



# Ames Historical Controls

In regulatory Ames studies, historical control data must be presented with the findings of the study. The latest addition to the Ames Study Manager suite from Perceptive Instruments, the **Ames Historical Controls** module, provides a friendly easy-to-use method of reporting, auditing and producing statistics from your historical control data.

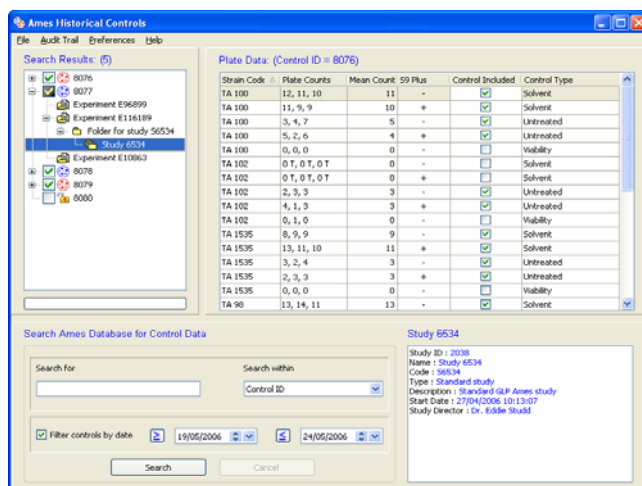
- **Achieve full regulatory compliance** by including historical controls in your Ames reports
- **Includes all statistics required by OECD 471** including ranges, means and standard deviations
- **Seamless integration with Microsoft Excel** for customised reporting and presentation
- **Easy searching, 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

## 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 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.

# PERCEPTIVE INSTRUMENTS

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