

NordVal Certificate

Issued for:	<i>Salmonella</i> ELISA Test OPTIMA
NordVal No:	010
First approval date:	4 May 2001
Renewal date:	1 April 2009
Valid until:	1 April 2011

***Salmonella* ELISA Test OPTIMA, RayAI *Salmonella* OPTIMA**

Manufactured by:

Bioline Aps
Fredericiavej 414
7080 Børkop
Denmark

Supplied by:

RayAI Ltd Mansfield i-centre Oakham Business Park Hamilton Way Mansfield NG18 5 BR United Kingdom	Bioline Aps Fredericiavej 414 7080 Børkop Denmark
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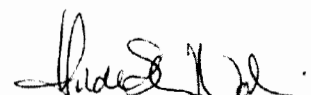
fulfils the requirements of the NordVal validation protocol. The *Salmonella* ELISA Test OPTIMA has been validated according to ISO 16140 against the reference methods ISO 6579:2002 and NMKL 71. The results document no statistical difference in the performances between the methods.

Yours sincerely

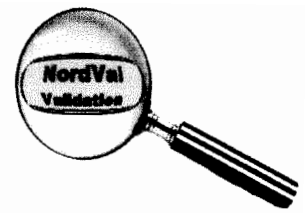
Date:

23/4-09


Sven Qvist
Chair of NordVal



Hilde Skår Norli
NMKL Secretary General



PRINCIPLE OF THE METHOD:

Salmonella ELISA Test OPTIMA / RayAI *Salmonella* OPTIMA is an immuno-enzymatic test using a microtiter plate coated with specific antibodies directed against *Salmonella*, and ready-to-use reagents. The test allows the detection of *Salmonella*, after enrichment steps (for about 40 hours) and a heat shock releasing *Salmonella* antigens that might be present in the sample. The antigens are detected by a sandwich ELISA (Enzyme Linked Immuno Sorbent Assay).

Confirmation of positive samples is not necessary, i.e. if it is not required according to legislation.

FIELD OF APPLICATION:

The method has been tested on food and animal feed.

COMPARISON STUDY

COMPLIANCE BETWEEN *SALMONELLA* ELISA TEST OPTIMA / RAYAL *SALMONELLA* OPTIMA AND THE REFERENCE METHOD:

Comparison studies performed show that there are no significant differences between the alternative method and the reference method. The following results were obtained:

- √ Relative accuracy: 99%
- √ Relative specificity: 99%
- √ Relative sensitivity: 99%
- √ Detection level: 1-10 cfu/ 25 grams.
- √ Inclusivity: 55 strains of *Salmonella* were detected out of 55 tested.
- √ Exclusivity: 30 strains not belonging to *Salmonella* was all negative; no interferences.

COLLABORATIVE STUDY:

The collaborative study was conducted in November 2001, 2004 and 2008.

Number of laboratories: > 10

The results showed that there were no significant differences between the reference and the alternative method, as the following results were:

- √ Sensitivity: 100%
- √ Specificity: 100%
- √ Relative accuracy: 100%

CONCLUSION:

According to the comparison and the collaborative study no statistical differences were found between the *Salmonella* ELISA Test OPTIMA / RayAI *Salmonella* OPTIMA the reference methods, ISO 6579:2002 and NMKL 71 for the detection of *Salmonella* in foods and animal feeds.