

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 |
| Cefacetrile | 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 doxycyline, 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

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