

CERTIFICATION

AOAC[®] *Performance Tested*SM

Certificate No. 011102

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

Delvotest® SP NT Visual

manufactured by

DSM Food Specialties P. O. Box 1 2600 MA Delft 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 (September 23, 2020 – December 31, 2021). Renewal may be granted at the end of one year under the rules stated in the licensing agreement.

Scott Gates

Scott Coates, Senior Director Signature for AOAC Research Institute November 28, 2020

Date

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| METHOD AUTHORS | SUBMITTING COMPANY | |
|---|---|--|
| Faragher John and Hennart Stéphen | DSM Food Specialties | |
| | Fleminglaan 1 | |
| | 2613AX Delft | |
| | The Netherlands | |
| | | |
| KIT NAME(S) | CATALOG NUMBERS | |
| Delvotest [®] SP NT Visual | Delvotest [®] SPNT 100 #84231/13323/11605/13530 | |
| | Delvotest [®] SPNT 5 Pack #8422 | |
| | Delvotest [®] SPNT MCS #8421 | |
| | | |
| INDEPENDENT LABORATORY | AOAC EXPERTS AND PEER REVIEWERS | |
| DairyOne | Joe Boison ¹ , Jim Agin ² , Mark Mitchell ³ | |
| 730 Warren Road | ¹ Canadian Food Inspection Agency, Saskaton, SK, CANADA | |
| Ithaca, NY | ² Q Laboratories, Cincinnati, OH, USA | |
| USA | ³ University of Guelph, Guelph, Ontario, CANADA | |
| | | |
| APPLICABILITY OF METHOD | | |
| Target drugs – Ampicillin, Amoxicillin, Cephapirin, and Penicillin G | | |
| Matrixes – raw commingled bovine milk | | |
| Performance claims - Delvotest [®] SP NT is a test system that is designed to | | |
| test milk for the presence of antibacterial substances such as antibiotics. | | |
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| ORIGINAL CERTIFICATION DATE | CERTIFICATION RENEWAL RECORD | |
| January 14, 2011 | Renewed annually through December 2021 | |
| METHOD MODIFICATION RECORD | SUMMARY OF MODIFICATION | |
| 1. November 2019 Level 1 | 1. Editorial and formatting changes. | |
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| | | |
| Under this AOAC [®] Performance Tested SM License Number, 011102 this | Under this AOAC [®] Performance Tested SM License Number, 011102 this | |
| | Under this AOAC [®] <i>Performance TestedsM</i> License Number, 011102 this method is distributed as: | |

Delvotest [®] SP NT is a test system that is designed to test milk for the presence of antibacterial substances such as antibiotics. The test is incubated in a water bath (or dry incubator). The test contains a solid and buffered agar medium including all required nutrients, a standardised number of spores of the test organism *Bacillus stearothermophilus var. calidolactis* and a purple colored pH indicator bromocresol purple. The principle of the test is based on the diffusion of possible inhibitory substances that may be present in the milk sample into agar. This reduces growth and acid production by the test organism and delays or prevents the agar from changing color from purple to yellow.

DISCUSSION OF THE VALIDATION STUDY (1)

Conclusions from the studies carried out by DairyOne:

- 1. The detection sensitivity conforms to the claims
- 2. The test selectivity conforms to the claims
- 3. There is no influence of the test kit lot used
- 2. There is no influence caused by the age of the test kit lot used
- 3. Ruggedness Study: There is no influence when the volume of milk pipetted is done with an accuracy of +/-10%.
- 4. Effect of storage sample condition: after 2 weeks of storage at -16°C, a sample with penicillin might give negative results.
- 5. Drug Interference study: there is no interference that might lead to a false negative result.
- 6. There is no interference from somatic cells
- 7. There is no interference from bacteria

| Claim | Accuracy claim | Results of the Validation |
|--|----------------|---------------------------|
| | | Study |
| Detection sensitivity of Amoxicillin (ng/g) | 2.5 ng/g | 2.5 ng/g |
| Detection sensitivity of Ampicillin (ng/g) | 3.0 ng/g | 3.0 ng/g |
| Detection sensitivity of Cephapirin (ng/g) | 5.8 ng/g | 5.8 ng/g |
| Detection sensitivity of Penicillin G (ng/g) | 1.5 ng/g | 1.5 ng/g |
| Rate of False positive results (%) | 0% (0/60) | 0% (0/60) |

REFERENCE CITED

John, Faragher and Stéphen, Hennart., Evaluation of the DSM Food Specialties Delvotest[®] SP NT Visual for Antibiotics in Milk, AOAC[®] Performance TestedSM certification number 011102.