HYRIS bKIT™
Virus Finder COVID-19

Datasheet

Version 2.0
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REF:
bKTH-SCV2.02-32
bKTH-SCV2.02-72

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Visit our website at
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Included items

Item	REF	Description
HYRIS bKIT™ Virus Finder COVID-19	bKTH-SCV2.02-32	2 x Master mix 1 (up to 12 sample each) 2 x Master mix 2 (up to 12 sample each) 2 x Quality control Positive and Negative
HYRIS bKIT™ Virus Finder COVID-19	bKTH-SCV2.02-72	2 x Master mix 1 (up to 32 sample each) 2 x Master mix 2 (up to 32 sample each) 2 x Quality control Positive and Negative

All reagents are ready to use (no reconstitution needed)

Other material provided separately by Hyris in order to operate with HYRIS bKIT™ Virus Finder COVID-19

Item	REF	Description
HYRIS bCUBE™	bCUBE 2.0	Miniaturized thermal cycler PCR system
HYRIS Cartridges for HYRIS bCUBE™	HyCT16.01 and HyCT36.01	16 wells cartridges 36 wells cartridges
Optional – Starter Kit	Sk.1x-Acc.01 - Customizable	3 micropipettes 1 mini-vortex of 3000 rpm 1 minicentrifuge 6 slots

All the system components above detailed allow the professional user to carry out the test.

Detailed system information

Intended Use	The ***HYRIS bKIT™ Virus Finder COVID-19*** is a real-time RT-PCR assay intended to be used as near-patient testing on the **HYRIS bCUBE™** instrument for the in-vitro diagnostic qualitative detection of SARS-CoV-2 nucleic acid in human upper respiratory tract specimens such as, nasopharyngeal swabs (NPS), nasal swabs (NS), a combination of oropharyngeal swabs (OPS) and NPS, oropharyngeal and NS specimens collected by a healthcare professional from individuals suspected of COVID-19 disease. The assay is intended for the detection of SARS-CoV-2 RNA, which is generally present in detectable quantity in upper respiratory specimens during the acute phase of the disease. This assay is an aid in the diagnosis of COVID-19 disease. The results of this test should not be used as the sole basis for diagnosis, treatment, or other patient management decisions. Clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status.
Target Population/patient	Individuals suspected of COVID-19 disease: patients with acute or subacute respiratory symptoms or fever or other suspicious symptoms (diarrhea, anosmia) and either a known contact with a confirmed or probable COVID-19 patient or living in an area of cluster or community transmission, and close contacts (with or without symptoms) of index patients (confirmed COVID-19 patients).
Target use setting	The test can be used in a laboratory and outside of laboratory including: ▪ at routine ▪ in a triage/screening points of health care facilities like for instance emergency units, ▪ in a mobile unit ▪ in the community (contact tracing) by healthcare workers or laboratory technicians with appropriate training in sample collection, biosafety and in the use of the test.
Target molecule (analyte to be detected)	**SARS-CoV-2 RNA** specific for acute and subacute infection (e.g., first week after onset of symptoms/current infection): The **HYRIS bKIT™ Virus Finder COVID-19** is a **multi-target** assay using the sequences identified by CDC (**genes N1 and N2**).
Analytical sensitivity/Limit of detection	The Sensitivity in direct amplification is 100% at **10^4 genomic copies/mL**.
Analytical specificity	The assay detects all SARS-CoV-2 viral strains including the most emergent variants (alpha, beta, gamma and delta) and does not cross react with common tested interfering substances or other human coronaviruses or any other common human diseases of the upper respiratory way which presents similar symptoms of COVID-19, like for instance influenza A and B, RSV). **The kit is specific in the >99% of cases assessed.**
Type of analysis	Qualitative real time RT-PCR by direct amplification of whole samples
Interpretation	Digital readout of raw and printed results via web application
Sample type	▪ Nasopharyngeal (NPS) ▪ Oropharyngeal swab (or combination with NPS) ▪ Nasal swab (or combination with oropharyngeal)
Sample collection device	The device is compatible with existing swabs (e.g., flocked swabs). The validate transport medium are the Copan Universal Transport Medium (UTM) or equivalent; in alternative it was also validated the Copan MSwab® (Copan) or equivalent;
End user profile	For professional use only
Testing procedure	
Number of timed steps (use of different reagents/incubation steps)	▪ Step 1: mix loading into the cartridge well ▪ Step 2: sample loading into the cartridge well Step 3: load cartridge into the **HYRIS bCUBE™**
Sample minimum volume per reaction	5µL ± 10% of whole sample (crude sample)
Additional characteristics	

Quality Control	• Internal endogenous control for sampling quality (RNase P gene detection in multiplex reaction with the viral target) Reaction quality control Positive and Negative (NTC) provided with the reagents.
Specimen capacity & throughput	▪ Up to 6 samples with the **HYRIS 16 well cartridge** + Controls • Up to 16 samples with the **HYRIS 36 well cartridge** + Controls
Operating conditions	15-35°C; 25-80% relative humidity up to 1500m.
Remote connectivity capacity	The instrument (**HYRIS bCUBE™**) is connected to the **HYRIS bDATA™** (proprietary cloud) and is remotely managed through the **HYRIS bAPP™**, a web application specifically designed to work with the **HYRIS bCUBE™**
Result validity stability	Results are stored on cloud without any time limit
Need for additional equipment	The **HYRIS bCUBE™** management requires an internet browser which can be used from any available platform: smartphone, laptop, PC, Mac, iPhone, tablet. It is not necessary a dedicated device.
Need for maintenance/spare parts	None, the device maintenance is provided by remote. In case of instrumental defection: replacement with ancillary device when needed.
Waste/disposal requirements	Routine biohazard waste
Manufacturing	Quality Management Systems Procedures
References	• Doi: 10.1101/2020.03.20.001008 - *"RT-qPCR detection of SARS-CoV-2 RNA from patient nasopharyngeal swab using qiagen rneasy kits or directly via omission of an RNA extraction step".* • Doi: 10.1186/s12967-020-02651-y- *"Evaluation of the diagnostic accuracy of a new point-of-care rapid test for sars-cov-2 Virus detection".* • Doi: 10.1101/2020.03.28.013508 – *"SARS-CoV-2 detection from nasopharyngeal swab samples without RNA extraction"*

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Further information

- For safety information refer to the WHO-WPE-GIH-2020.3-eng "laboratory biosafety guidance related to coronavirus disease (COVID-19)"
- The **HYRIS bKIT™ Virus Finder COVID-19** is **CE- IVD** compliant with the 98/79/EC Directive and D. Lgs. 332/2000.
- The whole system has been designed and produced in Italy