CIRCULATING TUMOR CELLS (CTC) TECHNOLOGIES
A MARKET INSIGHT REPORT

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- ANGLE plc (UK)
- ApoCell, Inc. (USA)
- Applied Precision, Inc. (USA)
- Applied Spectral Imaging, Inc. (USA)
- Atossa Genetics, Inc. (USA)
- AVIVA BioSciences Corporation (USA)
- BioCEP Ltd. (Israel)
- Biocept, Inc. (USA)
- BioFluidica, Inc. (USA)
- BioView Ltd. (Israel)
- Cancer Research UK Manchester Institute (UK)
- Canopus Bioscience Ltd. (Canada)
- CellTraffix, Inc. (USA)
- Celsee Diagnostics (USA)
- Clearbridge BioMedics (Singapore)
- Creatv MicroTech, Inc. (USA)
- Cynvenio Biosystems, Inc. (USA)
- CytoTrack ApS (Denmark)
- DTU Fotonik (Denmark)
- EMD Millipore Corporation (USA)
- eOptra LLC (USA)
- Epic Sciences, Inc. (USA)
- F. Hoffmann-La Roche Ltd. (Switzerland)
- Fluidigm Corporation (USA)
- Fluxion Biosciences, Inc. (USA)
- Genoptix, Inc. (USA)
- GILUPI GmbH (Germany)
- Greiner Bio-One GmbH (Germany)
- iCellate® AB (Sweden)
- Ikonisys, Inc. (USA)
- IMEC (Belgium)
- IV Diagnostics, Inc. (USA)
- Janssen Diagnostics BVBA (Belgium)
- Janssen Diagnostics, LLC (USA)
- Laboratory Dr. Pachmann (Germany)
- Miltenyi Biotec, Inc. (USA)
- OncoGenex Pharmaceuticals, Inc. (USA)
- OncoVista Innovative Therapies, Inc. (USA)
- Progenics Pharmaceuticals, Inc. (USA)
- R.G.C.C. International GmbH (Switzerland)
- RareCells SAS (France)
- RareCyte, Inc. (USA)
- ScreenCell (France)
- Silicon Biosystems SpA (Italy)
- SIMFO GmbH (Germany)
- STEMCELL Technologies, Inc. (Canada)
- TeloVISION, LLC (USA)
- Transgenomic, Inc. (USA)
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- Fluxion Biosciences Launches IsoFlux™ NGS Assay Kits for Circulating Biomarker Detection
- Biocept Introduces Clinical Research Services for Biomarker Detection in Circulating Tumor DNA
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Thermo Fisher Acquires Life Technologies
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Liquid Biopsy - Enhances Cancer Diagnosis and Treatment
Circulating Tumor Cell Enumeration Separation and Isolation of Live Tumor Cells
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1. SCOPE AND METHODOLOGY

Scope of the Study

RI Technologies brings an informative update on the Global Circulating Tumor Cell (CTC) Technologies market. This report on Circulating Tumor Cells (CTC) Technologies gives a market insight into technologies and services used for cancer detection. The market is analyzed by Cancer type into Prostate, Breast and Other; and by Function into Prognostics, Diagnostics and Therapy Management. The report serves as a guide to CTC industry, covering more than 200 companies that are engaged in CTC studies/screening, products and services. Major Contract Research Organizations, Research Institutes and Universities serving the CTC market are also covered in the corporate directory section of this report. Information related to recent product releases, product developments, partnerships, collaborations, and mergers and acquisitions is covered in the report. Compilation of Worldwide Patents related to CTC Technologies is also provided. A global perspective is presented along with regional analysis covering the regions of North America, Europe, and Asia-Pacific with 29 exclusive graphically represented exhibits.

The Circulating Tumor Cell (CTC) Technologies report is an ideal research tool providing strategic business intelligence to the corporate sector. This report may help strategists, investors, cancer product development companies, and biotechnology companies in--

- Gauging Competitive Intelligence
- Identifying Key Growth Areas and Opportunities
- Understanding Geographic Relevance to Product
- Knowing Regional Market Sizes and Growth Opportunities and Restraints
- Keeping Tab on Emerging Technologies
- Equity Analysis
- Tapping New Markets
2. REPORT SYNOPSIS

CTC Technologies – Introduction

Circulating Tumor Cells (CTCs) are assuming importance as a biomarker for companion diagnostics and early detection for cancer treatment. There are many unmet needs in cancer drug development. Studying of tumor clusters, cell circulation, assessing and correlating types of tumors with their functionalities are vital aspects of CTC studies. Hundreds of clinical studies testify the requirement of detection and molecular characterization of CTCs. Risk estimation, therapy monitoring, identification of targets, and understanding metastatic developments are essential research areas. CTCs are known to represent the biology of cancer, and high counts of CTC lead to negative prognosis. Phenotyping and genotyping CTC and further studies will reveal whether CTC can be used for directing general or targeted anti-cancer therapy.

CTCs were first identified in 1869 in an autopsy of the peripheral blood of cancer patients. The widely accepted definition of CTC is “cells associated with cancer in the blood of patients with solid tumors”. CTC cells have a nuclei, cytokeratin+ EpCAM+, and CD45-. Research studies suggest that CTC in other rare cancer have CD45+ cytokeratin+ cells. Oncology clinical trials include CTC assays while choosing a platform, method development, validation, and clinical trial implementation.

Personalized cancer care is possible with CTC detection and therapeutic research. The fluid phase of solid tumors is an emerging clinical tool in personalized cancer care and is an important third microenvironment in the development and progression of carcinomas. The HD-CTC assays (Scripps Research Institute) help in investigating the metastatic pathways in cancer patients and give more information on disease progression. Cancer cells that originate from primary or secondary sites circulate in the blood and either come out or lead to new tumor growth. Efforts are ongoing on translational research to identify the origin of CTCs, their circulation patterns, their destinations, and their influence on disease progression. CTCs can be now used as biopsy material and as a biomarker. Using molecular and cellular approaches, CTCs can be subtyped at the single cell level.

CTCs in Blood and DTCs in Bone Marrow

CTC is a good diagnostic marker but these might not provide the same information as the DTCs. A comparative study of CTCs and DTCs has not been done to a great extent. Firstly the number of CTCs obtained was lower than that of DTCs but this was probably dependent on the procedure used for CTC/DTC detection. There are some who believe that the CTC count was higher in bone-marrow positive cases and high-risk patients. Both CTCs and DTCs have been studied in patients at the same time but the concordance rates have been different. The differences might have been cased due to difference in technology used for study CTC and DTCs. Incidentally the disparity of CTC and DTCs count was seen in patients after adjuvant therapy and not before that and this indicates a difference in sensitivity of CTCs and DTCs to chemotherapy. DTCs are more likely to display stress response proteins that may help these to survive chemotherapy.

Circulating Tumor Cells and Their Clinical Significance

When a tumor progresses into malignant cancer, it sheds some of its cells which adhere to the outer layer of the blood vessel and then invade into the blood stream. These cells are referred to as circulating tumor cells or CTCs. These cells get lodged in another tissue or organ at a distant site and transform those cells
into malignancy. The result is development of cancer at a different site in the patient. In other words, the CTCs are the progenitors of cancer at a new site in the patient’s body. This phenomenon was named by Recamier as metastasis in 1800 itself. Metastasis is the major cause of death from cancer. The presence of CTCs was reported in the blood of a cancer patient as early as 1869 by Thomas Ashworth.

It is understood that initiation of breast cancer occurs generally when the size of the primary tumor is around 0.2 cm³. Some of the tumor cells undergo genetic changes that facilitate detachment from the basement membrane, pass through the extracellular matrix, and penetrate the capillary to get into the blood stream. After being transported by blood they get attached to the endothelium of blood vessel and escape from the blood vessel into the surrounding tissue. If the microenvironment there is favourable they begin to induce angiogenesis and initiate the onset of metastatic tumor.

**Detection of CTCs and its Significance**

Oncologists believe that detection of cancers other than blood cancers and their characterization would be greatly facilitated by identification of CTCs originating from epithelial tumors. This approach could be a suitable non-invasive biopsy that can substitute the conventional tumor detection and is largely applicable to breast cancer, prostate cancer, and colorectal cancer. In many breast cancer patients bone marrow shows the presence of certain cells known as disseminated tumor cells. These cells are different and do not respond to the chemotherapy given to the patient to control the breast cancer. They are potential metastatic cancer cells and are responsible for the recurrence of cancer elsewhere in the body despite chemotherapy treatment given for the primary cancer. Therefore, the importance of detection and characterization of CTCs need not be overemphasized.

In breast cancer a positive correlation between bone marrow CTCs and cancer prognosis has been supported by some researchers and negated by others. This controversy may probably be attributed to the differences pertaining to the methodologies followed for detection of these cells. Research works reveal that it is not necessary that every CTC should culminate in the formation of metastasis. In fact, many of these detached cells are destroyed while circulating in the blood. However, the early detection of these cells may guide the physician to decide on the appropriate course of treatment that would prevent metastatic cancer. In fact, it is difficult to detect CTCs that exist in low concentration in the range of one cell per million hematopoietic cells. It is imperative that evolving accurate analytical methods is the need of the hour. At present the prediction with regard to the onset of metastasis in patients treated for breast cancer gives only statistical figure pertaining to a population. But what is actually needed is to predict the possibility for recurrence of this disease at a new site in each individual patient.

### 2.2 Segmentation

**Exhibit 1. Segmentation of Global CTC Technologies Market by Cancer Type and by Function**

<table>
<thead>
<tr>
<th>Cancer Type</th>
<th>Function</th>
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<td>Prostate</td>
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<tr>
<td>Breast</td>
<td>Prognostics</td>
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<tr>
<td>Other*</td>
<td>Therapy Management</td>
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</table>

*Other* includes Colon, Pancreatic, etc.

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2.3 CTC Technologies - Global Market Analysis

Global CTC Technologies market is predicted to reach US$ XX.XX billion in 2020, at a CAGR of XX.XX %, from an estimated US$ XX.XX billion in 2014. The market is further projected to cross US$ XX.XX billion mark by 2022.


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<td><strong>CAGR% (2015-2022)</strong></td>
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3. MARKET DYNAMICS

3.2 Global CTC Technologies Market Analysis

North America is the largest CTC Technologies market holding share of \(XX.XX\%\) worth US$ \(XX.XX\) million in 2014. At a CAGR of \(XX.XX\%\), the North American market is expected to reach about US$ \(XX.XX\) billion in 2018 and about US$ \(XX.XX\) billion by the year 2022. Asia-Pacific is projected to represent the fastest growing market with a CAGR of \(XX.XX\%\), followed by Europe with \(XX.XX\%\) for the analysis period 2015-2022. The global market shares of North America, Europe, Asia-Pacific and Rest of World are expected to be \(XX.XX\%\), \(XX.XX\%\), \(XX.XX\%\), and \(XX.XX\%\) respectively by the year 2022.


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<th>Year/Region</th>
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Exhibit 5. CTC Technologies – Global Market Shares (2012, 2018 & 2022) for North America, Europe, Asia-Pacific and Rest of World

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### 3.7 Analysis by Cancer Type

In the global market, CTC Technologies for Prostate cancer has the largest share with \( xx.xx \% \) in 2014 and is worth around US$ \( xx.xx \) million. The value is expected to rise to US$ \( xx.xx \) million by 2015, and is further projected to reach a high US$ \( xx.xx \) million in the year 2020. Also, the market value of Breast Cancer CTC Technologies is expected to grow at the fastest rate with a CAGR of \( xx.xx \% \).

**Exhibit 18. CTC Technologies by Type – Global Market – Historic, Current, and Forecast (2010 - 2022) in US$ Million for Prostate Cancer, Breast Cancer and Other**

<table>
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3.9 Circulating Tumor Cells (CTC) Technologies – Market Outlook

Global CTC Technologies market is predicted to reach US$ XX.XX billion by 2022, from an estimated US$XX.XX billion in 2014.

The biggest technical challenge is CTC detection despite the continued development of many new technologies. The key need is for a technology that will detect the real metastasis-initiating CTC which in turn will trigger distant metastases. This may be a combination of complementary technologies or even several technologies optimized for specific tumor types. CTC enrichment depends on the different properties of CTCs that distinguish them from the surrounding normal hematopoietic cells; physical properties; and biological properties. Most of the current technologies are still based on epithelial cell adhesion molecule (EpCAM) expression. New emerging technologies may try to capture EpCAM-negative CTCs.

4. COMPETITOR DYNAMICS

4.1 CTC Technologies Providers – Competitor Profiles

Abnova Corporation (Taiwan)
AdnaGen AG (Germany)
Advanced Cell Diagnostics, Inc. (USA)
Affymetrix, Inc. (USA)
ANGLE plc (UK)
ApoCell, Inc. (USA)

More….

4.2 Significant Market Developments

Fluxion Biosciences Enters into Liquid Biopsy Collaboration with University Of Texas Health Science Center
Biocept and MedStar Georgetown University Hospital Collaborates for Liquid Biopsy Study
Menarini-Silicon Biosystems Launches DEPArray™ NxT Digital Cell-Sorting System
Fluxion Biosciences Launches IsoFlux™ NGS Assay Kits for Circulating Biomarker Detection
Biocept Introduces Clinical Research Services for Biomarker Detection in Circulating Tumor DNA
DeNovo Sciences Introduces JETTA100, Its First Commercial Instrument and Consumables
Thermo Fisher Acquires Life Technologies
Fluxion Biosciences Includes Clinical Sample Procurement to Expand IsoFlux Discovery Services
Epic Sciences and LabCorp Collaborate to Expedite European Clinical Sample Processing for CTC Technology
National Cancer Centre Singapore Partners with Clearbridge BioMedics Establishes "Singapore CTC CoRE"

More…….
5. PRODUCT/TECHNOLOGY RESEARCH

Circulating Tumor Cells (CTCs) – Key Observations

CTCs and their biological relevance are not free from controversies. Technical issues related to detection and quantification methods, shedding from primary sites, and heterogeneous cell populations are some of the areas of focus. Though millions of CTC are shed during the course of a given cancer, some may gain dormancy for a few years and may regain activity in generating metastasis.

Single circulating tumor cells captured with Geometrically Enhanced Differential Immunocapture (GEDI) are being probed to identify genomic content and functional response to chemotherapeutics. GEDI microdevices are used to isolate CTCs from patients with prostate and pancreatic cancer while rejecting contaminating leukocytes. Functional response is probed by using both genomic analysis and in situ immunostaining.

CTC Detection

The Hampering Facts

- lack of concordant results obtained from the various detection methods
- Isolation and detection is difficult owing to their low concentration in bone marrow or blood
- CTC detection is a technical challenge owing to the presence of other cellular contaminants, including other circulating blood cells and normal epithelial cells

Exhibit 1. Novel Methods for Circulating Tumor Cell Identification and Main Conclusion(s)

<table>
<thead>
<tr>
<th>Study</th>
<th>CTC Enumeration Method</th>
<th>Main Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antolovic et al.</td>
<td>Immunomagnetic enrichment and CK20 RT-PCR</td>
<td>The clone used as an antibody for EpCAM-based enrichment alters results significantly</td>
</tr>
<tr>
<td>Chen et al.</td>
<td>KRAS membrane array</td>
<td>KRAS membrane array is sensitive and specific when used on CRC blood samples.</td>
</tr>
<tr>
<td>Findeisen et al.</td>
<td>346 candidate genes</td>
<td>SERPINB5 expression is elevated in CRC blood</td>
</tr>
<tr>
<td>Gervasoni et al.</td>
<td>CK20, CK19, CEA, and GCC RT-PCR</td>
<td>CTCs can be predicted by CK20, CK19, CEA, and GCC together</td>
</tr>
</tbody>
</table>

More...

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- Gauging Competitive Intelligence
- Identifying Key Growth Areas and Opportunities
- Understanding Geographic Relevance to Product
- Knowing Regional Market Sizes and Growth Opportunities and Restraints
- Keeping Tab on Emerging Technologies
- Equity Analysis
- Tapping New Markets

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<th>Potential Client Speak –</th>
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<tbody>
<tr>
<td>&quot;I need to focus on strategic opportunities&quot;</td>
<td>- Sales &amp; Marketing Professional</td>
</tr>
<tr>
<td>&quot;Am I spending on the right content?&quot;</td>
<td>- Resource Librarian</td>
</tr>
<tr>
<td>&quot;I require easy methods to search and share reports and insights&quot;</td>
<td>- Market Research Professional</td>
</tr>
<tr>
<td>&quot;I need market research that helps us make strategic decisions, keep pace and lets us keep control too&quot;</td>
<td>- Company Head</td>
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