

icgene  
HEALTH

LAB BEYOND

SARS-COV-2 E-NAT



# SARS-COV-2 E-NAT

Cat. No. EBT 103\_48 SARS-COV-2 E-NAT (Environmental Nucleic Acid Testing) 48 test

**KIT COMPONENTS AND REAGENTS** – The diagnostic kit consists of the following ready-to-use reagents

Extraction buffer	Yellow cap bottle with extraction buffer
Primer mix	Liophilised primer targeted for SARS-Cov-2
LAMP mix test tube	Test tube with green cap containing the enzyme and a storage buffer
Mineral oil	Test tube with blue cap containing mineral oil
Positive test	Test tube with red cap containing plasmid DNA
Negative test	Test tube with white cap containing extraction buffer
SARS-Cov-2 Badge	Contactless badge providing digital traceability of kit batch numbers and expiration date data, as well as extraction and amplification parameters

## THE KIT – FEATURES

- Nucleic acid extraction system in minutes
  - Ready-to-use components to reduce risks from environmental contamination or human error
  - Simplicity and speed of testing (about 30 minutes)
  - Analysis of samples from environmental swabs
  - Genetic testing directly in the field
  - Transportability of the kit at room temperature
  - Conservation of reagents at 4 degrees C
- Specific kit for rapid detection of SARS-Cov-2 RNA from environmental pads.
- The kit includes reagents and materials for the rapid extraction of nucleic acids and amplification with LAMP technology using the ICGENE<sup>1</sup> system.
- The kit has been tested for RNA detection.

## ANALYTICAL PROCEDURE – The ICGENE 3 step system

1. { Extraction of Nucleic acid
2. { Genetic amplification
3. { Interpretation of results

After a few minutes of RNA extraction, samples can be analyzed using LAMP amplification. For each sample, the recommended volume of extracted RNA is added to the Primer mix, the LAMP mix and the mineral oil.

Through contactless radio-frequency identification (RFID) technology, the system recognizes the specific kit in use and automatically sets the analytical parameters for test detection.

## INTERPRETATION OF RESULTS

The ICGENE system interprets results automatically. The data is displayed on an Android tablet connected via Bluetooth to the ICGENE device, whereby the relevant analytical steps can be controlled, and results viewed in real time. A sigmoid curve indicates a positive sample, while a straight line indicates a negative sample. In the left section of the display, near the name of the sample, the symbol "+" will appear for positive samples. The results can be automatically uploaded and stored onto the ICGENE WEB portal.

## PERFORMANCE CRITERIA

**Stability:** The kit is stable at room temperature during transport. On arrival, the kit must be stored at 4 degrees Celsius. At this temperature, the kit is stable for 1 year.

Companies with ISO 9001:2015 quality system

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<sup>1</sup> The system is also available in a portable version with a bespoke suitcase that contains all the accessories to perform tests in the field. Automatic real-time transmission of results from the field to the lab can be made through the ICGENE WEB platform.