Tube Test - Listeria Plus Kit

IVD CE

Tube agglutination test for titration of antibodies to Listeria

Instructions for use (IFU)

ORDERING INFORMATIONS

Code	Suspension	Composition
REF CSI087249	Listeria Plus Kit	n° 4 vials x 20 ml

INTENDED USE

In Vitro Diagnostic Medical Device for performing the agglutination test in a test tube for the titration of antibodies to Listeria. Test results should always be interpreted in relation to the clinical context. For professional use only.

CLINICAL SIGNIFICANCE

Listeria Monocytogenes is an anaerobic gram-positive bacterium that causes Listeriosis, an infectious disease transmitted mainly through the consumption of contaminated food. The reported incidence of human listeriosis increased in several countries during the 1980s, but remains generally low compared to other foodborne infections such as salmonellosis. Incubation periods for the disease ranged from 1 day to 90 days with a typical incubation period of a few weeks. Symptoms of the disease, which are more likely to develop in pregnant women, the very young or elderly, and immunocompromised women, can range from mild influenza-like illness to septicemia, meningitis, and meningoencephalitis.

PRINCIPLE OF THE METHOD

The test is based on the ability of specific antibodies, produced by the body's contact with a causative agent, to agglutinate the corresponding antigen "in vitro". The serological diagnosis of infectious diseases characterized by persistent fever is based on the agglutination reaction that occurs between the antigen and any specific antibodies present in the patient's serum.

COMPONENTS

Inactivated bacterial suspensions of Listeria *monocytogenes*

Listeria 1 O antigen suspension

1 vl 20 mL of Inactivated bacterial suspension in Sodium azide 0,9 g/l

Listeria 1 H antigen suspension

1 vl 20 mL of Inactivated bacterial suspension in Sodium azide 0,9 g/l

Listeria 4b O antigen suspension

1 vl 20 mL of Inactivated bacterial suspension in Sodium azide 0,9 g/l

Listeria 4b H antigen suspension

1 vl 20 mL of Inactivated bacterial suspension in Sodium azide 0,9 g/l

Positive Control

1x2 mL, positive serum, animal origin, ready to use, in Sodium azide 0,9 g/l

Negative Control

1x2 mL, negative serum, animal origin, ready to use, in Sodium azide 0,9 g/l

Caution: Products Containing Sodium azide can react with lead and copper to form explosive deposits of metal azides. For the elimination, dilute with large amounts of water.

Other materials required but not supplied:

- PBS
- Automatic Pipettes (variable volumes)
- Serologic tubes

REAGENT PREPARATION

Reactives and sera, brought to room temperature, are ready to use. Mix gently suspension to obtain a homogeneous solution. After opening the reagents are stable if maintained as indicated in "Preservation and Stability".

Preservation and Stability

= Storage Temperature 2-8 °C

Mainatine at 2-8°C, avoiding direct light, reactives are stable until the expiry date printed on the label. Do not freeze. Avoid microbial contamination

Stability tests repeated on three different batches confirmed a validity for almost 36 months if stored 2-8°C. Slight variations in composition from batch to batch do not affect test result.

PRECAUTIONS and WARNINGS

1. Reagents and waste materials shall be disposed of in accordance with Community waste provisions or national or regional provisions.
2. Reagents may contain non-active components such as preservatives and detergents. The total concentration of these components is below the limits set out in Regulation 1272/2008 EC and subsequent amendments and additions.
3. It is recommended that the reagent be handled in accordance with the rules of good laboratory practice and that appropriate personal protective equipment be used.
4. Do not use the reagent if it is visibly degraded (e.g. presence of corpuscles).
5. All human samples shall be handled and disposed of as potentially infectious material.
6. The kit should only be used by qualified and properly trained technical personnel.
7. Diagnoses shall be carried out exclusively by authorised and qualified personnel.
8. Comply with national directives on occupational safety and quality assurance.
9. Use equipment that complies with current regulations.

Reporting of serious incidents

In the event of a serious incident in relation to the use of the device, please inform the manufacturer (via your distributor) and the competent authority of the European Union member state where the incident occurred. For other jurisdictions, reporting must be made in accordance with regulatory requirements. Reporting serious incidents helps provide more information about the safety of the diagnostic medical device

PROCEDURE

Quality control

Kit suspensions should be tested respectively with both positive and negative control. Failure to obtain a positive and negative reaction with the respective controls shows deterioration of suspension and/or controls.

Sample

Clear serum, diluted 1:20 with PBS

Diagnostic suspension

Bring reactives and materials to room temperature before use. Mix well antigen bottles to obtain an homogeneous suspension.

Test

Tube	Nr	1	2	3	4	5	K +	K -
PBS	mL	-	0.5	0.5	0.5	0.5	-	-
Serum diluted 1:20	mL	0.5	0.5	→	→	→	-	-
Positive Control	mL	-	-	-	-	-	0.5	-
Negative Control	mL	-	-	-	-	-	-	0.5
Perform two-fold dilutions by transferring 0.5 mL from Tube No.2 into the next, up to Tube No.5 discarding the last 0.5 mL residues.								
Diagnostic Susp.	mL	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Mix well and incubate as indicated for the specific antigen								
		1:40	1:80	1:160	1:320	1:640		

Incubation

O Agglutination Incubate in water bath at 50-52°C for 18 hours and then at room temperature for at least 1 hour.

H Agglutination

Incubate in water bath at 50-52°C for 4 hours and then for 30 min at room temperature

Reading

Without shaking the tubes, the degree of sedimentation and the clarification of the supernatant is observed. Read against a black background. The negative control tube must not show evident sedimentation. The positive control tube must show evident sedimentation. The titre of antibodies is given by the reciprocal of the highest dilution of the sample that shows a granular agglutination when observed with nacked eye.

O Agglutination

Appears as a granular precipitate when observed with nacked eye.

H Agglutination

Appears as a flocculent precipitation with an almost clear supernatant.

Test limits

Positive results obtained with the Listeria Kit can be further confirmed with the direct isolation of the bacterium. Serological test must be interpreted with caution because cross reactions are described with staphylococcus and other gram-positive antigens.

Normal values

For the diagnosis of disease a titer of at least 1:320 is necessary. Must be considered that individual immunological response against bacterial agents can be influenced by multiple factors. Analysis of multiple samples taken at a distance of 7-21 days allows a more reliable diagnosis.

Validation test

Specificity

Tests performed with three different lots of Listeria suspension on negative human samples had repeatedly shown negative results.

Precision

Test of repeatability (within run) and reproducibility (between run) performed with three different lots of Listeria suspension, on human samples and animal sera with known title, had unchangingly shown the expected results.

Symbols used in IFU and Packaging	
IVD In vitro diagnostic medical device vitro	Manufacturer
REF Catalogue Number	Instruction for use
LOT Lot Number	Temperature limitation
Expiration date	

References

1. **J. Bojsen** 1981; Moller in Human Listeriosis, Acta Pathologica et Microbiologica Scandinavica, Section B, Suppl. 229, pag 696
2. **P. Nicoletti.** 1972, in: F. Pasquinelli, Diagnostica e Tecniche di Laboratorio • Firenze 1981- Rosini et al.

REVISION	DATE	CHANGES
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