NordVal / NMKL
c/o Norwegian Veterinary Institute
PB 750 Sentrum, 0106 Oslo, Norway
www.nmkl.org

NordVal Certificate

Issued for:	TRANSIA® PLATE Listeria
NordVal No:	002
First approval date:	12 December 2000
Renewal date:	12 June 2016
Valid until:	12 June 2018

TRANSIA® PLATE Listeria

Manufactured by:
BioControl
12822 SE 32nd Street,
Bellevue, WA 98005,
USA.

Supplied by:
BioControl
12822 SE 32nd Street,
Bellevue, WA 98005,
USA.

fulfils the requirements of the NordVal validation protocol. The performance of the TRANSIA® PLATE Listeria has been compared with the following reference method:

- EN ISO 11290-1:2004: Horizontal method for the detection and enumeration of *Listeria monoctyogenes* -- Part 1: Detection method.

The results document no statistical difference in the performances between the methods.

Date: 9 June 2016

Yours sincerely

Sven Qvist
Chairman of Nordval

Hilde Skaar Norli
NMKL Secretary General

PRINCIPLE OF THE METHOD

TRANSIA® PLATE Listeria is an Enzyme Linked Immuno Sorbent Assay (ELISA) based on a two step sandwich-type reaction.

The method describes:

- enrichment on ½ Fraser broth for 20-26 h at 30°C ± 1°C, then
- inoculation of 0.25 mL of the ½ Fraser broth in 10 mL Fraser broth, incubated at 22-26 h at 30°C ± 1°C, followed by
- TRANSIA® PLATE Listeria test after heating of 1 to 2 mL of the enrichment broth Fraser at 95-100°C (boiling water) for 20 minutes.

The reading of the microtitre plate is carried out using a spectrophotometer at a wavelength of 450 nm.

FIELD OF APPLICATION

The method has been tested on foods and environmental samples.

COMPARISON STUDY

The latest study of the method was conducted in 2007 by Institut Pasteur de Lille, France according to the Validation Protocol ISO 16140:2003.

Accuracy, sensitivity, specificity

A total of 325 samples were analysed, 165 positives and 16 negatives, representing the following categories: meat products, dairy products, seafood products, vegetables and environmental samples.

The following results were obtained:

- √ Relative accuracy: 98%
- √ Relative specificity: 99%
- √ Relative sensitivity: 97%
- √ Agreement between the methods, kappa > 0.80, indicates very good agreement.

Detection Level

The different matrices have been analysed 6 times at 4 different contamination levels by both methods. The detection level was found to be 1-10 cfu in a sample of 25 g or 25 ml for all matrices.

Inclusivity /exclusivity

Inclusivity: 55 strains of *Listeria* (25 strains of *Listeria monocytogenes* and 25 strains of other *Listeria*) gave all positive results.
Exclusivity: The study of the 30 non-*Listeria* strains by the TRANSIA® PLATE Listeria test did not detect the presence of any cross-reaction.

COLLABORATIVE STUDY:

The collaborative study was conducted in 2007.
Number of laboratories: 14
Valid results were obtained from 10 of the 14 laboratories. Exclusion of four laboratories was necessary due to shipment and delivery problems.

The analyses were performed on samples of pasteurized milk, artificially contaminated with a strain of *Listeria innocua* at the following levels:

- 0 cfu/25 ml
- 1-10 cfu/25 ml
- 10-50 cfu/25 ml

The laboratories analysed 8 replicates for each level using both the alternative method and the reference method. The following results were obtained:

		Reference Method		
		+	-	Sum
Alternative Method	+	**146**	**0**	146
	-	**1**	**93**	94
	Sum	147	93	240

- Sensitivity: 99%
- Specificity: 100%
- Relative accuracy: 100%
- Kappa: 0.99

Thus, the collaborative study showed no statistical difference between the results obtained by the two methods.

CONCLUSION:

According to the comparison and the collaborative study no statistical differences were found between the TRANSIA® PLATE Listeria and the reference method, EN ISO 11290-1:2004 for the detection of *Listeria* spp in foods and environmental samples.