



# HYRIS bKIT™ SARS-CoV-2 Environmental

Datasheet

Version 2.0  
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REF:  
bKTE-SCV2.01-32  
bKTE-SCV2.01-72

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### Included items

| Item  | REF             | Description   |
|---|-----------------|---|
| <b>HYRIS bKIT™ SARS-CoV-2 Environmental</b> | bKTE-SCV1.01-32 | 2 x Master Mix 1 (up to 12 sample x each tube)<br>2 x Master Mix 2 (up to 12 sample x each tube)<br>2 x Internal Control<br>2 x Quality Control Positive and Negative |
| <b>HYRIS bKIT™ SARS-CoV-2 Environmental</b> | bKTE-SCV1.01-72 | 2 x Master Mix 1 (up to 32 sample x each tube)<br>2 x Master Mix 2 (up to 32 sample x each tube)<br>2 x Internal Control<br>2 x Quality Control Positive and Negative |

### Other material provided separately by Hyris to operate with HYRIS bKIT SARS-CoV-2 Environmental

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

| Validated Sample collection devices               | REF                          | Description   |
|---|------------------------------|---|
| <b>NRS II Transwab® (MWE)</b>                     | MW786 (1 mL fill and Swab) * | Sample collection device composed by environmental swabs and transport medium containing neutralizing solution to test the surfaces |
| <b>ESC Swabs BPW + Neutralizing (Liofilchem®)</b> | 85623 (1 mL)*                | Sample collection device composed by environmental swabs and transport medium containing neutralizing solution to test the surfaces |

\* The validated sample collection devices are equivalent and depending on the warehouse availability shipment will be carried out accordingly. Only environmental validated swabs will be provided by Hyris. For any additional information on this argument to know the list of validated transport media please contact Hyris at [info@hyris.net](mailto:info@hyris.net)

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

## Detailed system information

|   |   |
|---|---|
|   |   |
| <b>Intended Use</b>   | <b>The HYRIS bKIT™ SARS-CoV-2 Environmental</b> is an <i>in situ</i> qualitative reverse transcription real time polymerase chain reaction (RT-PCR) performed on the HYRIS bCUBE™ instrument for the detection of SARS-CoV-2 nucleic acid. The kit is intended for the direct amplification of specimen obtained by environmental swabs (surfaces and fomites) before and after the sanitization procedures. This test is used for research purpose only and to monitor the presence of SARS-CoV-2 on surfaces. <b>This kit is NOT for human diagnostics.</b> |
| <b>Target use setting</b>   | This test can be used in a laboratory and outside of laboratory to: <ul style="list-style-type: none"> <li>● screen industrial and working environments</li> <li>● protect the health of the employees</li> <li>● reduce the risk of an interruption of key services</li> <li>● determine whether your' s Company's disinfection procedures are working</li> </ul> by trained users with appropriate training in sample collection, biosafety and in the use of the test.   |
| <b>Target molecule (analyte to be detected)</b>                           | <b>SARS-CoV-2 RNA</b> specific for acute and subacute infection. The <b>HYRIS bKIT™ SARS-CoV-2 Environmental</b> is a <b>multi-target</b> assay using the sequences identified by CDC ( <b>N gene sequences 1 and 2</b> )   |
| <b>Analytical sensitivity/Limit of Detection</b>                          | The Sensitivity in direct amplification is 100% at <b>10<sup>4</sup> genomic copies/mL</b>  |
| <b>Analytical specificity</b>   | The assay detects all SARS-CoV-2 viral strain 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 disease of the upper respiratory way which presents similar symptoms of COVID-19, like for instance influenza A and B, RSV.<br><b>The kit is specific in the &gt;99% of cases assessed</b>  |
| <b>Type of analysis</b>   | Qualitative real time RT-PCR by direct amplification of whole samples   |
| <b>Interpretation</b>   | Digital readout of raw and printed results via web application  |
| <b>Sample type</b>  | Environmental samples collected from herd top non-porous surfaces   |
| <b>Sample collection device</b>   | The device is compatible with existing swabs. The validate transport medium are MWE NRS II Transwab® or equivalent and Liofilchem® ESC Swabs BPW + Neutralizing or equivalent   |
| <b>End user profile</b>   | For trained users   |
| <b>Testing procedure</b>  |   |
| <b>Number of timed steps (use of different reagents/incubation steps)</b> | <ul style="list-style-type: none"> <li>● Step 1: Reconstitute both reaction mixes 1 and 2 with the Internal Control</li> <li>● Step 2: Mix loading into the cartridge well</li> <li>● Step 3: Sample loading into the cartridge well</li> <li>● Step 4: Load cartridge into the <b>HYRIS bCUBE™</b></li> </ul>  |
| <b>Sample minimum volume per reaction</b>                                 | 2 µL ± 10% of whole sample (crude sample)   |
| <b>Additional characteristics</b>   |   |

|   |  |
|---|--|
| <b>Quality Control</b>                    | <ul style="list-style-type: none"> <li>● Internal synthetic heterologous control (IC-RNA) for excluding false-negative results due to PCR inhibitors</li> <li>● Reaction quality Positive and Negative Control (NTC) provided with the reagents</li> </ul> |
| <b>Specimen capacity &amp; throughput</b> | <ul style="list-style-type: none"> <li>● Up to 6 samples with the <b>HYRIS 16 well cartridge</b> + Controls</li> <li>● Up to 16 samples with the <b>HYRIS 36 well cartridge</b> + Controls</li> </ul>  |
| <b>Operating conditions</b>               | 15-35°C; 25-80% relative humidity up to 1500m  |
| <b>Remote connectivity capacity</b>       | The instrument ( <b>HYRIS bCUBE™</b> ) is connected to the <b>HYRIS bDATA™</b> (proprietary cloud) and is remotely managed through the <b>HYRIS bAPP™</b> , a web application specifically designed to work with the <b>HYRIS bCUBE™</b>                   |
| <b>Result validity stability</b>          | Results are stored on cloud without any time limit   |
| <b>Need for additional equipment</b>      | 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  |
| <b>Need for maintenance/spare parts</b>   | None, the device maintenance is provided by remote. In case of instrumental deflection: replacement with ancillary device when needed  |
| <b>Waste/disposal requirements</b>        | Routine biohazard waste  |
| <b>Manufacturing</b>                      | Quality Management System Procedures   |
| <b>References</b>                         | <ul style="list-style-type: none"> <li>● DOI: 10.1056/NEJMc2004973 – “<i>Aerosol and Surface Stability of SARS-CoV-2 as Compared with SARS-CoV-1</i>”</li> </ul>   |

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### Further information

- The HYRIS bKIT™ SARS-CoV-2 Environmental is a kit RUO not for human testing
- The whole system has been designed and produced in Italy