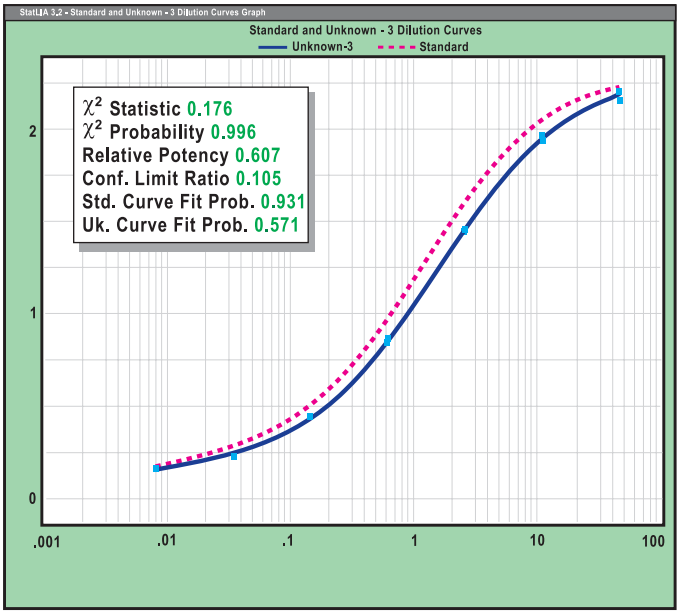

StatLIA®

χ^2 Method Well Referenced in Literature

European Pharmacopoeia. 5.3 Statistical Analysis of Results of Biological Assays and Tests.

Bates DM, Watts DG. *Nonlinear Regression Analysis and Its Applications* 1988, Wiley.

Draper NR, Smith H. Extra Sum of Squares and Tests for Several Parameters Being Zero, *Applied Regression Analysis* 1988, 3rd ed., 149-165.

Dudley RA, Edwards P, Ekins RP, Finney DJ, McKenzie IGM, Raab GM, Rodbard D, Rodgers RPC. Guidelines for Immunoassay Data Processing, *Clinical Chemistry* 1985; 31:1264-1271.

Finney DJ. Parallel Line Assays, *Statistical Methods in Biological Assays* 1978; 3rd ed., 69-132.

Gottschalk PG, Dunn JR. Measuring Parallelism, Linearity and Relative Potency in Bioassay and Immunoassay Data, *Journal of Biopharmaceutical Statistics* 2005; 3:437-463.

Gottschalk PG, Dunn JR. The Five-Parameter Logistic: A Characterization and Comparison with the Four-Parameter Logistic, *Analytical Biochemistry* 2005; 343:54-65.

BrendanScientific
TRUE STATISTICAL RELIABILITY

Research Center Plaza
2236 Rutherford Road, Suite 107
Carlsbad, California 92008
760.929.7500 760.929.7504 *Fax*
800.824.8842 sales@brendan.com

www.brendan.com

Full Curve χ^2 Parallelism Method Improves Accuracy and Reliability

Full Logistic Curve Parallelism
Are the two curves parallel? The new χ^2 method for computing parallelism, now available in StatLIA Version 3.2, significantly improves the accuracy and reliability of that determination.

Extension of Finney Method
The χ^2 method uses the well characterized extra-sum-of squares approach to calculate the optimal maximum likelihood estimate of non-linear curves for parallelism analysis.

Direct Measurement of Nonparallelism
This method provides, for the first time, a direct measure of the amount of nonparallelism present between the two curves. This means that you can use the nonparallelism metric, χ^2 Statistic, to establish a threshold empirically based upon historical data, or use the χ^2 Probability.

Powerful 5PL, Custom Weighting Improve Accuracy
StatLIA's industry leading weighted 5 parameter logistic model will fit the most severe nonlinear curve shapes. When compounds are not identical, their differences are often only apparent at the low or high ends of the dose response curve.

Ill-Behaved Cell-Based Bioassays
Because StatLIA determines weighted residuals from historical data, results are reliable whether data are from a well-behaved immunoassay or an ill-behaved cell-based bioassay.

Avoids Limitations of Other Methods
The χ^2 approach corrects the limitations of the F test, and provides a better result no matter how your data behaves. The χ^2 method does not falsely flag curves as nonparallel when the reference or unknown curves tightly fit the data points, or have large relative potencies.

Detailed Analysis of Data
The data provided in StatLIA's reports enable analysts to monitor assay performance to a degree not possible in other systems. By statistically comparing each assay's performance, StatLIA can identify failed assays before their results are reported, and verify good assays that otherwise would have been rejected.

21 CFR Part 11
StatLIA includes 10-level security, password aging, audit trails, and a complete Validation Package.

Proven Reliability
StatLIA is commercial off-the-shelf software that is used daily by thousands of scientists in the biopharmaceutical industry.

Adjust for Matrix Effect
The accuracy of the χ^2 method enables StatLIA to measure and correct for differences between different matrices.