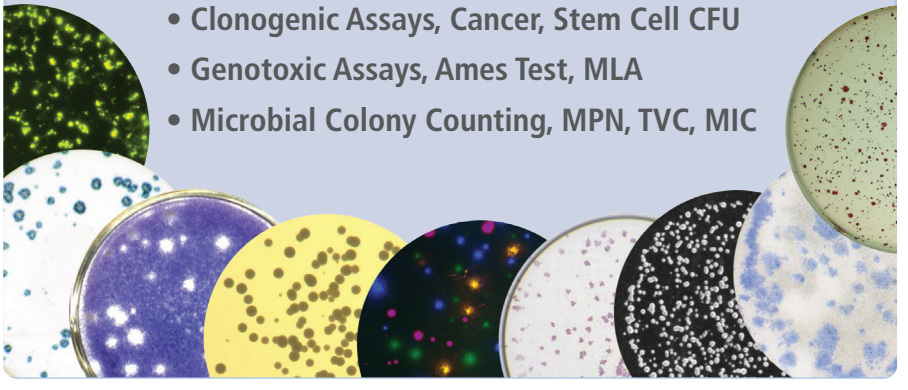
BioSpot™:High-throughput Analysis of Morphometric Bioassays™

The evaluation of many bioassays requires accurate recognition of complex optical patterns in test wells. While the expert's eye is remarkable in judging morphologies, visual evaluation is tedious, does not leave transparent audit trails, and is error prone. CTL has created a reader platform, BioSpot™, that evaluates these assays with the accuracy of an expert's eye, minus the shortcomings.

SOME OF THE MOST FREQUENTLY USED BIOASSAYS ARE PRESENTLY STILL READ BY EYE

- Viral Plaque Assays (PRNT, FRNT, PFU)
- Bacterial Colony Counting (SBA, SBT, OPK, OPA)
- Clonogenic Assays, Cancer, Stem Cell CFU
- Genotoxic Assays, Ames Test, MLA
- Microbial Colony Counting, MPN, TVC, MIC



Accuracy and Objectivity

Unlike visual analysis by different investigators or repeat analysis by the same one, the results produced by the BioSpot™ Platform will be identical and user-independent each time a plate is analyzed. Reading with the BioSpot™ Platform will eliminate the largest variable in these assays: subjective evaluation.

QC & Documentation

Regulatory agencies require stringent and transparent documentation of test results. The BioSpot™ Platform automatically retains complete audit trails for regu-lated work, including the tamper-proof archiving of the original digital images to-gether with counting results and possible revisions made in the quality control step.

Productivity and Streamlined Work Flow

Visual evaluation is typically the rate-limiting step that prevents the utilization of these assays to their fullest potential. The BioSpot® Platform acquires, images, counts, and documents in a fully-automated fashion at a rate of approximately one well per second. Plate loader integration, barcoding, and automated data evaluation further increase the high-throughput capability of the system.

Validation

Regulatory compliance requires validation of the assay itself, and of instruments used for evaluating such assay results. CTL offers an optional GLP package that enables 21 CFR Part 11 compliant work and we even provide IQ/OQ/PQ at installation.

Versatility

Morphometric assays are performed in a range of well formats (384-well plates to 100mm Petri dishes), using either visible or flourescent light for multicolor analysis. The requirements for optical resolution are unique to each assay. CTL offers a range of BioSpot™ instruments to accommodate these requirements. The CTL Technical Support Team will gladly assist you in tailoring a platform to suit your specific needs.

Adaptability

Each morphometric assay has unique requirements regarding optics, resolution, and pattern recognition for analysis. Also, high-throughput and GLP requirements are unique. CTL can help you customize a solution that meets your specific needs.

Realiability

With 20 years of experience, Cellular Technology Limited leads the field of bio-medical image analysis. More than 1600 customers worldwide have trusted CTL Readers and Software Solutions to meet their requirements, including the "who's who" of the biopharmaceutical industry.

BioSpot™ Main Features

- Compatible with all plate formats from 100mm Petri dish to 384-well microplates.
- Proprietary illumination enables detection of colonies as small as 25 micrometers in diameter.
- Ideally suited for rapid, high-throughput operations.
- Compliant with 21 CFR part 11 and GLP regulations when operated with BioCompliance™.

BioSpot™ Applications Microbial Assays

The ability to rapidly and reliably enumerate bacterial colonies is paramount for microbial load and bioburden testing in product safety markets. These include the food and dairy industries, environmental screening (water and air), personal care product testing, toxicology screening, and pharmaceutical testing.

Conventionally, these tests have been conducted manually with minimal throughput and high error rates. Recently though, there has been an extensive effort to develop alternative (rapid) methods to replace the slow and tedious traditional methods. The BioSpot™ product line enables miniaturization and automation of the standard plate count, thereby producing a dramatic increase in throughput and reproducibility.

Mammalian Colony Assays

Mammalian colony formation assays are an important tool in oncology and stem cell research, both of which rely on manual enumeration of colonies. Clonogenic assays, for example, are typically used for testing ionizing radiation and drug treatments for cancer therapeutic potential.

Stem cell assays are used to identify multipotent progenitor cells from bone marrow, cord blood and peripheral blood. Mammalian colony formation assays rely on the ability to distinguish colonies from a background of single cells. The BioSpot™ product line enables colonies to be size-selected for enumeration, thus only counting true colonies.

Viral Plaque Assays

Localized lysis of virus-infected cells in a confluent monolayer produces a plaque that can be detected through direct staining or by staining cells in the monolayer. Viral plaque assays utilize either a monolayer of mammalian cells or a bacterial lawn. The size and morphology of viral plaques is highly variable and notoriously difficult to detect and count.

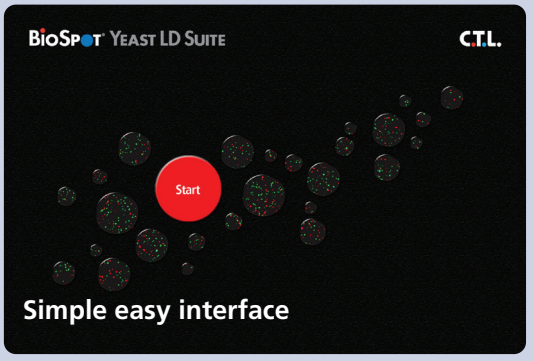
The BioSpot™ product line conducts multiple object-oriented morphometric measurements, enabling user-defined gating to separate plaques from a complex background. This compensates for the inherent variability in plaque assays and enables reliable enumeration.

Genotoxic Assays

Genotoxic assays are used to measure mutagenic potential by detecting forward or reverse mutations with selective media. Genotoxic assays use either mammalian cells (ie: mouse lymphoma assay) or microbes (ie: Ames test) and are easily imaged and counted using the BioSpot™ system.

CE
CTL Analyzers are manufactured under an ISO 9001:2008 Certified Quality Management System

SEEING IS BELIEVING



Schedule a demonstration today so we may present the sophisticated solutions the BioSpot™ platform offers.

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