

# NordVal Certificate

Issued for:	BAX® <i>Salmonella</i> PCR (BAX® Classic and BAX® Q7) BAX® System with Automated Detection PCR Assay for Screening <i>Salmonella</i>
NordVal No:	030
First approval date:	20 November 2003
Renewal date:	1 June 2009
Valid until:	1 June 2011

**BAX® *Salmonella* PCR (BAX® Classic and BAX® Q7)  
BAX® System with Automated Detection PCR Assay for  
Screening *Salmonella***

Manufactured by:  
Dupont Qualicon,  
Bedford Bldg. 3531  
Silverside Road,  
Wilmington,  
DE 19810 USA,

Supplied by:  
OXOID A/S  
Thermo Fisher Scientific  
Lunikvej 28,  
DK-2670 Greve,  
Denmark

fulfils the requirements of the NordVal validation protocol. The performance of the BAX® System with Automated Detection PCR Assay for Screening *Salmonella* in food, feed and environmental samples, has been compared against the following reference method:

- √ EN ISO 6579:2002: Microbiology of food and animal feeding stuffs -- Horizontal method for the detection of *Salmonella* spp.

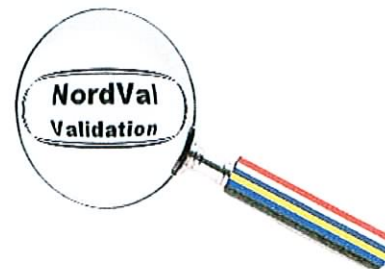
The results document no statistical difference in the performances between the methods.

Date: 28.05.2009

Yours sincerely

  
Sven Qvist  
Chair of NordVal

  
Hilde Skår Norli  
NMKL Secretary General



## PRINCIPLE OF THE METHOD

The BAX® System for detection of *Salmonella* is a detection kit using PCR (Polymerase Chain Reaction) technology. The method procedure consists of the following four steps:

- √ enrichment
- √ preparation of DNA
- √ amplification
- √ detection

The Bax® system for detection of *Salmonella* is targeting a specific bacterial DNA fragment, which is specific for *Salmonella* and is not present in any other bacteria, and hence is an indicator of *Salmonella* presence.

The PCR allows the BAX® system to realize a specific and rapid amplification of the DNA. After the lysis step, the Bax® cyclor/detector is doing both amplification and automated detection.

The BAX *Salmonella* PCR System (BAX Classic and BAX Q7) can be used without further confirmation.

## FIELD OF APPLICATION

The method has been tested on foods, feeds and environmental samples.

## COMPARISON STUDY

### COMPLIANCE BETWEEN BAX® CLASSIC, BAX® Q7 AND THE REFERENCE METHOD

Studies have been carried out both by AFNOR in 2002, 2004 and 2006 respectively. A number of products, both naturally and artificially contaminated, have been tested. The matrices tested belongs to the following categories: Dairy products, meat, fish, vegetables, pastries, egg products, ready to eat meals, animal feed and environmental samples. The following results are obtained:

**Relative accuracy:** 98.4%

**Relative sensitivity:** 96.9%

**Relative specificity:** 99.6%

**Detection level:** 1-10 cfu/g/ 25g

**Selectivity:** Inclusivity: 55 strains of *Salmonella* were detected out of 55 tested.

Exclusivity: Of the 47 non-*Salmonella* strains included, no cross reaction was detected.

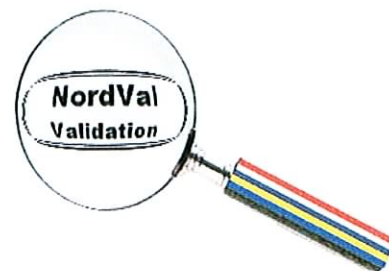
## COLLABORATIVE STUDY RESULTS

The collaborative study was conducted in 2006. Results were received from 11 laboratories. The analyses were carried out on samples of pâté artificially contaminated with a *Salmonella* *thyphimurium* strain at three levels of contamination. The following results were obtained:

Contamination level	No of results	No of negative results		No of positive results	
		REF	ALT	REF	ALT
0	88	86	88	2	0
3 cells / 25 mL	88	0	0	88	88
30 cells / 25 mL	88	0	0	88	88



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**Relative accuracy:** 99.2%

**Relative sensitivity:** 100%

**Relative specificity:** 97.7%

**The degree of agreement, kappa:** 0.98 (a kappa of  $\geq 0.80$  is satisfactory)

## CONCLUSION

According to the comparison study and the collaborative study, no statistical differences were found between the alternative method and the reference method.