testing, Hospital Santa Maria delle Scotte in Siena, Center of Civil Health from Ministry of Health of Ukraine). More studies ongoing to be published.
- The test has been approved as a point-of-care test in Canada for human diagnostics as an Interim Order
- European CE-IVD marked.
- In the US, FDA EUA is under evaluation.
- Detects SARS-CoV2 despite new variants of concern identified by WHO, ECDC, CDC ([https://www.hyris.net/images/download/01\\_Hyris\\_monitoring\\_updater02\\_2IN1.pdf](https://www.hyris.net/images/download/01_Hyris_monitoring_updater02_2IN1.pdf))
  - UK variant VOC 202012/01
  - South Africa variant 501Y.V2
  - Brazil variant 484 K.V2
  - Indian variant B.1.617
  - Californian variants B.1.429 and B.1.427

<https://www.cdc.gov/coronavirus/2019-ncov/lab/rt-pcr-panel-primer-probes.html>

<https://www.cdc.gov/coronavirus/2019-ncov/downloads/rt-pcr-panel-primer-probes.pdf>

[https://www.who.int/docs/default-source/coronaviruse/whoinhouseassays.pdf?sfvrsn=de3a76aa\\_2](https://www.who.int/docs/default-source/coronaviruse/whoinhouseassays.pdf?sfvrsn=de3a76aa_2)

<https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/laboratory-guidance>

## DISCLAIMERS

### GENERAL DISCLAIMER

The BKIT VIRUS FINDER COVID-19 is intended for professional and in vitro diagnostic use only. Nasal swab testing, even if collected by a healthcare professional, is limited to patients suspected of being positive to COVID-19. Positive results are indicative of the presence of SARS-CoV-2 RNA. To determine the status of an infected patient, clinical correlation with the patient's diagnostic data and medical history is required. Positive results do not rule out presence of bacterial infections or other viruses concomitant infections. This test cannot rule out diseases caused by other bacterial or viral pathogens. Customer shall be solely responsible for the proper use of BKIT VIRUS FINDER COVID-19 in strict accordance with the product's instructions for use. BKIT VIRUS FINDER COVID-19 is provided "AS IS" without warranty, representation or guarantee of any kind. Except for HYRIS Ltd's intentional misconduct, fraud, fraudulent misrepresentation, or any other liability that cannot be excluded by law, HYRIS Ltd. shall not be liable for any loss, claim, damage, or liability of any kind or nature that may arise from Customer's improper use of BKIT VIRUS FINDER COVID-19, or use of BKIT VIRUS FINDER COVID-19 by any third party who obtains BKIT VIRUS FINDER COVID-19 directly or indirectly from Customer in a manner that is not consistent with the instructions given in the BKIT VIRUS FINDER COVID-19 instructions for use.

### SPECIMEN COLLECTION DISCLAIMER

Customer shall be solely responsible for the safe collection and handling of specimens to be used in connection with the BKIT VIRUS FINDER COVID-19 and it is Customer's sole responsibility to ensure that all sample collection and handling is done by qualified healthcare professionals. Customer shall be solely responsible to ensure that during and following sample collection, all proper infection control practices, including the use of necessary and appropriate personal protective equipment, are followed. Customer assumes all risks of infection related to and/or in connection with the possible transmission of COVID 19 when collecting samples for analysis by the BKIT VIRUS FINDER COVID-19, during their analysis and their disposal.



Hyris is an innovation based company founded in 2014 by an entrepreneurial team with deep experience in biotechnology, electronics and the tech business. The company offers its partners and clients disruptive technologies that enable genetic testing of biological sample in any setting, at any time, all available in real time on dedicated software platforms.

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