# Ames Historical Controls for the Ames Study Manager

Ames Historical Controls provides a friendly easy-to-use method of reporting, auditing and producing statistics from your historical control data.

In regulatory Ames studies, historical control data must be presented with the findings of the study. Ames Historical Controls is the secure solution for the selection and presentation of Ames historical control data. Achieve full regulatory compliance

by including historical controls in your Ames reports

Includes all statistics required by OECD 471 including ranges, means and standard deviations

Seamless integration with Microsoft Excel for customised reporting and presentation

**Easy searching, sorting and filtering** of all your control and audit data

Full audit trails and GLP reasons for changes record all actions taken within the program

**User account management options** for GLP and FDA 21 CFR Part 11 compliance

#### Comprehensively tested and validated

in accordance with our Quality Management System which is approved to ISO 9001:2008 incorporating ISO 90003:2004



## The secure solution for selection and presentation of Ames historical control data

As part of the OECD 471 guideline on the bacterial reverse mutation assay, laboratories are required to submit historical control data as part of a regulatory study. The historical controls module provides you with everything you need to achieve this, integrating with the Ames Study Manager to provide the complete solution for regulatory Ames testing.

We recognise that different laboratories take different approaches to how they manage their historical controls data. Whilst some laboratories include the very latest control data within their

Audit Trail Preferences Help							
earch Results: (5)	Plate Data:	(Control ID = 8	076)				
- 🔽 🕃 8076	Strain Code	A Plate Counts	Mean Count	59 Plus	Control Included	Control Type	
- 🔽 😳 8077	TA 100	12, 11, 10	11	-		Solvent	
Experiment E96899	TA 100	11, 9, 9	10	+	<b>v</b>	Solvent	
🖶 🚔 Experiment E116189	TA 100	3, 4, 7	5	-	<b>V</b>	Untreated	
😑 🖻 Folder for study 56534	TA 100	5, 2, 6	4	+	<b>v</b>	Untreated	
Study 6534     System 10863     Society 6534     Society 6534	TA 100	0, 0, 0	0			Viability	
	TA 102	0 T, 0 T, 0 T	0	-		Solvent	
e 🗸 😯 8079	TA 102	0 T, 0 T, 0 T	0	+		Solvent	
6 00 (s) 	TA 102	2, 3, 3	3	-	<b>V</b>	Untreated	
	TA 102	4, 1, 3	3	+	<b>v</b>	Untreated	
	TA 102	0, 1, 0	0	-		Viability	
	TA 1535	8, 9, 9	9	-	<b>V</b>	Solvent	
	TA 1535	13, 11, 10	11	+	<b>V</b>	Solvent	
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	TA 1535	2, 3, 3	3	+	<b>v</b>	Untreated	
	TA 1535	0, 0, 0	0	-		Viability	
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earch Ames Database for Control Da Search for					Study 6534           Study 10 : 2038           Atmin : Study 6534           Code: : 6554           Type: : Sandatardiad GLP Areas study           Study Debrie: : 0:: Edde Study           Study Debrie: : 0:: Edde Study		
Filter controls by date	/2006 🗘 🗸		06 🗘 💌				

reports, others will update their statistics on a monthly or yearly basis. Whichever method you use, the Ames Historical Controls program ensures that your data is kept safe and secure.

### Fast viewing and searching for quick access to all your historical control data

The program is designed to provide maximum flexibility, allowing you to instantly see which control sets have been included, as well as those that have been excluded. You can quickly search on controls from any date range, or see all controls performed using a specific methodology, e.g. pre-incubation. You can choose to include all controls used by a specific experiment or any subset of plates based on type, strain, S9 mix etc.

### Secure reporting via Excel for fast filtering and customisation of reports

The system comes with a set of pre-defined tabular reports, charts and graphs. Because reporting is managed through Microsoft Excel, you can quickly adapt these reports or even design your own to match your current format. Pivot tables within Excel allow instant filtering of control data based on strain, S9 mix, solvent or any other control information stored within the Ames Study Manager. This makes it easy to quickly create statistical tables, with ranges, means and standard deviations, based on precise search criteria.

#### Auditing and user administration helping you meet regulatory requirements

Audit trails monitor and record all changes to the historical controls data, including recording reasons for including and excluding individual controls. Audit data can be viewed from within the program or exported to Excel. The Ames Historical Controls program itself is protected using the same system of user control as the Ames Study Manager, allowing for centralised administration of all users through the System Access Manager for full compliance with the FDA 21 CFR part 11 final rule on Electronic Records and Electronic Signatures.

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