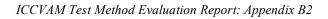
APPENDIX B2

COMPARISON OF PERFORMANCE CHARACTERISTICS OF FOUR IN VITRO TEST METHODS FOR IDENTIFICATION OF EPA OCULAR CORROSIVES OR SEVERE IRRITANTS



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| Statistic | IRE | ICE | HET-CAM | HET-CAM | BCOP |
|-----------------------|---------------|-----------|------------|---------------|-----------|
| | $(n = 107)^1$ | (n = 145) | $(n=98)^2$ | $(n = 133)^3$ | (n = 143) |
| Accuracy | 64% | 84% | 65% | 52% | 79% |
| | $(68/107)^4$ | (122/145) | (64/98) | (69/133) | (113/143) |
| Sensitivity | 69% | 52% | 68% | 89% | 75% |
| | (31/45) | (15/29) | (21/31) | (25/28) | (30/40) |
| Specificity | 60% | 92% | 64% | 42% | 81% |
| | (37/62) | (107/116) | (43/67) | (44/105) | (83/103) |
| Positive | 55% | 63% | 47% | 29% | 60% |
| Predictivity | (31/56) | (13/24) | (21/45) | (25/86) | (30/50) |
| Negative | 73% | 89% | 81% | 94% | 89% |
| Predictivity | (37/51) | (107/121) | (43/53) | (44/47) | (83/93) |
| False Positive | 40% | 8% | 36% | 58% | 19% |
| Rate | (25/62) | (9/116) | (24/67) | (61/105) | (20/103) |
| False Negative | 31% | 48% | 32% | 11% | 25% |
| Rate | (14/45) | (14/29) | (10/31) | (3/28) | (10/40) |

Abbreviations: BCOP = Bovine Corneal Opacity and Permeability assay; GHS = Globally Harmonized System; HET-CAM = Hen's Egg Test – Chorioallantoic Membrane assay; ICE = Isolated Chicken Eye assay; IRE = Isolated Rabbit Eye assay.

¹n = number of substances tested; the numbers in parentheses in each row indicates the data on which the percentage calculation is based. ²These data are for the IS(B) method (described by Kalweit et al. 1987) when testing substances as a 10%

solution in vitro.

³These data are for the IS(B) method (described by Kalweit et al. 1987) when testing substances at a 100% concentration in vitro.

⁴These results are for the Pooled Data Set.