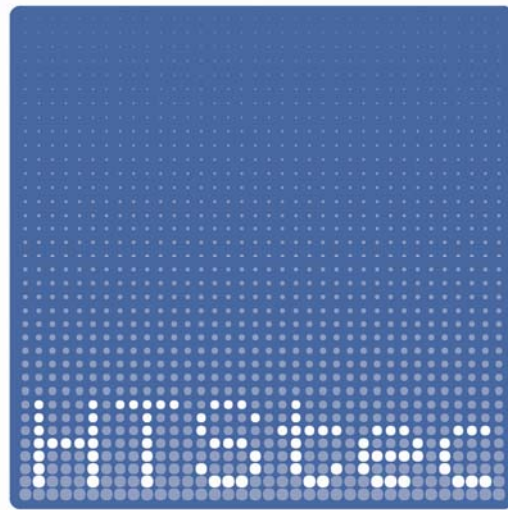


Cell-Based Label-Free Detection Trends 2008



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Executive Summary

- This market report summarizes the results of HTStec's global Pharma and Biotech web-based benchmarking survey on cell-based label-free (LF) detection carried out in January 2008.
- The study was initiated by HTStec to comprehensively document current interest, application focus and future market requirements for new plate-based LF detection technologies with application to cell-based assays. The report provides valuable information for vendors developing novel cell-based LF detection systems and assays, by providing them with the latest market intelligence in this rapidly emerging area.
- Equal emphasis was given to soliciting opinion from Pharma, Biotech and Academic Screening segments, in both North America and Europe.
- The survey looked at the following aspects of cell-based LF detection: familiarity with plate-based LF technologies; % of cell-based assays performed using LF technologies; plans to purchase new cell-based LF instruments; most important factors in the decision to purchase a plate-based LF technology; what respondents must be convinced about to move forward with the purchase of LF technology; reasons why the purchase of LF technology did not proceed; why some groups are still putting off adopting cell-based LF technologies; % of cell-based assays performed in different microplate formats; importance of 384-well and 1536-well biosensors plates to the adoption of a microplate cell-based LF technology; the importance of coated plates and of different microplate coatings; target class/application area where LF cell-based assays are expected to make the greatest impact; key cell-based application areas where respondents would like to deploy LF technologies; drug discovery areas where cell-based LF have shown potential; use of LF detection to successfully perform testing of 'difficult' targets; main advantages and limitations of LF cell-based assays; whether cell-based LF technologies are complimentary with or will displace existing assay technologies; real throughput (data point) experiences and user requirements for cell-based LF technologies; features or functionalities needed in a new microplate cell-based LF detection system; annual capital detection equipment and consumable budgets; and maximum price points for LF biosensor plates that could be used for cell-based assays. In many of the survey questions feedback was obtained for today (2008), together with best estimates planned for the future (2010).
- The main questionnaire consisted of 26 relatively simple multi-choice questions and 3 open-ended questions. In addition, there were 7 questions related solely to survey demographics.
- The survey collected 107 responses (87 complete and 20 partially filled out) from 59 different organisations. Responses were split geographically 60% North America and 40% Europe.
- Survey respondents were drawn from persons or groups that are actively engaged (key users) in assay development and screening of cell-based assays who are currently using LF detection. Feedback was also obtained from persons considering the application of new plate-based LF technologies to cell-based assays in the future or those about to initiate the investigation/evaluation of LF readouts.
- Respondents came from the following types of different organizations: 29 Small-Medium Pharma & All Biotech; 13 Large Pharma; 16 University, Research Institute or Government Labs; and 1 Contract Research Organisation. The majority (82%) of survey respondents had a senior job role or position which was in descending order either: section/group leader; senior scientist/researcher; principal investigator; director; department head; lab manager; principal scientist; professor/assistant professor; and vice president.
- Survey respondents represented: 36 labs with multiple drug discovery roles; 21 assay development labs; 19 primary screening (HTS) labs; 8 hits-to-leads (lead optimization) labs; 6 secondary screening labs; 4 other labs; 3 compound profiling labs; 2 basic research labs; 2 life science research lab; 2 leads-to-candidate (ADME Tox/preclinical research) lab; 2 primary screening (focused libraries); and 2 therapeutic area (target identification/validation) labs.
- Survey results were expressed as an average of all survey respondents. In addition, the data was fully reanalyzed after sub-division into the following 6 survey groups: 1) Using Cell-Based LF Assays Today; 2) NOT Using Cell-Based LF Assays; 3) Large Pharma; 4) Medium/Small Pharma & All Biotech; 5) Europe; and 6) North America.
- Respondent's familiarity with plate-based LF technologies with application to cell-based assays was greatest for MDS Analytical Technologies CellKey™ System, followed closely by Corning Epic®.

- The median % all cell-based assays performed using LF technologies today (2008) was none, this % is expected to increase to 11–25% of assays in the future (2010).
- Quality of information was rated the most important decision factor in the purchase a plate-based LF technology with application to cell-based assays.
- Data reliability and robustness was rated the greatest influence that respondents must be convinced about before considering the purchase of a new LF technology.
- The main reason given for not proceeding with the purchase of a LF technology for cell-based assays was not enough interest across the organisation to justify purchase at this time.
- The proportion of all cell-based assays performed today (2008) in the main microplate formats were: 39% in 96-well; 47% in 384 well; 8% in 1536-well; and 6% in other. In the future (2010) use of 96-wells and other formats will decline, whilst use of 384-well and 1536-well formats will increase.
- The need for 384-well biosensor plates today, to aid the adoption of cell-based LF technology, was rated very important in all areas of drug discovery, apart from Hit ID (Primary Screening/HTS) where it was rated as critical. The need for 1536-well biosensor plates in the future was rated not important in all areas of drug discovery, apart from Hit ID (Primary Screening/HTS) where it was rated very important.
- The majority of survey respondents said that the availability of coated plates for LF cell-based assays was very important, with around a third of all LF cell-based assays estimated to need coated plates.
- Poly-D-lysine (PDL) was the microplate coating respondents most often used for their cell-based assays.
- GPCRs were rated the target class where LF cell-based assays are expected to impact the most, with a universal GPCR screen the key cell-based application.
- The drug discovery areas where LF approaches have already shown most potential today were assay development, compound profiling and lead identification/secondary screening. The areas where LF approaches are expected to make a significant role in future were hit ID (HTS) and lead optimization.
- A third of respondents have successfully used LF detection to perform testing against 'difficult' targets.
- The ability to work with primary or non-engineered cells was rated the main advantage of LF assays.
- Interpretation of the results was rated the most significant limitation of cell-based LF assays.
- The majority of respondents don't see LF displacing any existing cell-based assay technologies; they view LF to be complimentary with existing assay technologies.
- In terms of real screening experiences with the available commercial platforms for cell-based LF detection only limited throughput has so far been demonstrated, with users of Corning Epic® recording the highest number of wells (data points) processed per week.
- Respondent's throughput requirements for cell-based LF technologies in different areas of drug discovery were documented. For the most part these requirements greatly exceed that offered by existing instrument platforms.
- Thermal control was rated the feature/functionality respondents most needed in a new microplate-based cell-based LF detection system.
- Respondent's median annual budgets for capital (Capex) purchases (such as detection equipment like LF instruments) and consumables purchases (such as assay reagents, microplates and other consumables) were both in the range \$250K–\$500K per lab.
- Respondent's feedback on the unmet needs in cell-based drug discovery which they feel LF technologies may be able to address is documented.
- A total of 116 new cell-based LF instrument purchases were identified over the next 3 years. The market share of MDS Analytical Technologies CellKey™ System was estimated to be around 32% share, Corning Epic® 28% share and ACEA Biosystems RT-CES 20% share.
- A bottom-up model was developed around respondent's purchasing plans identified in this survey to calculate the global market for cell-based LF instruments instrument sales. The total market was estimated to be around \$25Million in 2008, equivalent to sales of at least 60 units per year. The market is expected to grow strongly in 2009 and 2010 and was segmented between Large Pharma and Small/Medium Pharma & All Biotech, and between Europe and North America. CAGR estimates for 2009 and 2010 were made for all market segments.
- Although for the most part the survey groups responded similarly, several interesting differences in the group responses were identified.

Table of Contents

Executive Summary	2
Table of Contents	4
Survey Methodology	5
Lab Origin of Survey Respondents	6
Geographic Origin of Survey Respondents	7
Organisational Origin of Survey Respondents	8
Respondent Breakdown by Lab Origin & Organisation	9
Makeup of Survey Groupings Used for Data Analysis (1)	10
Makeup of Survey Groupings Used for Data Analysis (2)	11
Job Role of Survey Respondents	11
Respondents Use of Cell-Based Assays	12
Familiarity with Plate-Based Label-Free Technologies with Application to Cell-Based Assays	13
Percentage of all Cell-Based Assays Performed Using Label-Free Technologies	14
Main Decision Factors in the Purchase of Plate-Based Label-Free Technologies for Cell-Based Assays	15
Greatest Influences in the Purchase of Plate-Based Label-Free Technologies for Cell-Based Assays	16
Reasons Given for Not Proceeding with the Purchase of Label-Free Technology for Cell-Based Assays	17
Reasons Given for Not Planning to Adopt Cell-Based Label-Free Technologies in the Next Few Years	18
Percentage of all Cell-Based Assays Performed in Main Microplate Formats Today and in the Future	19
Importance of Microplate Formats in the Adoption of Cell-Based Label-Free Technology (1)	20
Importance of Microplate Formats in the Adoption of Cell-Based Label-Free Technology (2)	21
Requirements for Coated Plates in Label-Free Cell-Based Assays (1)	22
Requirements for Coated Plates in Label-Free Cell-Based Assays (2)	23
Microplate Coatings Most Often Required For Cell-Based Assays	24
Summary of Survey Findings (1)	25
Target Classes/Application Areas Where Label-Free Cell-Based Assays Are Expected To Impact Most	27
Key Cell-Based Application Areas Where Respondents Would Most Like to Deploy Label-Free Technologies	28
Drug Discovery Areas Where Cell-Based Label-Free Approaches Have or Are Expected to Play a Significant Role (1)	29
Drug Discovery Areas Where Cell-Based Label-Free Approaches Have or Are Expected to Play a Significant Role (2)	30
Use of Label-Free Detection to Successfully Perform Testing of any 'Difficult' Cell-Based Targets	31
Most Significant Advantages of Label-Free Cell-Based Assays	32
Most Significant Limitations of Current Label-Free Cell-Based Assays	33
Existing Cell-Based Assays Respondents Expect Label-Free Technologies to Displace	34
Are Cell-Based Label-Free Technologies Complimentary to Any Existing Assay Technologies?	35
Respondent's Screening Experience Using Label-Free Technologies Platforms - Wells (Data Points) Processed per Week	37
Respondent's Throughput Requirements For Cell-Based Label-Free Technologies - Wells (Data Points) Processed per Day	38
Summary of Survey Findings (2)	39
Features/Functionalities Most Needed in a Microplate Cell-Based Label-Free Detection System	40
Interest in an Integrated Tip Wash Station Within a Cell-Based Label-Free Detection System	41
Annual Capital (Capex) Budgets for Purchasing Detection Equipment	42
Annual Consumables Budgets for Purchasing Assay Reagents, Microplates and Other Consumables	43
Maximum Price Points for Label-Free Biosensors Plates That Could Used for Cell-Based Assays (1)	44
Maximum Price Points for Label-Free Biosensors Plates That Could Used for Cell-Based Assays (2)	45
Respondent's Feedback on Unmet Needs in Cell-Based Drug Discovery Which They Feel Label-Free Technologies May Be Able to Address	46
Plans to Purchase New Cell-Based Label-Free Instruments	47
Vendor Market Share For New Cell-Based Label-Free Instrument sales	48
Cell-Based Label-Free Instruments Market Estimate (1)	49
Cell-Based Label-Free Instruments Market Estimate (2)	50
Summary of Survey Findings (3)	51

General Information on HTStec and HTStec's Trends Market Reports

- HTStec Limited an independent market research consultancy founded in September 2003 whose focus is on assisting clients delivering novel enabling platform technologies (liquid handling, laboratory automation, detection instrumentation and assay reagent technologies) to drug discovery. Over the past 4¼ years HTStec has published 31 market reports on drug discovery technologies and authored 21 review articles in Drug Discovery World.
- HTStec's Trends reports owe their origins to the need by developers and vendors of new enabling technologies in drug discovery to get up-to-date relevant market metrics on which to base informed business decisions.
- Typically focused on a specific market niche or segment, in many cases overlooked or frequently misunderstood by broader market studies.
- Investigations are mainly initiated in response to a sponsor's specific requests.
- HTStec's extensive experience of the market, both as a Pharma End-User and working for a major Life Science Tool Provider ensures the industry relevance of the market research collected.
- Based entirely on web-based feedback from potential customers drawn mainly from Pharma and Biotechs, although increasingly University and Research Institute labs are also being researched.
- Produced extremely rapidly and typically published within 3 weeks of starting the collection phase.
- Reports are short, concise and focused on giving readers the basic data, analyzed in several different ways.
- Limited to reporting the main findings alone, without exhaustive discussion on the relevance of the results.
- Market estimates are mainly based on bottom-up calculations and usually avoid attempts to forecast widely beyond the next 2-3 years. Full details on the derivation of market estimates are given so readers can apply their own factors and easily make alternative estimates if they prefer.
- Owing to the sensitivity of some of the data collected, all reference to the origin of participating companies is removed, data is pooled to get an industry average and the anonymity of all respondents fully preserved and guaranteed.
- Critically HTStec's Trends reports have generated much interest and acclaim amongst survey respondents, to whom they are made available free of charge (subject to acceptance of HTStec's copyright terms) so they can benchmark their internal processes.
- Unlike alternatives HTStec's Market Surveys and Report are aimed at giving readers, information they want and can rely on, not information they don't need, cannot easily discern or is of dubious authenticity.
- HTStec aims to be the premier global provider of highly focused market research on enabling technologies in drug discovery.
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