Circulating Nucleic Acids (CNAs) Based Non-invasive Cancer Diagnostics: Global Market Report

Executive Summary

ES.1 Introduction to the Circulating Nucleic Acid Market Report

The aim of this report was to review recent advances in use of circulating cell-free miRNA, DNA and mRNA as novel biomarkers which can be used for the detection and diagnosis of cancer, and the impact on making the ongoing research closer to clinical application. The report will also provide a market analysis of the market value, growth rates, market development as well as examining the dynamics and factors influencing the growth and development of this market. This report also looks at the challenges and potential threats facing the industry players, and the factors influencing the market shares of both the major market suppliers and smaller indigenous manufacturers in local markets.

The data collection and forecasting methods used in the preparation of this report are broadly divided into three methods. These are primary data and information gathering, secondary data and information gathering and market share analysis and market forecast prediction. Information and data including estimates on market values, growth rates and market share data were gathered from the methods described and were incorporated into proprietary computer forecasting and market share analysis models. The forecast model was used to derive market estimates for future years. It incorporates a rate factor, which helps determine the speed with which the market develops, which is similar to that observed for markets for other medical products and is adjusted to match historic data for the market under analysis.

ES.2 Background to Circulating Nucleic Acids

This chapter reviews the historical developments that have excited researchers and clinicians alike illustrating the practical applications for elevated circulating nucleic acids (CNA) levels for the detection of cancer and identifying the different categories or types of CNAs which are known to be present circulating in serum and plasma. This chapter also identifies the top molecular CNA characterisation techniques and technologies which are used to identify and measure CNAs.

Since the discovery of circulating nucleic acids in plasma in 1948, many diagnostic applications have emerged. For example, diagnostic and prognostic potentials of circulating tumor-derived DNA have been demonstrated for many types of cancer. The parallel development of foetal-derived DNA detection in maternal plasma has opened up the possibility of non-invasive prenatal diagnosis and monitoring of many pregnancy-associated disorders. This is the subject of a distinct report also available from Veracity Health.

ES.3 Cancer: A Statistical Analysis of the Disease Incidence and Prevalence

Cancer is a class of many diseases characterized by uncontrolled division of cells and the ability of these cells to invade other tissues, either by direct growth into adjacent tissues or transportation through the blood or lymphatic system into distant sites by metastasis. Although cancer may occur at any age, risk increases as one ages, and the disease is one of the leading causes of death in industrialized countries.

Severity of symptoms depends on the site and character of the malignancy and whether metastasis is involved. A definitive diagnosis typically requires histologic examination of tissue obtained by biopsy or surgery. Most cancers may be treated and some cured, depending on the type, location, and stage. Once diagnosed, cancer typically is treated with a combination of methods including chemotherapy, radiotherapy, and surgery.

A detailed analysis of the estimated global incidence rates, mortality rates and 5-year prevalence rates for both males and females by cancer types in 2012 has been carried out illustrating the depth and breadth of this global issue.

ES.4 CNA Based Cancer Diagnostics Market: Revenue Analysis

An analysis of the revenues and forecasts for the global cancer CNA biomarker market with a further more detailed analysis and forecast of the revenues for the global market sub-divided by major market sub-segments by geographic region and finally by selected country.

This chapter also reviews the principal market drivers and restraints affecting and influencing the development of this market.

Please note that with the exception of North America each of the geographic regions analyzed include other individual countries in these geographic regions. For the purposes of clarity within this report although these other remaining countries in these geographic regions have been analyzed the market values and market shares have not been included. Should the reader require more detailed information about these countries the author of this report will be able to provide a customized report providing the additional information that would be required.

Exhibit E.S. 1 provides a summary review of the revenue forecasts analysis for global non-invasive cancer diagnostics market utilising technologies associated with the detection of circulating nucleic acids between 2010 and 2020.

Exhibit E.S. 1: Global Market Revenue Forecast - CNA Based Non-invasive Cancer Diagnostic Products (2010 – 2020)

Year	Revenues ($ millions)	Revenue Growth Rate (%)
2010	0	---
2011	3.6	>10,000
2012	30.8	760.9
2013	186.8	507.5
2014	xxx	xxx
2015	xxx	xxx
2016	xxx	xxx
2017	xxx	xxx
2018	xxx	xxx
2019	xxx	xxx
2020	6,216.5	33.3
CAGR (2013-2020)		65.0

Source: Veracity Health

Veracity Health has determined that the global market was almost non-existent as products had not been available commercially in 2010. By the year 2013 a number of commercially available products had entered the market. By 2013 the global market had increased in value to an estimated $186.8 million and by using a proprietary forecast spreadsheet which took into account the market variables a prediction that by the end of the forecast period the market is predicted to grow to $6,216 million (CAGR 2013-2020 of 65.0%).

The valuation of the market reflects the changes to the economic, demographic and market variables which are affecting the value of the market. These include the:

- predicted relative decrease in product pricing as the market matures and as new lower priced products enter the market over the forecast period,

- impact of the greater access and acceptability of non-invasive cancer diagnostic testing in preference to the traditional methods of invasive sample testing and imaging technologies.

- impact of the current global recession and its effect on the funding of national healthcare systems and specifically the diagnostics services within each national state.

ES.5 CNA Based Cancer Diagnostics Market: Market Share Analysis

An analysis of the global market share together with a further more detailed analysis of the market share by geographic regions and finally by selected country has been provided. This illustrates the structure and organisation of the current market, highlighting the leading players and other companies operating in it.

Exhibit E.S. 2 provides a summary of the market shares for the global non-invasive cancer diagnostics market based on circulating nucleic acids and technologies associated with the detection of CNAs market in 2013. The global market is highly fragmented as a result of the wide variety of different new and innovative technologies which have been developed and

currently available and new technologies which are presently in the research phase and/or being developed.

The leading companies as identified in this analysis are Qiagen N.V., Invitrogen, Roche, Thermo Fischer Scientific, Inc (Life Technologies), Illumina, Affymetrix, Becton, Dickinson and Company, Siemens and Hologic Gen-Probe. It has been estimated that the top 6 majorplayers as shown in Exhibit E.S. 2 and illustrated in Exhibit E.S. 3 account for an estimated 60.4% of the global market in 2013 with the market leader Qiagen N.V., accounting for 18.8% of the market or the equivalent of $35.1 million in revenues.

Veracity Health has determined that Invitrogen is the second largest supplier of current non-invasive cancer diagnostic products with an estimated 10.1% of the global market or the equivalent of sales valued at $19.0 million. Invitrogen is one of several brands under the Life Technologies brand of the Thermo Fischer Scientific corporation. The market share of Invitrogen in combination with Life Technologies is estimated to be approximately 19.1% and in some specific countries is higher.

Exhibit E.S. 2: Global Market Share Analysis – CNA Based Non-invasive Cancer Diagnostic Products (2013)

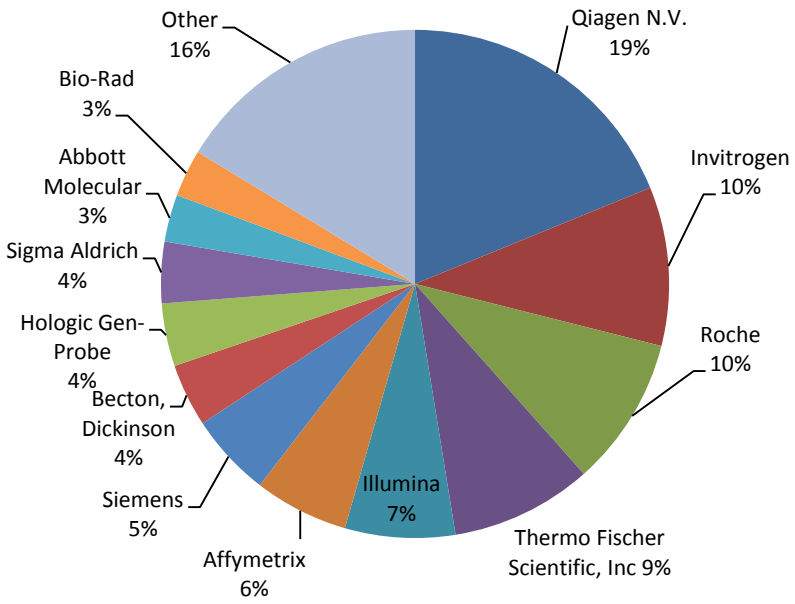
Company	Market Share (%)
Qiagen N.V.	18.8
Invitrogen	10.1
Roche	9.5
Thermo Fischer Scientific, Inc (Life Technologies)	9.0
Illumina	7.0
Affymetrix	6.0
Siemens	5.3

Becton, Dickinson and Company	4.0
Hologic Gen-Probe	4.0
Sigma Aldrich	3.9
Abbott Molecular (Abbott Laboratoires)	3.0
Bio-Rad	3.0
Other	16.3
Total	100.0

Others include: bioMérieux, Dako (Agilent), Promega Corporation, Cytocell, Novartis Diagnostics, Myriad Genetics, Cepheid and Others.

Source: Veracity Health

Exhibit E.S. 3: Global Market Share Analysis – CNA Based Non-invasive Cancer Diagnostic Products (2013)



Others include: Biomérieux, Dako (Agilent), Promega Corporation, Cytocell, Novartis Diagnostics, Myriad Genetics, Cepheid and Others.

Source: Veracity Health

ES.6 Company Profiles

This chapter provides the profiles of the leading 25 companies involved in the development, manufacture and marketing of devices which incorporate the technologies used for the detection of CNAs. It provides a review of their historical development, main product areas, including products in developments, as well as short reviews of their key proprietary technologies.

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