



NordVal

c/o National Veterinary Institute
P.O.Box 8156, Dep.
N-0033 Oslo
Norway

12.03.2007

Renewal

Application form for renewal of validation of an alternative microbiological method.

<i>Salmonella ELISA Test SELECTA</i>	<i>2006-30-5408-00059</i>	<i>28 April 2004 28 April 2006</i>
Name of Product	NordVal Ref.No.	Approval Date

The application to be sent to:

NordVal

c/o National Veterinary Institute
P.O.Box 8156, Dep. N-0033 Oslo, Norway

Filled in by NordVal	
Jour.no.:	
Case no.	Received, date
Principle	Case terminated, date
Responsible:	

1.	Company name: <i>Bioline ApS</i>
2.	Contact person (name and title): <i>Torben Jensen, Director</i>
3.	Postal address: <i>Polarvej 60, 7100 Vejle, Denmark</i>
4.	Phone no.: <i>+45 76 62 07 09</i>
5.	Fax no.: <i>+45 76 62 07 05</i>
	E-mail: <i>Info@bioline.dk former email contact@bioline.dk not valid anymore</i>
6.	Producer (name, address, phone no., fax, e-mail): <i>Bioline ApS, Polarvej 60, 7100 Vejle, Denmark, +45 76 62 07 09, +45 76 62 07 05, info@bioline.dk Production site: Fredericiavej 414, 7080 Børkop, Denmark</i>
7.	Producer quality system (e. g. ISO 9000): <i>DS EN 9001:2000 + AFNOR requirements acc ISO13485</i>
8.	Description of method/brand: <i>Using a shortened specified 2-step enrichment procedure of 24 hours, a part of enriched sample is boiled and tested with sandwich ELISA method.</i>

9.	Product type/catalogue no. (if such): <i>Cat no 0096-1 (1-plate version), Bioline Salmonella ELISA kit</i> <i>Cat no 0096-5 (5-plate version), Bioline Salmonella ELISA kit</i> <i>Cat no 31-500, Bioline SELECTA medium</i>
10.	Analytical parameter/microorganisms: <i>Salmonella spp.</i>
11.	Method's analytical principle (short description): <i>Using a shortened specified 2-step enrichment procedure of 24 hours, a part of enriched sample is boiled and tested with sandwich ELISA method.</i>
	Has the method been changed: (Yes/No) No (Specify changes, if any):
	Has the package insert been changed: (Yes/No) No (Package insert enclosed, specify changes, if any).
12.	Description of the application field (name matrices). Is the method intended to be used as an alternative to a reference method (name reference method)? <i>All food matrices including animal feed. Reference method ISO6579:2002</i>
13.	The potential user: <i>Laboratories of food/feed manufacturers, commercial service labs and official labs</i>
14.	Validation organisation that has tested the method: <i>AFNOR</i> Newest validation certificate from other validation organisations. <i>March 2004</i>
15.	Method test characteristics: (specify changes, if any)

Qualitative method

- a) relative selectivity *100%*
- b) relative accuracy *100%*
- c) relative detection limit *1-10cfu/25 gram sample*
- d) relative sensitivity *100%*
- e) relative specificity *100%*

Quantitative method

- a) relative selectivity
- b) relative accuracy
- c) repeatability
- d) reproducibility
- e) relative standard deviation

16.	Advantages of the method compared to the reference method(s):
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	(Specify any changes since last approval)
	<i>No changes since last approval</i>
	Disadvantages of the method compared to the reference method(s): (Specify any changes since last approval)
	<i>No changes since last approval</i>
17.	Relevant literature and data since last approval enclosed <i>None</i>
18.	Renewal policy.

The NordVal certificate is valid for 2 years. The NordVal secretariat sends a reminder to the manufacturer including the Nordval renewal formula 6 months before the expiry of the certificate.

The manufacturer shall specify on the renewal formula if the method and the package insert have been changed since last approval. The Nordval steering group evaluates these changes – if any – and decides to which extent new comparative and collaborative studies should be carried out.

If the reference method used for the validation has been changed since last approval the NordVal steering group evaluates these changes and decides to which extent new comparative and collaborative studies should be carried out.

16. February 2008
Date

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Signature