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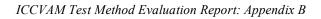
COMPARISON OF PERFORMANCE CHARACTERISTICS OF FOUR *IN VITRO* TEST METHODS FOR THE IDENTIFICATION OF OCULAR CORROSIVES OR SEVERE IRRITANTS

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APPENDIX B1
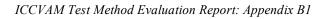
COMPARISON OF PERFORMANCE CHARACTERISTICS OF FOUR *IN VITRO* TEST METHODS FOR IDENTIFICATION OF GHS OCULAR CORROSIVES OR SEVERE IRRITANTS

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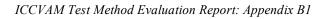| Statistic	IRE (n = 107)[1]	ICE (n = 144)	HET-CAM (n = 101)[2]	HET-CAM (n = 138)[3]	BCOP (n = 147)
Accuracy	65% (70/107)[4]	83% (120/144)	68% (69/101)	54% (75/138)	81% (119/147)
Sensitivity	70% (33/47)	50% (15/30)	70% (28/40)	87% (34/39)	84% (36/43)
Specificity	62% (37/60)	92% (105/114)	67% (41/61)	41% (41/99)	80% (83/104)
Positive Predictivity	59% (33/56)	63% (15/24)	58% (28/48)	37% (34/92)	63% (36/57)
Negative Predictivity	73% (37/51)	88% (105/120)	77% (41/53)	89% (41/46)	92% (83/90)
False Positive Rate	38% (23/60)	8% (9/114)	33% (20/61)	59% (58/99)	20% (21/104)
False Negative Rate	30% (14/47)	50% (15/30)	30% (12/40)	13% (5/39)	16% (7/43)

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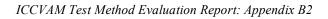
[3] These data are for the IS(B) method (described by Kalweit et al. 1987) when testing substances at a 100% concentration *in vitro*.

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

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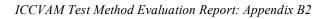| Statistic	IRE (n = 107)[1]	ICE (n = 145)	HET-CAM (n = 98)[2]	HET-CAM (n = 133)[3]	BCOP (n = 143)
Accuracy	64% (68/107)[4]	84% (122/145)	65% (64/98)	52% (69/133)	79% (113/143)
Sensitivity	69% (31/45)	52% (15/29)	68% (21/31)	89% (25/28)	75% (30/40)
Specificity	60% (37/62)	92% (107/116)	64% (43/67)	42%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

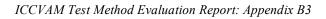[1] n = number of substances tested; the numbers in parentheses in each row indicates the data on which the percentage calculation is based.
[2] These data are for the IS(B) method (described by Kalweit et al. 1987) when testing substances as a 10% solution *in vitro*.
[3] These data are for the IS(B)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

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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.

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