

APPENDIX B1

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

[This Page Intentionally Left Blank]

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.

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.