Arcis Pathogen Kit

(Bulk Kit)

UFL004 Arcis Pathogen Kit 48 rxn

CE IVD

Instructions for use

1. General Information

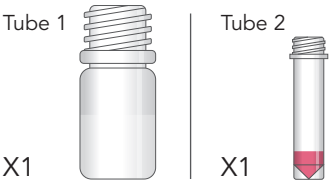
The Arcis Pathogen Kit is a ready to use kit comprising two reagents enabling pre-analytical processing of biological samples. The product is intended to be used by trained users proficient in molecular biological techniques.

In 3 minutes the Arcis Pathogen Kit allows you to go from bacterial samples to downstream nucleic acid investigations without the need for isolation or purification.

The Arcis Pathogen Kit is intended for in vitro diagnostic use.

2. Materials Provided

Material Provided	Quantity	Number of Preps
Tube 1: Lysis Buffer	1 Tube	48
Tube 2: Wash buffer	1 Tube	



3. Storage Conditions

Recommended storage conditions: 4°C to 40°C. If the reagents are required to be used for an extended period of time after initial opening they can be pre-aliquoted and then stored for later use.

4. Intended Use and Samples

The Arcis Pathogen Kit is a sample prep system that has been validated as an in vitro diagnostic product for the release of bacterial DNA from bacteria grown on common microbiological growth substrates. The material released is suitable for use in molecular diagnostic investigations such as PCR. The product should only be used by professional operators trained in the appropriate in vitro diagnostic procedures.

The product has been tested on the following sample types: bacterial cells on agar, liquid broth and standard laboratory buffers such as PBS. Gram positive and Gram negative bacteria have been used in validation studies including E. coli, S. aureus and K. pneumoniae.

The product can also be used on a research only basis for the release of other types of pathogen nucleic acids (e.g. RNA from viruses) and other sample types (e.g. blood).

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Instructions for Use continued

5. Typical Protocol

Ensure samples have thawed completely before starting this procedure.

5.1. Add 90µl of liquid sample (bacteria in buffer or broth) to 150µl of Reagent 1 (or scale up for larger sample volume). At this point nucleic acids are stable for 90 days at room temperature, provided there is no further processing.

5.2. Incubate for one minute at room temperature.

5.3. Take 5µl of the above mixture and combine with 20µl of Reagent 2 (or scale up for larger sample volume). Once processed with Reagent 2 samples should be used immediately or frozen at -20˚C.

5.4. Add appropriate volume into PCR master mix (e.g. 5µl per 25µl reaction) or continue directly to other downstream technique.

Samples that have been processed in step 5.1 can be added to Reagent 2 at 1:3, 1:2 or 1:1 ratio to reduce sample dilution (See Table 1).

Table 1: Washing samples in Reagent 2

Extract from Tube 1 (µl)	Reagent 2 Volume (µl)	Ratio
5	15	1:3
10	20	1:2
20	20	1:1

6. Manufacturer Contact Details

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