

Case 1 A

Interesting negative results from a GLP bacterial mutagenicity test

Ames results for an important new compound

		Number of colonies per plate									
		with s9 microsomes					no metabolic activation				
Plate #	TA 98	TA 100	TA 1535	TA 1537	<i>E. coli</i> WP2*	TA 98	TA 100	TA 1535	TA 1537	<i>E. coli</i> WP2*	
DMSO	1	21	103	22	9	169	23	99	19	11	168
	2	20	100	20	12	172	19	104	21	10	175
	3	23	100	24	11	170	20	102	23	9	170
	Lawn	4+	4+	4+	4+	4+	4+	4+	4+	4+	4+
5000 mg test article	1	19	102	21	10	174	22	105	20	9	172
	2	20	104	19	11	172	18	103	23	11	175
	3	22	99	22	9	170	20	101	21	10	171
	Lawn	4+	4+	4+	4+	4+	4+	4+	4+	4+	4+
2500 mg test article	1	21	105	21	12	175	22	100	22	12	169
	2	20	100	20	10	173	19	98	20	9	174
	3	20	101	21	11	170	21	104	21	7	173
	Lawn	4+	4+	4+	4+	4+	4+	4+	4+	4+	4+

		Number of colonies per plate									
		with s9 microsomes					no metabolic activation				
Plate #	TA 98	TA 100	TA 1535	TA 1537	<i>E. coli</i> WP2*	TA 98	TA 100	TA 1535	TA 1537	<i>E. coli</i> WP2*	
1250 mg test article	1	21	98	23	9	175	21	100	23	10	175
	2	20	103	19	11	176	18	99	20	11	177
	3	19	101	20	12	176	21	105	19	11	169
	Lawn	4+	4+	4+	4+	4+	4+	4+	4+	4+	4+
625 mg test article	1	20	100	22	12	169	19	103	23	12	178
	2	19	104	21	9	170	19	104	19	9	170
	3	20	99	19	11	168	23	101	20	7	173
	Lawn	4+	4+	4+	4+	4+	4+	4+	4+	4+	4+
Positive control	1	407	382	141	123	388	408	382	141	121	389
	2	409	385	140	120	387	409	384	140	123	387
	3	408	381	139	124	387	406	380	139	120	385
	Lawn	4+	4+	4+	4+	4+	4+	4+	4+	4+	4+

MEGATVFE!!!

Comparison with another lab

	TA 1537		E. coli WP2 uvrA	
	Lab A	Lab B	Lab A	Lab C
DMSO	11	8	169	198
	10	6	172	190
	9	10	170	169
5000 µg test article	9	7	174	179
	11	9	172	196
	10	8	170	180
2500 µg test article	12	11	175	176
	9	7	173	152
	7	12	170	163

	TA 1537		E. coli WP2 uvrA	
	Lab A	Lab B	Lab A	Lab C
1250 µg test article	10	8	175	178
	11	7	176	152
	11	5	176	138
625 µg test article	12	7	169	176
	9	6	170	167
	7	7	168	184

Questions for the Panel

- What do you like most about the dataset from Lab A?
- What is an appropriate follow-up to these results?