

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 2011
Valid until:	1 June 2013

**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.

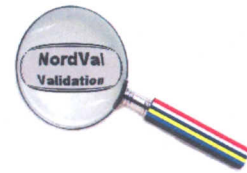
The results document no statistical difference in the performances between the methods.

Date: 01.06.2011

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® cycler/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

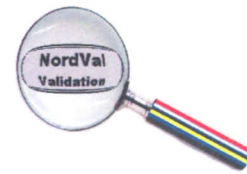
Selectivity: Inclusivity: 55 strains of *Salmonella* were detected out of 55 tested.

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



Relative accuracy: 99.2%

Relative sensitivity: 100%

Relative specificity: 97.7%

The degree of agreement, kappa: 0.98 (a kappa of ≥ 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.