

11 September 2013

The Chemical Surveillance Branch of the Agri-Food and Biosciences Institute, Belfast, UK carried out an independent evaluation of the AuroFlow™ BT Combo Strip Test Kit for the detection of β -lactams & tetracyclines in milk between the 4th and 10th September 2013. The evaluation was designed to assess the detection capability of the assay for 14 β -lactams and 4 tetracyclines in bovine milk. In addition the evaluation would assess the false positive and false negative rate of the assay. The evaluation plan is set out in Appendix 1 whilst Appendix 2 details the results of the assessment. The results are summarised below:-

Table 1 shows the β -lactams included in the evaluation process, the European Union (EU) Maximum Residue Limit in milk for each and the detection capability determined for the AuroFlow™ BT Combo Strip Test Kit. Table 2 provides this information for the tetracycline compounds assessed.

Drug	Milk MRL ($\mu\text{g kg}^{-1}$)	CC β ($\mu\text{g kg}^{-1}$)
Amoxicillin	4	< 4
Ampicillin	4	< 4
Benzylpenicillin	4	< 2
Cloxacillin	30	< 15
Dicloxacillin	30	< 15
Nafcillin	30	< 15
Oxacillin	30	< 15
Cefacetrole	125	< 62.5
Cefalonium	20	< 10
Cefapirin	60	< 30
Cefazolin	50	< 25
Cefoperazone	50	< 25
Cefquinome	20	< 10
Ceftiofur	100	< 100

Table 1 The detection capability of the AuroFlow™ BT Combo Strip Test Kit for the β -lactams included in the evaluation.

Drug	Milk MRL ($\mu\text{g kg}^{-1}$)	CC β ($\mu\text{g kg}^{-1}$)
Oxytetracycline	100	< 50
Tetracycline	100	< 50
Chlortetracycline	100	< 50
Doxycycline	Not Permitted	< 1

Table 2 The detection capability of the AuroFlow™ BT Combo Strip Test Kit for the tetracyclines included in the evaluation.

The false positive rate and false negative rates for the assay were established through the repeat analysis, over a three day period, of twenty drug-free milk samples and twenty milk samples spiked with either benzylpenicillin, in the case of the β -lactam assessment, or with oxytetracycline in the case of the tetracycline assessment. No false positive or false negative results were recorded for either the β -lactams or the tetracyclines.

In conclusion, the independent assessment of the AuroFlow™ BT Combo Strip Test Kit for the detection of β -lactams & tetracyclines in bovine milk showed the assay:

- capable of detecting all β -lactams assessed at concentrations less than their established EU maximum residue limits in milk
- capable of detecting all tetracyclines assessed at concentrations less than their established EU maximum residue limits in milk
- capable of detecting doxycycline, for which no EU maximum residue limit has been established, at concentrations of less than $1 \mu\text{g kg}^{-1}$ in milk
- to be reproducible
- to have a zero false positive rate
- to have a zero false negative rate

Signed



Date 12 September 2013

Dr Steven Crooks

Position

Senior Scientific Officer, Agri-Food and Biosciences Institute