

Experiment Number: A14443

Test Type: **Genetic Toxicology - Bacterial  
Mutagenicity**

**G06: Ames Summary Data**

Test Compound: **Clarithromycin**

CAS Number: **81103-11-9**

Date Report Requested: **09/16/2018**

Time Report Requested: **01:19:19**

**NTP Study Number:**

A14443

**Study Result:**

Negative

Experiment Number: A14443

Test Type: Genetic Toxicology - Bacterial  
Mutagenicity

## G06: Ames Summary Data

Test Compound: Clarithromycin

CAS Number: 81103-11-9

Date Report Requested: 09/16/2018

Time Report Requested: 01:19:19

## Strain: TA100

Dose (ug/Plate)	Without S9	Without S9	With 10% Rat S9	With 30% Rat S9	With 10% Hamster S9
Vehicle Control <sup>1</sup>	88 ± 25.7	127 ± 4.8	104 ± 7.3	110 ± 6.9	108 ± 8.4
0.03	113 ± 7.5				
0.1	121 ± 3.3	126 ± 12.1			
0.3	116 ± 5.6	118 ± 8.6	121 ± 6.2	123 ± 10.1	129 ± 6.4
1.0	137 ± 15.0	125 ± 6.3	113 ± 1.5	119 ± 10.3	106 ± 9.7
3.0	63 ± 35.0 <sup>s</sup>	132 ± 9.7	79 ± 35.5	133 ± 10.6	126 ± 13.4
6.0		91 ± 7.8 <sup>s</sup>			
10.0			104 ± 5.8	146 ± 11.3	102 ± 2.8
33.0			25 ± 4.9	77 ± 6.4	28 ± 5.0
Trial Summary	Negative	Negative	Negative	Negative	Negative
Positive Control <sup>2</sup>					1081 ± 26.2
Positive Control <sup>3</sup>			628 ± 36.7		
Positive Control <sup>4</sup>	1166 ± 94.4	884 ± 22.8			
Positive Control <sup>5</sup>				828 ± 30.6	

Experiment Number: A14443  
Test Type: Genetic Toxicology - Bacterial  
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G06: Ames Summary Data  
Test Compound: Clarithromycin  
CAS Number: 81103-11-9

Date Report Requested: 09/16/2018  
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Strain: TA100

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Dose (ug/Plate)	With 30% Hamster S9
Vehicle Control <sup>1</sup>	100 ± 7.9
0.03	
0.1	
0.3	96 ± 4.6
1.0	111 ± 6.4
3.0	101 ± 1.7
6.0	
10.0	131 ± 11.6
33.0	71 ± 10.6
Trial Summary	Negative
Positive Control <sup>2</sup>	
Positive Control <sup>3</sup>	857 ± 9.3
Positive Control <sup>4</sup>	
Positive Control <sup>5</sup>	

Experiment Number: A14443

Test Type: Genetic Toxicology - Bacterial  
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## G06: Ames Summary Data

Test Compound: Clarithromycin

CAS Number: 81103-11-9

Date Report Requested: 09/16/2018

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## Strain: TA1535

Dose (ug/Plate)	Without S9	Without S9	With 10% Rat S9	With 30% Rat S9	With 10% Hamster S9
Vehicle Control <sup>1</sup>	13 ± 2.5	16 ± 2.4	11 ± 1.9	11 ± 0.9	12 ± 2.0
0.03	15 ± 3.5				
0.1	12 ± 2.0	17 ± 2.1			
0.3	15 ± 3.5	17 ± 0.3	9 ± 1.3	15 ± 2.9	8 ± 0.7
1.0	18 ± 0.7	14 ± 3.2	13 ± 2.2	12 ± 2.3	10 ± 1.0
3.0	14 ± 3.7	14 ± 2.7	16 ± 1.3	17 ± 3.5	12 ± 1.2
6.0		10 ± 2.0 <sup>s</sup>			
10.0			13 ± 0.7	12 ± 2.6	13 ± 1.2
33.0			7 ± 0.7	7 ± 1.2	7 ± 1.3
Trial Summary	Negative	Negative	Negative	Negative	Negative
Positive Control <sup>3</sup>					183 ± 4.1
Positive Control <sup>4</sup>	1156 ± 21.9	1066 ± 33.5			
Positive Control <sup>5</sup>			189 ± 10.5		
Positive Control <sup>6</sup>				491 ± 4.1	

Experiment Number: A14443  
Test Type: Genetic Toxicology - Bacterial  
Mutagenicity

G06: Ames Summary Data  
Test Compound: Clarithromycin  
CAS Number: 81103-11-9

Date Report Requested: 09/16/2018  
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Strain: TA1535

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Dose (ug/Plate)	With 30% Hamster S9
Vehicle Control <sup>1</sup>	14 ± 3.0
0.03	
0.1	
0.3	14 ± 4.2
1.0	11 ± 1.7
3.0	13 ± 3.2
6.0	
10.0	15 ± 0.6
33.0	8 ± 3.2
Trial Summary	Negative
Positive Control <sup>3</sup>	
Positive Control <sup>4</sup>	
Positive Control <sup>5</sup>	550 ± 10.2
Positive Control <sup>6</sup>	

Experiment Number: A14443

Test Type: Genetic Toxicology - Bacterial  
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## G06: Ames Summary Data

Test Compound: Clarithromycin

CAS Number: 81103-11-9

Date Report Requested: 09/16/2018

Time Report Requested: 01:19:19

## Strain: TA97

Dose (ug/Plate)	Without S9	Without S9	With 10% Rat S9	With 30% Rat S9	With 10% Hamster S9
Vehicle Control <sup>1</sup>	149 ± 8.6	152 ± 12.7	153 ± 5.8	131 ± 4.8	144 ± 5.5
0.03	159 ± 3.8				
0.1	156 ± 7.8	155 ± 7.2			
0.3	153 ± 11.9	167 ± 18.2	171 ± 13.9	123 ± 4.0	150 ± 2.6
1.0	161 ± 6.6	165 ± 10.2	166 ± 6.9	136 ± 12.1	156 ± 1.3
3.0	110 ± 17.3	136 ± 14.4	164 ± 1.2	134 ± 9.2	158 ± 6.8
6.0		74 ± 4.0 <sup>s</sup>			
10.0			111 ± 2.2	145 ± 16.8	94 ± 4.4
33.0			108 ± 35.8	101 ± 7.3	54 ± 13.3
Trial Summary	Negative	Negative	Negative	Negative	Negative
Positive Control <sup>2</sup>					828 ± 2.4
Positive Control <sup>3</sup>			624 ± 15.8		
Positive Control <sup>5</sup>				479 ± 2.0	
Positive Control <sup>7</sup>	581 ± 4.7				
Positive Control <sup>8</sup>		515 ± 29.5			

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G06: Ames Summary Data  
Test Compound: Clarithromycin  
CAS Number: 81103-11-9

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Strain: TA97

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Dose (ug/Plate)	With 30% Hamster S9
Vehicle Control <sup>1</sup>	154 ± 10.7
0.03	
0.1	
0.3	167 ± 10.0
1.0	169 ± 7.8
3.0	179 ± 4.1
6.0	
10.0	171 ± 14.3
33.0	108 ± 4.6
Trial Summary	Negative
Positive Control <sup>2</sup>	
Positive Control <sup>3</sup>	739 ± 24.3
Positive Control <sup>5</sup>	
Positive Control <sup>7</sup>	
Positive Control <sup>8</sup>	

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## G06: Ames Summary Data

Test Compound: Clarithromycin

CAS Number: 81103-11-9

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## Strain: TA98

Dose (ug/Plate)	Without S9	Without S9	With 10% Rat S9	With 30% Rat S9	With 10% Hamster S9
Vehicle Control <sup>1</sup>	23 ± 2.7	28 ± 1.5	29 ± 7.3	25 ± 3.3	34 ± 4.3
0.03	27 ± 1.5				
0.1	34 ± 2.5	33 ± 3.8			
0.3	26 ± 5.2	27 ± 2.3	40 ± 4.4	27 ± 4.5	31 ± 5.0
1.0	25 ± 2.6	30 ± 1.2	37 ± 3.8	31 ± 5.9	28 ± 2.7
3.0	23 ± 3.3	24 ± 3.5	35 ± 4.1	26 ± 2.6	36 ± 1.0
6.0		14 ± 4.2 <sup>s</sup>			
10.0			32 ± 2.0	30 ± 1.5	27 ± 4.2
33.0			17 ± 1.5	18 ± 0.6	16 ± 2.1
Trial Summary	Negative	Negative	Negative	Negative	Negative
Positive Control <sup>2</sup>					870 ± 49.4
Positive Control <sup>3</sup>			535 ± 10.3		
Positive Control <sup>9</sup>	682 ± 50.2	600 ± 14.3			
Positive Control <sup>5</sup>				557 ± 19.5	

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G06: Ames Summary Data  
Test Compound: Clarithromycin  
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Strain: TA98

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Dose (ug/Plate)	With 30% Hamster S9
Vehicle Control <sup>1</sup>	28 ± 5.3
0.03	
0.1	
0.3	26 ± 2.9
1.0	25 ± 0.9
3.0	34 ± 2.7
6.0	
10.0	27 ± 6.7
33.0	14 ± 2.1
Trial Summary	Negative
Positive Control <sup>2</sup>	
Positive Control <sup>3</sup>	592 ± 37.8
Positive Control <sup>9</sup>	
Positive Control <sup>5</sup>	

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## LEGEND

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Values given as Mean or Mean  $\pm$  Standard Error Mean

The number of samples = 3, unless samples marked toxic or contaminated were excluded from mean and SEM calculations

CAS Number = Chemical Abstracts Service registry number

1: Vehicle Control: Dimethyl Sulfoxide

2: 1.0 ug/Plate 2-Aminoanthracene

3: 2.0 ug/Plate 2-Aminoanthracene

4: 5.0 ug/Plate Sodium Azide

5: 5.0 ug/Plate 2-Aminoanthracene

6: 10.0 ug/Plate 2-Aminoanthracene

7: 50.0 ug/Plate 9-Aminoacridine

8: 50.0 ug/Plate Sodium Azide

9: 2.5 ug/Plate 4-Nitro-O-Phenylenediamine

s: Slight Toxicity

\*\* END OF REPORT \*\*