

## Astellas BQT Infectivity Assay Single Run Script SOP

## BAS-10228

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# Purpose

This standard operating procedure (SOP) describes how to set up and use the Astellas BQT Infectivity Assay Single Run JMP script to analyze and report relative potency calculations from the Astellas BQT Infectivity bioassay.

# Scope

JMP software and the JMP script are utilized according to procedures outlined in this SOP.

Details pertaining to the statistical analysis, acceptance criteria, and other details for the generated analysis report are beyond the scope of this SOP.

Details of the development of the Astellas BQT Infectivity Assay Single Run JMP script, including the automation of the statistical analysis for the Astellas BQT Infectivity bioassay, are outlined in the development report BAS-10205.

This document pertains to users with standard user access levels. System administration is beyond the scope of this SOP.

All instructions in this SOP are based on Microsoft Windows 11 Professional Edition. Any deviation between these instructions and the user’s operating system should be reported to Bioassay Sciences.

The JMP instructions in this procedure are based on JMP version 18.1.

# Resource Requirements

The following software and files are required for running the script:

1. Installation of JMP® 18.1.0.
2. Astellas – BQT Single Run.jmpaddin
3. Configuration file – A2767-BQT\_Infectivity-Configuration (.xlsx)
4. 2 Data files (.csv)
5. Astellas BQT Assay Tracking and Trending (.jmp)

Purchase and installation of the required version of JMP software is the responsibility of Astellas Gene Therapies. Data files are generated by Astellas Gene Therapies. The JMP script, JMP add-in, run file master, and tracking and trending table are provided by Bioassay Sciences.

# Directory Structure

## Parent Directory

The user must establish a parent directory where all subdirectories will be created. It is recommended that the user name the parent directory after the script name, such as ‘Astellas-BQT-INFECTIVITY1’.

## Environment Variables

An environment variable must be set within Windows to define an absolute path to the parent directory.

The user must set an environment variable for the script to read and store data in the correct path. The environment variable sets a path for the parent directory that contains all required folders.

To set an environment variable to the parent directory:

1. Open Windows ‘Settings’.
2. Navigate to ‘System’.
3. Select ‘About’.
4. Select ‘Advanced system settings’.
5. Select the ‘Advanced’ tab.
6. Select the ‘Environment Variables…’ button.
7. Under the ‘User variable for <username>’ window, select the ‘New’ button.
8. In the ‘Variable name’ text field, type ‘BQT\_INFECTIVITY1’.
9. In the ‘Variable value’ text field, select the ‘Browse Directory’ button and select the parent directory.
10. Select the ‘OK’ button.
11. After this window closes, select the ‘OK’ button again to accept and close the Environment Variables window.

## Folder Structure

Within the parent directory, the following folders must be created prior to inserting the required files:

1. Data File
2. Reports
3. Run File
4. Script
5. Tracking and Trending

Additionally, the following folders must be created within the ‘Reports’ folder:

1. Data Table
2. Journal
3. PDF

# File Setup

Before running the script for the first time, the required files must be placed into the folder structure established in the previous section as follows:

1. Place completed run files in the ‘Run File’ folder.
   1. Please see Section 7 for instructions on setting up run files.
2. Save exported data files into the ‘Data File’ folder.
   1. Organizing files in descriptive folder names based on the study is recommended.
3. Place the provided tracking and trending file ‘Astellas BQT Assay Results Tracking and Trending.jmp’ in the ‘Tracking and Trending’ folder.

# JMP Add-In Installation

A JMP add-in is a file in .jmpaddin format that allows the user to run the script from the JMP menu. Before first use, a JMP add-in must be installed within JMP 18.1.0.

## First Time Use Set-Up

Install the JMP add-in file (\*.jmpaddin):

1. Open JMP.
2. From the JMP main menu, select:
   1. File > Open
3. In the Open Data File window, navigate to the ‘Astellas – BQT Single Run.jmpaddin’ file and select ‘Open’.
4. From the JMP Alert window, select ‘Install’.

The add-in file will be installed in the JMP main menu as a dropdown under Add-Ins.

To rename the Add-Ins menu:

1. Right-click over the menu and select:
   1. ‘Customize’ > ‘Menus and Toolbars’.
2. Select ‘Add-Ins’.
3. Select the add-in to be edited from the dropdown menu on the left.
4. Enter the menu item name in the ‘Caption’ section on the right.
5. Select ‘OK’.

# Run File Set Up

First, make a copy of the fun file master.

Rename the run file to include the date, analyst initials and run number:

* Run File <DDMonYY> <initials> <#>.

Save the run file.

* Sequentially increase the number (#) when running more than one report in a calendar day with the same analyst.

Open the run file and enter the required information.

Save the file and then import it into the ‘Run File’ folder located within the parent directory.

# Running the JMP Script

## Execution of JMP Add-In

From the JMP menu bar, select Astellas BQT Assay Single Run. A dropdown appears. Select ‘BQT Assay Single Run Analysis’.

## Run File

Upon script execution, a ‘Select Configuration File’ window will appear, prompting the user to select a configuration file (.xlsx).

Select the run file within the ‘Run Files’ folder and select ‘Open’.

## Data File

After an appropriate run file is selected, a ‘Select Data File’ window will appear, prompting the user to select two csv data files. Select both data files by holding down ‘Ctrl’ on the keyboard and clicking on the two csv data files.

## Script Execution

The JMP script automatically begins importing data, performing statistical analysis, and saving all files. The script will then run to completion. If the final window does not appear, this indicates a run error. Script run errors should be reported to Bioassay Sciences.

Prior to script completion, the script will save all output files to their respective folders:

1. The script generates a JMP journal (\*.jrn) and saves it in the following directory:
   1. ‘Reports’ > ‘Journal’
2. The JMP script generates a PDF report (\*.pdf) and saves it in the following directory:
   1. ‘Reports’ > ‘PDF’
3. The JMP script generates the primary JMP data table (\*.jmp) and saves it in the following directory:
   1. ‘Reports’ > ‘Data Table’

## Script Completion

Upon script completion, the script displays a Script Status window indicating successful completion of the script.

Select ‘OK’ to close the Script Completion window.

Navigate to the parent directory within the operating system. Next, navigate to the following folders and verify the following files have been generated by the script:

1. Navigate to ‘Reports’ > ‘PDF’.
   1. Verify that a PDF report (\*.pdf) has been generated by the script.
2. Navigate to ‘Reports’ > ‘Journal’.
   1. Verify that a JMP journal (\*.jrn) has been generated by the script.
3. Navigate to ‘Reports’ > ‘Data Table’.
   1. Verify that a JMP data table (\*.jmp) has been generated by the script.
4. Navigate to ‘Tracking and Trending’.
   1. Verify that a single row of data has been generated by the script.