



rev of 31/12/07

CHAIN REX BACTERIA KIT. Qualitative 100 Rx

Salmonella, Listeria Monocytogenes, Listeria Genere, E.Coli O:157, Campylobacter Jejuni, Pseudomonas A., Clostridium Perfringiens, Yersinia Enterocolitica, Bacillus Cereus, Staphilococcus Aureus and Enterobacter Sakazaky.

1. Characteristics and storage conditions

<u>Product Line:</u>	CHAIN REX
<u>Type:</u>	Qualitative 100 determinations
<u>Store at:</u>	2-8°C (35-46°F).
<u>Execution time:</u>	about 120 minutes.
<u>Expiry date:</u>	See date on the packaging
<u>Product validity:</u>	It refers to the product kept intact in its original packaging and constantly under suitable temperature conditions as mentioned above

2. Equipment and reagents not provided in the kit

- Set of laboratory micropipettes with interchangeable tips
 - RT Thermal cycler ABI PRISM™ 7900-7500-7300 Sequence Detection System (Applied Biosystems) or other instrument models.
 - Universal Mastermix Applied Biosystem part Number 4304437
 - Reaction plate or reaction tubes
 - Specific Enrichment Broth
 - Lysis Buffer
- Suggested extraction kits: Generon, Promega, Quiagen, Applied Biosystem.

3. Product validation

The Kit system was tested in-house by the producer in order to check its characteristics in food sample. The in-house validation data are available on demand.

4. Warning and Precautions

Do not interchange components between kits of different lot numbers. This kit is designed to be used by laboratory personnel following the usual molecular biology precautions.

5. Use

In-house research only.

6. Content:

REAGENT	QUANTITY (µl)
Standard	100
Primer Rev	100
Primer Fw	100
Probe	100
Steril water	1800

7. Enrichment Procedures (not supplied with the kit)

Please, refer to required target

8. Lysis procedure

Please, refer to required target

The cell Lysate in the plate contains a Bacterial DNA ready for subsequent amplification reactions.

9. Preparation of reagents

Prepare the reaction Mixture (RM) as follows:

Formula of RM	for 100 reactions
Universal Mmix	2,5 ml
Primer Rev	100µl
Primer Fw	100µl
Probe	100 µl
SW (sterile water)	1,2ml
Total volume	4 mL

The RM remains stable for 6 months at 4° C parting from the moment the component are mixed

Make MR homogeneous then transfer 40 µl in each well of the reaction plate.

To prepare the checks proceed as follows:

NTC = Check to verify the absence of contaminations in the reagents

STD = check to verify the presence of target.

UNK = samples to be analyzed.

NTC = Add 5µl of steril water to RM

STD = Add 5µl of STD to RM

UNK = Add 5µl of DNA of sample to RM

Seal the plate then put it into the thermal cycler and set up the following program:

Step 1 2' at 50°C

Step 2 10' at 95°C

Step 3 {15'' at 95°C and 1' at 60°C} x 45 cycles

10. Results

The analysis was carried out correctly if the following conditions are all met at the same time:

1. NTC does not show a significant amplification curve coinciding with the related standard.
2. STD shows an amplification curve

THE SAMPLE IS POSITIVE WHEN: A significant amplification curve appears

THE SAMPLE IS NEGATIVE WHEN : a significant amplification curve does NOT appear

The detection limit for each matrix can be evaluated by the user after carrying out in-house tests.

11. Warranty and Responsibilities

Generon s.r.l. guarantees the buyer exclusively concerning the quality of reagents and of the components used to produce the Kit. Generon S.r.l. is not responsible and cannot anyway be considered responsible or jointly responsible for possible damages resulting from the utilization of the product by the user. The user consciously and under his own responsibilities decides for the utilization purposes of the product and uses it the way he considers most suitable in order to reach his goals and/or objectives.

Generon S.r.l. is not responsible for the data resulting from the use of the products, for the utilization that the user independently decides to make of them or for the damages possibly resulting from the disclosure or transmission of the data themselves to third parties under any form or circumstance. This clause is automatically accepted by the user when purchasing the products. The patent for performing PCR is held by Hoffmann/La Roche. Authorization to use PCR can be obtained on licence from Hoffmann-LaRoche™. The product, equipment and information included in the kit consists of assembled and reagents. The licence and licence and authorisation for PCR use are not included in the kit. The user is responsible for setting prefixed goals, choosing whether or not to perform the PCR reaction and to apply for register his own licence. The use kit is designed for the services supply, quality control or any other application that is not exclusively an internal company's research and requires a specific licence for PCR use. This PCR use licence to supply a service on food analysis field has to be requested directly from Applied Biosystems®. This kit requires the use of Taq Polymerise enzyme.

The product has been internally tested by our quality control. Any responsibility is waived if the warranty of quality control does not refer to the specific product. The user is personally responsible for data that he will obtained and/or he will supply to third parties using this kit. Once the sealed package is open the user accepts all the conditions without fail; if the package is still sealed the product can be returned and the user can be refunded.

