precision bioassay inc

statistical solutions for practical bioassay problems

Precision Bioassay, Inc. presents Xymp® bioassay solution

Xymp® has three integrated modules, which provide a *comprehensive solution* designed to address challenging problems in cell culture bioassay.

- The first module drives pipetting robots to implement good plate layouts using statistical designs that incorporate blocks and randomization.
- The second module provides sophisticated outlier detection, permitting the user to choose whether or not to omit readings that deviate from expectation and may have resulted from procedural errors.
- The third module implements equivalence testing for similarity via mixed effects data analysis and delivers concise graphical summaries and potency estimates.

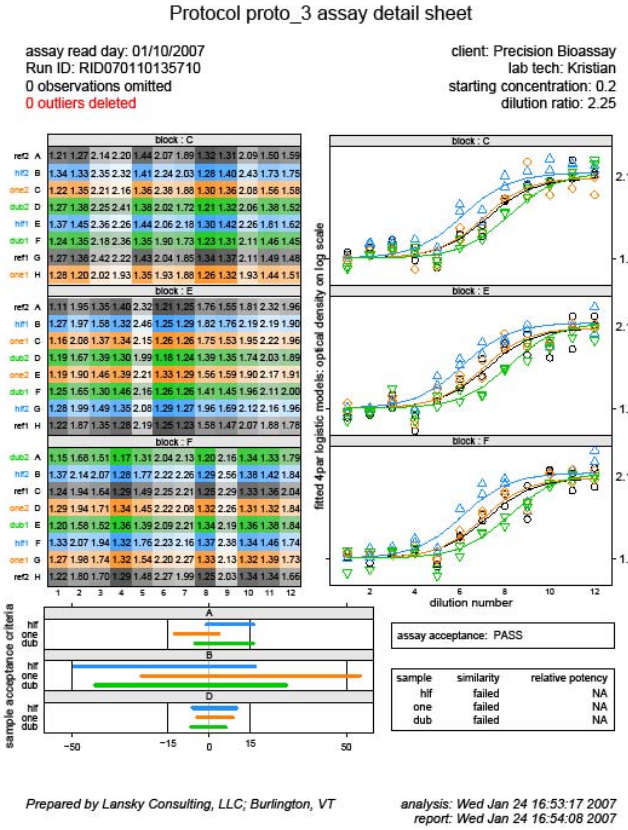
In a hand-in-glove fashion, robotically-randomized plate layouts coupled with sophisticated statistical analysis enable Xymp® to attain *higher precision* from existing bioassays. Higher precision bioassays require fewer replicates and allow *higher throughput*. Higher throughput equates with faster time to market and *increased value*.

The Xymp® Value

- Good experimental designs combined with state-of-the art statistical analysis lead to *high precision*
- High precision bioassay *cuts operating costs* bringing a value of approximately $350,000 per product during clinical development
- High precision translates to *high throughput*, which gets products to market sooner
- "A one-day speed advantage typically saves $37,000 in out-of-pocket development costs and nets an additional $1.1 million in daily prescription revenue for an average performing drug."
  (Tufts Center for the Study of Drug Development)

xymp®

Bioassay Solution



The Xymp® Detail Sheet concisely displays information about assay and sample acceptance criteria in a way that allows fast, easy diagnosis of assay problems. They enable bench scientists, managers, QA, and regulatory staff to quickly understand an assay and provide an impressive element of presentation to regulators.

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High Precision Bioassay

Our methods provide increased precision that routinely allows companies to cut lab effort in half and in some cases by an order of magnitude. This high precision is attained by applying the best of modern statistical methods for both design and analysis. Use of robotics allows routine randomization and sophisticated plate layouts for cell culture bioassay. Our statistical methods include appropriate selection of transformation, residual–based outlier detection, equivalence–based similarity assessment, and analysis via linear or nonlinear mixed models, shown to have clear advantages over weighted fits.

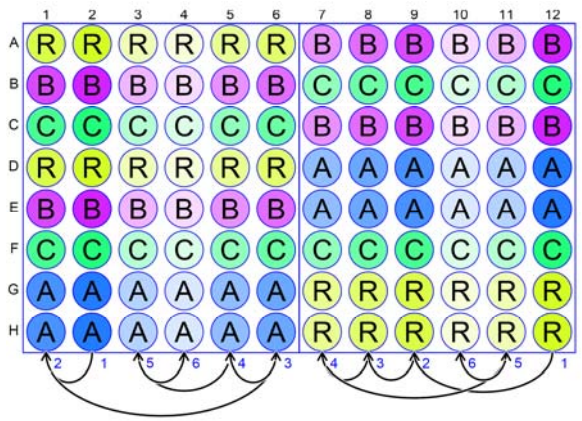
Benefits of Standardization

Our modular approach routinely delivers precise assays that require minimal development effort and enable standardized methods for validation. Experience with modular designs has shown that dozens of assays can be rapidly adapted to a standardized system with protocol changes isolated to a few modules. Best practices facilitate rapid regulatory approval.

Cost Effective Use of Robotics

Using our bioassay solution, four people and two pipetting robots were able to perform more assays on more samples with higher precision than seven people had been able to perform by hand. By spending less time hand–pipetting, the team had more time to focus on care of cells and designed experiments that refined the performance of the assays. They also were exposed to less risk of repetitive motion injuries.

Sophisticated Plate Layouts



use of blocks and random placement of samples

Sophisticated plate layouts, achievable using a pipetting robot such as the Precision™ XS, feature:

- Use of blocks (halfplate blocks illustrated) permitting variance decomposition analysis, which enables greater precision for focal variables
- Random placement of samples (A-C and Reference) in rows and serial dilution across a random sequence of columns (numbered arrows) guards against location effects and other sources of bias

Precision™ XS
Microplate Sample Processor

Precision Bioassay's Xymp® software drives pipetting robots. Sophisticated plate layouts that would be too confusing for technicians to implement manually are made feasible using this technology.

Image courtesy of BioTek

Payoff Table for Xymp® Bioassay Analysis

For an assay using good design (two plates, one reference sample and three test samples in each half–plate block), the Xymp® analysis required fewer than a third the number of passed assays to meet a 2–fold product spec compared to a typical analysis. Combining outlier detection and appropriate variance modeling tripled the rate at which assays passed compared to the typical analysis, yielding a combined impact of a 10–fold increase in expected throughput.

Analytic Method	Passed Assays Required per Sample	Pass Rate	Total Assays per Sample*	Throughput: Plates per Sample	
				Expected†	Ideal World§
Typical	**7.55**	**19.0%**	**39.74**	**26.42**	**5.03**
Xymp®	**2.40**	**61.9%**	**3.88**	**2.58**	**1.60**

* The total number of assays required is the passed number of assays divided by the pass rate.

† The expected number of plates needed per sample given the pass rate and the spec is 10 times lower using our analysis.

§ Even in an ideal world, where the pass rate would be 100% and the noise in the assay is unchanged, a Precision Bioassay analysis permits 3-fold increase in throughput.

Data derived from an actual experiment by one of our clients

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