

Bordetella R-gene™

The most versatile Real-Time PCR assay to efficiently detect ***Bordetella*** DNA in Nasopharyngeal Secretions

INTRODUCTION

- Argene offers a new solution to diagnose *Bordetella pertussis* and *Bordetella parapertussis*.
- The ***Bordetella R-gene™*** kit is a complete Real-Time PCR IVD assay which detects *B. pertussis* specifically as well as other *Bordetella* strains (*B. holmesii*, *B. bronchiseptica*) that contain the **IS481 region**.
- The ***Bordetella parapertussis r-gene™*** assay is a ready-to-use primers/probe set which detects *B. parapertussis* specifically as well as other *Bordetella* strains that contain the **IS1001 region**.

FEATURES

- ***Bordetella R-gene™*** assay is released as a **CE IVD** marked product under the European Directive on In Vitro Diagnostic Medical Devices:
 - **CE** marked with the **major extraction** and **Real-Time PCR systems**.
 - optimized and **clinically validated on Nasopharyngeal Secretions** and **Sputum** samples.
- Delivers highly accurate and consistent test results from extracted samples within **1hr 30min**.
- Rapid DNA typing test for *Bordetella* diagnosis:
 - **better specificity** than serologic methods;
 - **higher sensitivity** than traditional bacterial cultures.
- The **controls** provided with the kit are designed to **monitor the entire process**:
 - the Internal Control provided checks the process from **extraction to amplification**.
 - it controls the efficiency of the extraction step (especially the lysis), the yield of DNA recovery and detects the presence of PCR inhibitors for each sample.
 - the Internal Control (IC₂) provided is added into the sample before the extraction and detected in the same tube as the targeted bacterial gene.
 - a Positive control and Negative control are also included in the ***Bordetella R-gene™*** kit to validate the results.
- Provides the benefit to differentiate between *B. pertussis* and *B. parapertussis*.
- No cross-reactivity was observed with other respiratory bacterial agents.
- ***Bordetella R-gene™*** uses 5' nuclease technology (TaqMan probes) as the basis for the Real-Time PCR. This kit is fully licensed.
- ***Bordetella R-gene™***:
 - provides a valuable alternative to the classical serology and cell culture methods for the clinical management of patients with *Bordetella* infections.
 - allows the differentiation between the serological response after vaccination as well as the response caused by a pathogen.

Bordetella R-gene™



KIT PRESENTATION

Format: 60 tests

Bordetella R-gene™ Complete Real-Time PCR Kit Ref.: 69-011

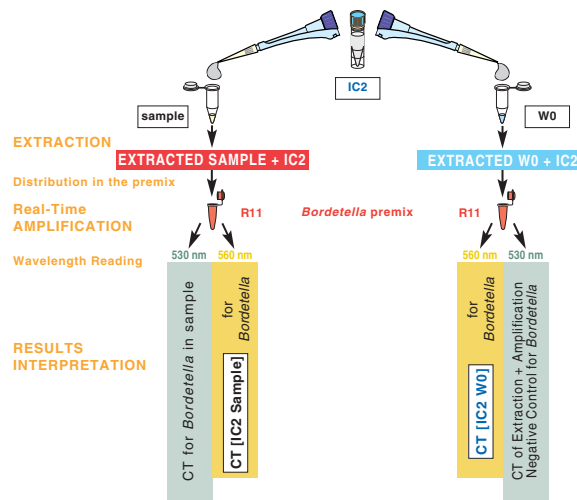
- Includes:**
- DNA Extraction Kit (Ref.: 67-000) - Number of extractions: 50
 - **Bordetella R-gene™ Real-Time PCR Kit** (Ref. : 69-011B) - Number of tests: 60

Bordetella R-gene™ Real-Time PCR Kit Ref.: 69-011B

Content of the Real-Time PCR kit: Number of tests: 60 reactions

- | | | |
|---------------|--|----------------------|
| • W0 | Water for extraction (molecular grade) | 18 extraction series |
| • IC2 | Internal Control 2 | 60 extractions |
| • RO | Water for amplification (molecular grade) | 30 reactions |
| • PC11 | <i>Bordetella</i> Positive Control | 30 reactions |
| • R11 | <i>Bordetella</i> and IC2 Amplification premix | 60 reactions |

PRINCIPLE for *Bordetella* DETECTION



Sample interpretation

$CT [IC \text{ Sample}] \leq CT [IC \text{ W0}] + 2$
and
final fluorescence $[IC \text{ Sample}] \geq 70\%$ final fluorescence $[IC \text{ W0}]$
The sample is correctly extracted and doesn't contain inhibitory agents of amplification.

GLOSSARY:

IC2 = Internal Control 2 CT = Crossing Threshold
R11 = *Bordetella* premix W0 = Water for extraction

ORDERING INFORMATION

Cat. No. Product Name:

Unit:

Format:

REAL-TIME PCR:

69-011	<i>Bordetella R-gene™</i> - Complete Real-Time PCR Kit	60 tests	2 kits: Extraction and RT PCR Detection
69-011B	<i>Bordetella R-gene™</i> - Real-Time PCR Kit	60 tests	1 kit: RT PCR Detection kit
71-012	<i>Bordetella parapertussis r-gene™</i> primers/probe	60 reactions	1 set: RT PCR ready-to-use Premix & IC2

Other Argene DNA bacterial detection assays:

END-POINT PCR:

Amplification and detection of *Chlamydophila*, *Mycoplasma* and *Legionella pneumoniae*.

67-025	CHLAMYLEGE - Complete Kit	50 samples	3 kits: Extraction / Amplification / Detection
67-025BC	CHLAMYLEGE - Amplification / Detection Kit	50 samples	2 kits: Amplification / Detection

FRANCE

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