CERTIFICATION

AOAC® *Performance Tested*SM

Certificate No.

060601

The AOAC Research Institute hereby certifies the performance of the test kit known as:

Premi®Test

manufactured by

DSM PREMI® Test B. V.
P. O. Box 6500
6401 JH HEERLEN
The Netherlands

This method has been evaluated in the AOAC® *Performance Tested Methods*SM Program, and found to perform as stated by the manufacturer contingent to the comments contained in the manuscript. This certificate means that an AOAC® Certification Mark License Agreement has been executed which authorizes the manufacturer to display the AOAC *Performance Tested*SM certification mark along with the statement - "THIS METHOD'S PERFORMANCE WAS REVIEWED BY AOAC RESEARCH INSTITUTE AND WAS FOUND TO PERFORM TO THE MANUFACTURER'S SPECIFICATIONS" - on the above mentioned method for a period of one calendar year from the date of this certificate (November 07, 2019 – December 31, 2020). Renewal may be granted at the end of one year under the rules stated in the licensing agreement.

Scott Coates

Scott Coates, Senior Director
Signature for AOAC Research Institute

November 07, 2019
Date

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CERTIFICATION MARK LICENSEE
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An der Neuen Bergstraße 17, 64297
Darmstadt, Germany

KIT NAME(S)
Premi® Test

CATALOG NUMBERS
R3925, R3900

INDEPENDENT LABORATORY
Central Science Laboratory (CSL)
York Y041 1LZ, England
USDA Agricultural Research Service
Eastern Regional Research Center
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APPLICABILITY OF METHOD
Target analyte – Penicillin G

Matrices – Bovine muscle tissue

Performance claims – See Table 1

ORIGINAL CERTIFICATION DATE
September 27, 2006

CERTIFICATION RENEWAL RECORD
Renewed Annually through December 2020

METHOD MODIFICATION RECORD
1. **November 2019 Level 1**

SUMMARY OF MODIFICATION
1. **Editorial changes to inserts**

Under this AOAC® *Performance Tested*^{SM} License Number, 060601 this method is distributed by:
NONE

Under this AOAC® *Performance Tested*^{SM} License Number, 060601 this method is distributed as:
NONE

PRINCIPLE OF THE METHOD (1)
The Premi®test is based on the inhibition of the growth of *Bacillus Stearothermophilus*, a bacterium which is very sensitive to many antibiotics and sulfa compounds. A standarized number of spores are imbedded in an agar medium with selected nutrients.
A small amount of meat juice is added to the test tube. After a pre-incubation period of 20 minutes at room temperature (18-22 ºC i.e. 64.4-71.6 °F), the test tube is washed and incubated for approximately 3 hours at 64°C (147ºF).
At this temperature, the spores will start to grow (germinate) and multiply with the production of acid if no antimicrobial (non-inhibitory) substances are present in the meat juice. This will be visible by a color change in the test tube from purple to yellow. When antimicrobial (inhibitory) substances are present (at or above the detection sensitivity), no growth will occur and the color in the test tube will remain purple.

DISCUSSION OF THE VALIDATION STUDY (1)
The results show that Premi®Test met all the requirements for this AOAC validation study for the detection of penicillin G residues in bovine muscle tissue. The results also show that there is cross reactivity with many other antimicrobial compounds. Premi®Test is a broad-spectrum screening test which can detect many relevant antimicrobials in meat.

Table 1: Summary of performance parameters of Premi®Test for penicillin G obtained in the study (1)

Laboratory	Study	Performance Pen G (ppb)	Remarks
CSL	Part 1: 6 out of 6	10	A range of 5 different concentrations from 0 – 50 ppb was tested. At 10 ppb, all 6 of 6 samples analysed tested positive.
USDA	Part 2: 30 out of 30	10	Results confirmed that the detection sensitivity of the PremiTest for pen G was 10 ppb with 95% confidence level
DSM	Part 3: Ruggedness, interference, cross-reactivity	10	The presence of other antimicrobial drugs did not interfere with the PremiTest kits ability to detect pen G residues at a concentration of 10 ppb added to bovine muscle tissue.
USDA	Part 4: Incurred tissue	10	The detection sensitivity determined using fortified tissue samples was further confirmed using incurred bovine muscle tissues. PremiTest was able to detect all pen G residues in incurred samples containing pen G at concentrations greater than or equal to 12 ppb .

Table 9: Scanner results to confirm the Premi®Test's detection sensitivity as 10 ppb for penicillin G (1)

Zero control			
Sample		**Sample**	
	Interpreted Scanner Results		**Interpreted Scanner Results**
	NEG		
1	NEG	**9**	NEG
2	NEG	**10**	NEG
3	NEG	**11**	NEG
4	NEG	**12**	NEG
5	NEG	**13**	NEG
6	POS	**14**	NEG
7	NEG	**15**	NEG
8			NEG
Penicillin G 10 ppb			
Sample	**Interpreted** Scanner Results	**Sample**	**Interpreted** Scanner results
	POS		POS
	POS		POS
1	POS	**16**	POS
2	POS	**17**	POS
3	POS	**18**	POS
4	POS	**19**	POS
5	POS	**20**	POS
6	POS	**21**	POS
7	POS	**22**	POS
8	POS	**23**	POS
9	POS	**24**	POS
10	POS	**25**	POS
11	POS	**26**	POS
12	POS	**27**	POS
13	POS	**28**	POS
14		**29**	
15		**30**	

REFERENCE CITED

1. de Rijk, Angelique., Validation Study Report Premi®Test, AOAC® *Performance Tested*℠ certification number 060601.