

Table 4.5 General Comparison of the Rat Skin TER Assay, EPISKIN™, EpiDerm™ (EPI-200), and Corrositex® Assays Based on a Weight-of-Evidence Approach^a by Chemical using Data from the ECVAM and Other Validation Studies (Fentem et al., 1998; ICCVAM, 1999; Liebsch et al., 2000)

	Rat Skin TER	EPISKIN	EpiDerm™ (EPI-200) (prediction model 2)	Corrositex®
Number of Chemicals	122	60	24	163
Overall Sensitivity^b	94% (51/54)	82% (23/28)	92% (11/12)	85% (76/89)
Overall Specificity^b	71% (48/68)	84% (27/32)	83% (10/12)	70% (52/74)
Overall Accuracy^b	81% (99/122)	83% (50/60)	92% (22/24)	79% (128/163)
False Positive Rate	29% (20/68)	16% (5/32)	17% (2/12)	30% (22/74)
False Negative Rate	6% (3/54)	18% (5/28)	8% (1/12)	15% (13/89)
Test Chemical Inter-laboratory Coefficient of Variation	34.7 ^c	11.3 ^c	12.3 ^c	30.3 ^c
	3.8-322 ^d	3.9-148.8 ^d	0.9-51.2 ^d	7.7-252.5 ^d
	120 ^e	20 ^e	144 ^e	180 ^e

^a A chemical is first classified as positive or negative for corrosivity within each laboratory based on the majority of test results obtained (when replicate testing was conducted). Next, the chemical is classified as positive or negative for corrosivity based on the majority of test results obtained in multiple laboratories (when multiple laboratory studies were conducted). In instances where discordant results could not be resolved (i.e., there was an equal number of positive and negative calls within or across laboratories), the chemical was eliminated from inclusion in the performance calculations.

^b Sensitivity is defined as the proportion of all positive chemicals that are correctly classified as positive in a test. Specificity is defined as the proportion of all negative chemicals that are correctly classified as negative in a test. Accuracy (concordance) is defined as the proportion of correct outcomes of a method.

^c Median value

^d Range of values

^e The total number of independent values, which is calculated as the number of chemicals tested multiplied by the number of participating laboratories.