APPENDIX B3

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

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Statistic	IRE (n = 114)[1]	ICE (n = 154)	HET-CAM (n = 95)[2]	HET-CAM (n = 164)[3]	BCOP (n = 143)
Accuracy	69% (79/114)[4]	87% (134/154)	67% (64/95)	57% (94/164)	80% (114/143)
Sensitivity	76% (37/49)	59% (19/32)	70% (23/31)	93% (31/33)	82% (33/40)
Specificity	65% (42/65)	94% (115/122)	66% (41/62)	48% (63/131)	79% (81/103)
Positive Predictivity	62% (37/60)	73% (19/26)	52% (23/44)	31% (31/99)	60% (33/55)
Negative Predictivity	78% (42/54)	90% (115/128)	80% (41/51)	97% (63/65)	92% (81/88)
False Positive Rate	35% (23/65)	6% (7/122)	34% (21/62)	52% (68/131)	21% (22/103)
False Negative Rate	24% (12/49)	41% (13/32)	30% (10/33)	6% (2/33)	18% (7/40)

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.

[1] n = number of substances tested; the numbers in parentheses in each row indicates the data on which the percentage calculation is based.

[2] These data are for the IS(B) method (described by Kalweit et al. 1987) when testing substances as a 10% solution *in vitro*.

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

[4] These results are for the Pooled Data Set.