Solentim

ICON™

A single instrument to measure titer, viable cell density and specific productivity (Qp) in the Cell Line Development of therapeutic antibodies

Exclude clones at multiple stages of Cell Line Development to select for the highest producers

ADVANCED INSTRUMENTS

The Cell Line Development workflow and where ICON fits...

STABLE POOL CREATION → SINGLE CELL ISOLATION → IN-WELL ASSURANCE → OUTGROWTH IMAGING → CLONAL GROWTH → CLONING PLATE ASSESSMENT → SHAKING EXPANSION → EXPANSION PRODUCTIVITY SELECTION → SUSPENSION VIABLE CELL DENSITY

Cloning Plate Titer Assessment

Productivity assessment at cloning plate stage to triage producing clones and focus on lead candidates.

InstiSHAKE™ Cell Supplement

Increased growth rates and viability when expanding from static to fed-batch shaking culture.

Productivity assessment

Measuring per well productivity at expansion stages to characterize lead clones.

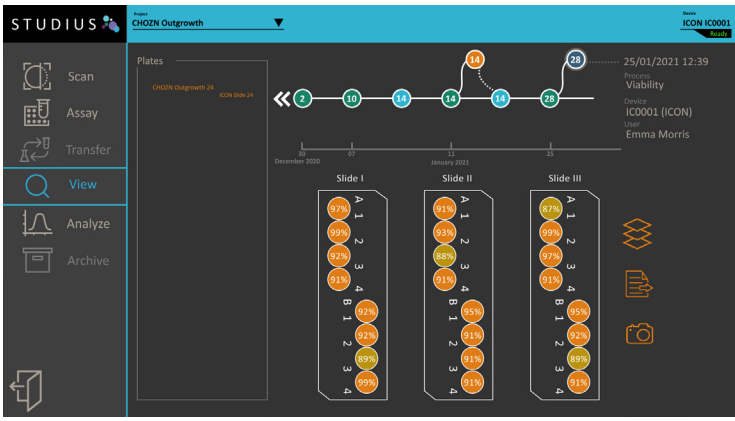
Automated cell counting

Rapid cell counting and viability measurements to track live cell concentration, growth and health.

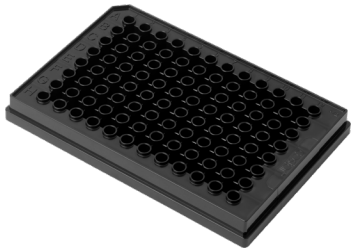
ICON and STUDIUS™ uniquely combine titer, viability and accurate productivity data using low volume assays on a single reader. ICON measures human IgG_1 titer, Viable Cell Density (VCD) and productivity (Qp) at various stages of the cell line development process for stable CHO cell lines producing therapeutic monoclonal antibodies. ICON is integrated into the STUDIUS decision making platform which combines ICON productivity data with clonality and confluence data from Cell Metric® and/or VIPS™ to rank clones automatically, instantaneously and without error.

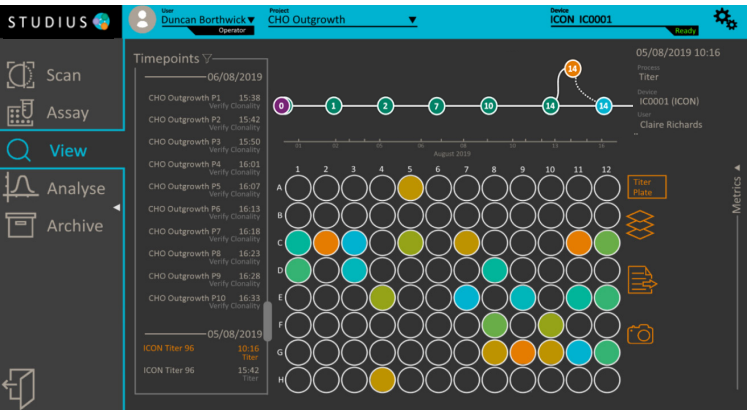
Viable cell density is measured on the ICON counting slides using Trypan blue exclusion

Cultures up to 10 million cells/mL can be rapidly counted using low sample volumes and the count result is qualified with a supporting high-resolution image showing the denotation of live versus dead cells with results stored in STUDIUS. ICON can run 24 cell viability samples in a single batch in under 4 minutes.

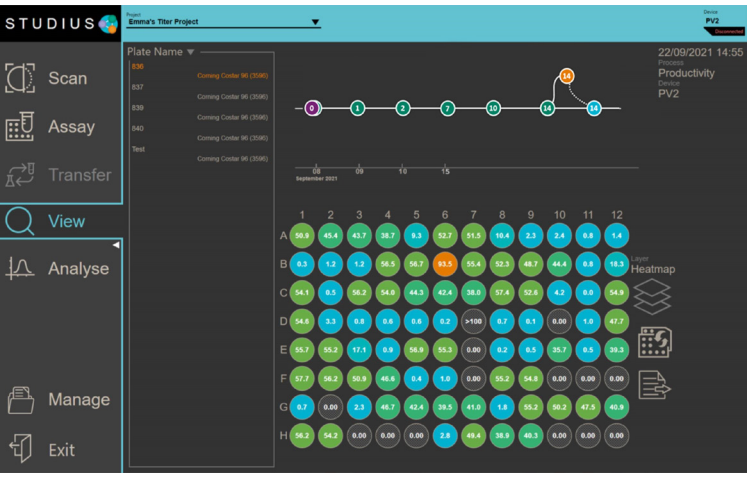


Titer is measured using fluorescence polarization with the proprietary ICON Titer and Titer PLUS plates



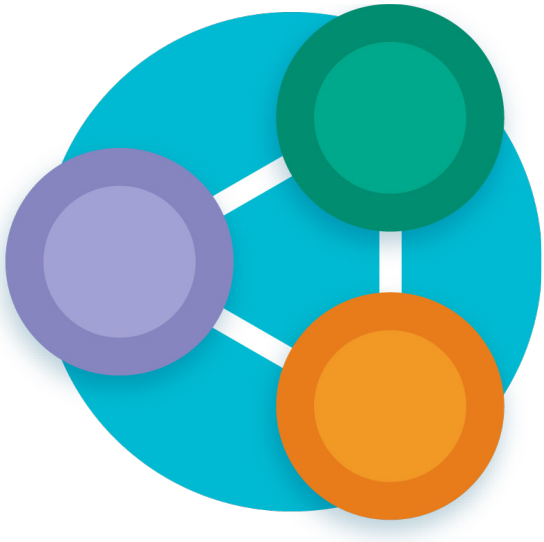


Titer results are stored in STUDIUS. ICON can measure 96 samples for titer in 6 minutes.



Titer and cell viability results can be combined within STUDIUS to generate a specific productivity (Qp) value.

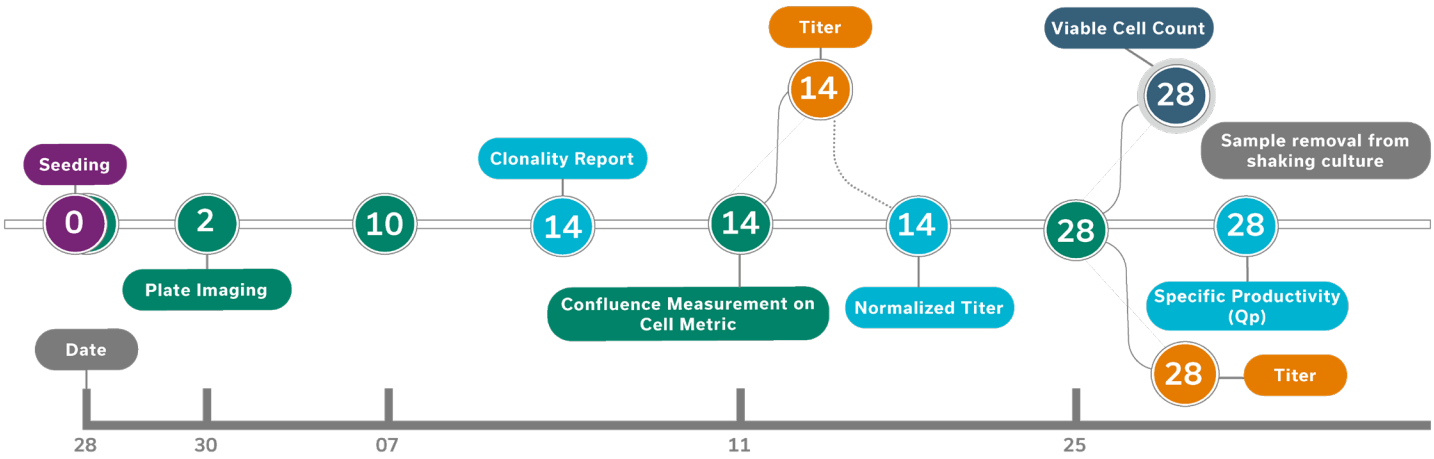
The STUDIUS powered ecosystem



STUDIUS is a data management and decision-making platform that drives ICON and provides consistency across the whole CLD process.

Titer and VCD data generated using ICON can be combined in STUDIUS to calculate specific productivity, allowing selection of the top producing clones.

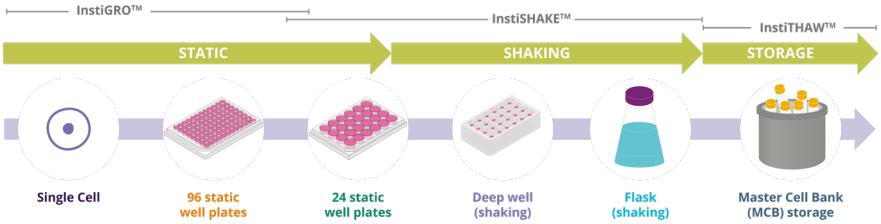
VIPS and Cell Metric data can be imported into STUDIUS to instantly rank best producing clones without the cumbersome, time-consuming and error prone process of comparing Excel spreadsheets and other data formats. STUDIUS also enables clones to be tracked throughout the CLD process from start to finish via nodes on the *HISTORYTREE*™ which enables the user to easily navigate each clone's journey through the workflow, with this tracking being agnostic to sample formats.



HISTORYTREE - a secure timeline showing a cell's journey through the cell line development process

Track and rank the best producers in fed-batch suspension cultures quickly and without error

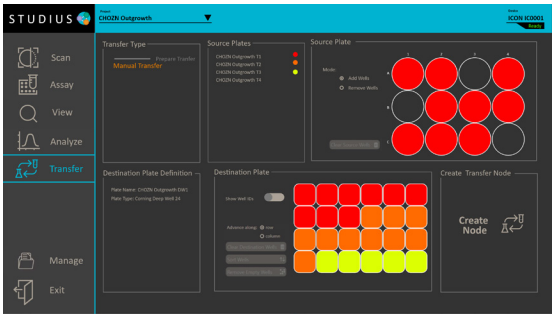
ICON occupies a unique position in the workflow between the cloning plate and scale down multi-parallel mini-bio-reactors such as the Ambr®.

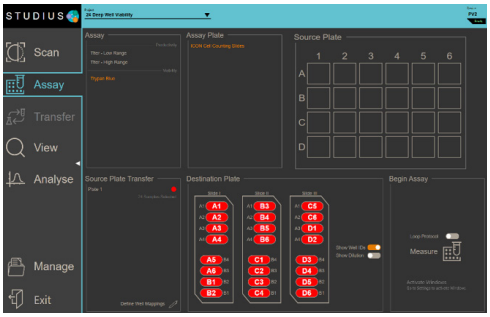


The Insti range of supplements is designed to enhance growth at different stages of cell line development for accelerated workflows.

At the suspension cell culturing stage of the CLD process, scientists are typically working with 80-100 clones in a variety of formats that could include 96, 48 and 24 deep well plates, spin tubes and flasks.

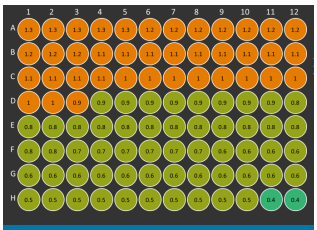
ICON together with STUDIUS allows samples to be tracked from their original cloning plates, onwards through other sample formats used during the suspension culture process up to scale down multi-parallel mini-bioreactor.





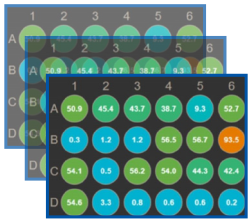
STUDIUS tracks the journey of individual clones from seeding to final selection, from 96 well plates through 24 DW blocks and other formats with an audit trail.

Consolidation of Producing Clones in Static Hit Plate



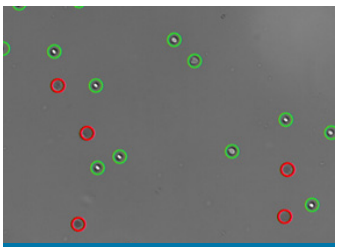
Check titer and normalize to confluence in static plates before suspension/shake culture stage

Expansion to Deep Well Shaking



Spin Tubes, Shake Flasks, Ambr 15

Titer

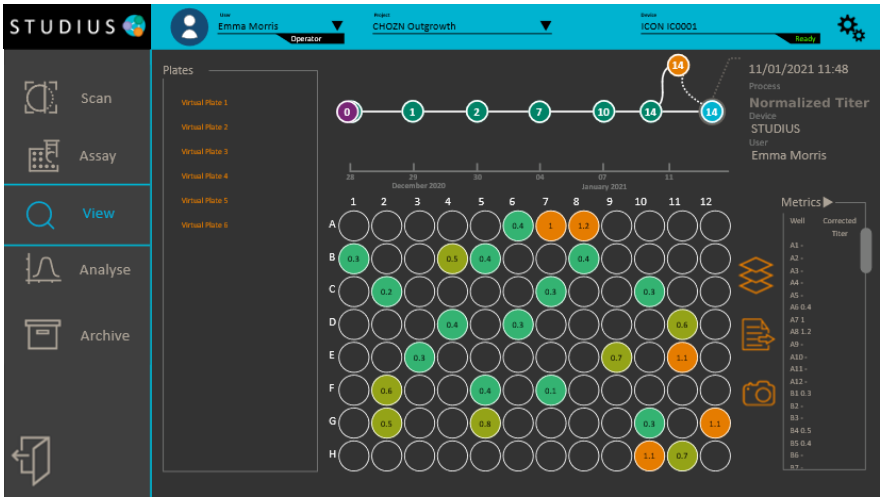


Automated Viable Cell Density

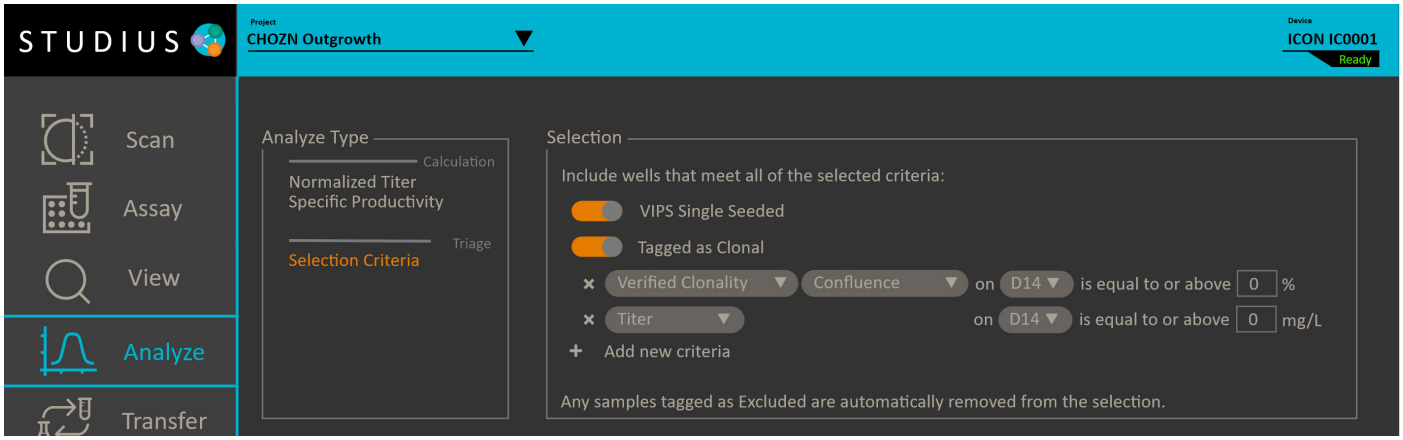
Specific Productivity (Qp) Calculations

ICON triages clones at multiple steps including IgG producers (versus non-producers) in the cloning plate, to the ranking of the highest producers in the suspension culture plates.

ICON can uniquely measure both titer and viable cell density in one instrument and can combine the results with confluence and clonality data within STUDIUS.



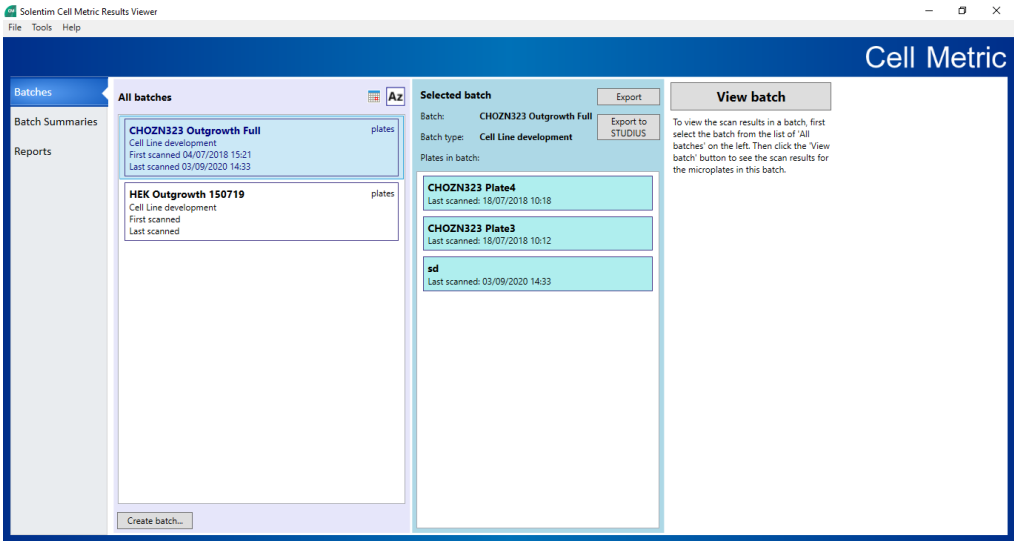
This process previously involved multiple instruments producing data in a range of formats leading to cumbersome, error prone analysis and Excel sheet comparisons. STUDIUS brings consistency and ranks clones automatically, instantaneously and without error.



Earlier stratification and ranking options for IgG producing clones

ICON titer assays need only a very small sample volume (60µL), allowing earlier titer measurements, for example in the Day 14 static cloning plates. “Producer” clones can then be selected from “non-producer” clones.

In addition, the imported confluence values from your Cell Metric or VIPS instrument can be combined with the ICON Titer measurements in STUDIUS to rank the clones for best producers. This calculation will generate another Analytical Node on the *HISTORYTREE*.



ICON is now part of the STUDIUS powered ecosystem for the digital transformation of Cell Line Development

Cell Metric

Cell Metric captures and records crucial evidence, whole well imaging of the single cell at day 0 and daily imaging after, all wrapped up in a clonality report defining industry-best practice for Master Cell Bank production.

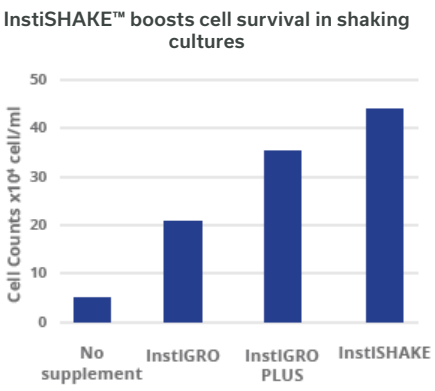
Available as a stand-alone single plate system, or with automated plate handling within a temperature-controlled environment from Cell Metric CLD or downstream third-party robotic integration.

Verified In-Situ Plate Seeding (VIPS)

Takes single cell cloning and image-based clonality assurance to a whole new level of quality. The multi-tasking, compact instrument delivers a high seeding efficiency, 'double-lock' imaging assurance solution for regulatory submission.

VIPS accelerates projects. Gentle, high efficiency seeding for both 96 and 384 well plates, single cloning round workflows for massively enhanced productivity and reduced timelines.

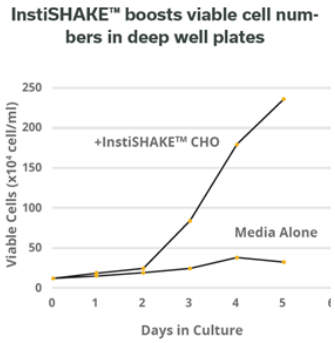
With VIPS, you get healthier cells, more confirmed single cells per plate and better colony outgrowth.



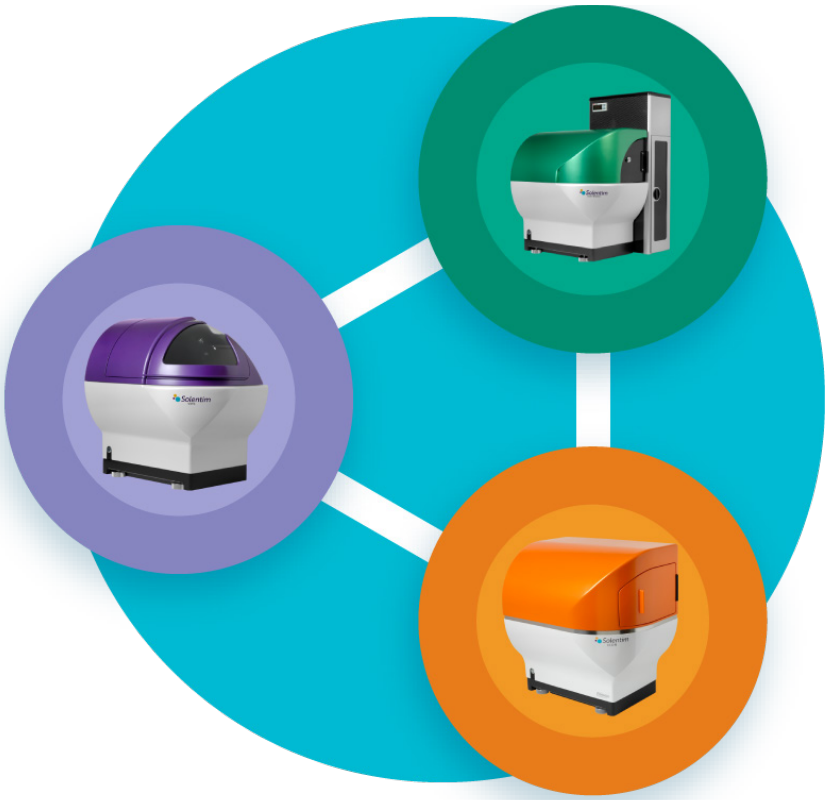
Impact of supplements when moving from 96 to 24 static wells at the day 15 cell count

Growth Supplements

Solentim offers a range of advanced cell growth supplements for use with CHO cells. The Insti range of supplements is designed to enhance growth at different stages of cell line development for accelerated workflows: InstiGRO™ to assist with early cell growth and single cell survival in the cloning plates, InstiSHAKE™ to boost cell survival in shaking culture and InstiTHAW™ to protect cells during freezing and thawing for cell banking.



Impact of InstiSHAKE supplement on the growth of CHO Cells in EX-CELL® CHO medium.



ICON forms part of an ecosystem of products along with the **Cell Metric** whole well imager and the **VIPS** single cell seeder for complete clonality documentation.

ICON, VIPS and Cell Metric data can be imported into the STUDIUS data mangement package and can be used for overall sample tracking from seeding to the top suspension IgG producing clones and for media optimization and growth studies on the Ambr. Using the STUDIUS software, high level analysis and enquiries can also be run to very quickly select the top producing clones which are additionally confirmed as being of clonal origin, courtesy of the Cell Metric/VIPS double-lock data.

This modular nature makes it a highly attractive platform for CDMOs where standardization around the industry-standard 96-well plate is essential. ICON combined with STUDIUS is also a powerful natural next progression for existing Solentim Cell Metric and VIPS customers.

STUDIUS driving the ICON makes this a 21 CFR part 11 compliant platform, which gives comfort for integrity and tracking of data.

About Advanced Instruments

Advanced Instruments is a global company offering a novel portfolio of analytical tools including, OsmoTECH®, a robust line of micro-osmometers to support bioprocessing and quality control (QC), and Solentim, a portfolio of best in class imaging and single-cell deposition technologies for cell line development workflows and assurance of clonality for regulatory bodies.

Our Solentim portfolio enables the clonal isolation, outgrowth, and characterization of the highest value cells for monoclonal antibody upstream development and cell and gene therapy. This enables our customers to use these clones and have the documentation they were clonally-derived to confidently form their Master Cell Banks.

ADVANCED INSTRUMENTS

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