The Global Non-invasive Prenatal Diagnostics Market

Executive Summary

ES.1 Introduction to the Non-invasive Prenatal Diagnostics Market

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 as a non-invasive method for prenatal diagnostics. The report will also provide a market analysis of the market value, growth rates and 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, and the factors influencing the market shares of the major market suppliers as well as 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 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 fetal-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 Market Revenue Analysis: Non-invasive Prenatal Diagnostics

An analysis of the revenues and forecasts for the global non-invasive prenatal diagnostics (NIPD) 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 principle 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 remaining countries in these geographic regions. For the purposes of clarity within this report although these other individual 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.

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 driving the global market to an estimated value of $329.6 million. By using a proprietary

forecast spreadsheet which took into account the market variables it is predicted that by 2020 the market is set to grow to $2.61 billion (CAGR of 34.4%).

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 prenatal diagnostic testing in preference to the traditional methods such as amniocentesis.

- 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.4 Market Share Analysis: Non-invasive Prenatal Diagnostics

Exhibit E.S.1 provides a summary of the market shares for the global non-invasive prenatal diagnostics (NIPD) market in 2013.

The global market is dominated by 5 major suppliers i.e. Sequenom, Inc, Ariosa Diagnostics, BGI Diagnostics (Division of BGI), Natera and Verinata Health (Illumina). These top 5 suppliers accounted for an estimated 92.9% of the global market in 2013 with the market leader Sequenom, Inc holding a 40.6% share of the market.

In addition a number of smaller companies such as, Ravgen, Cellular Research and Trovagene are emerging who could challenge the market leadership positions of the current leading suppliers.

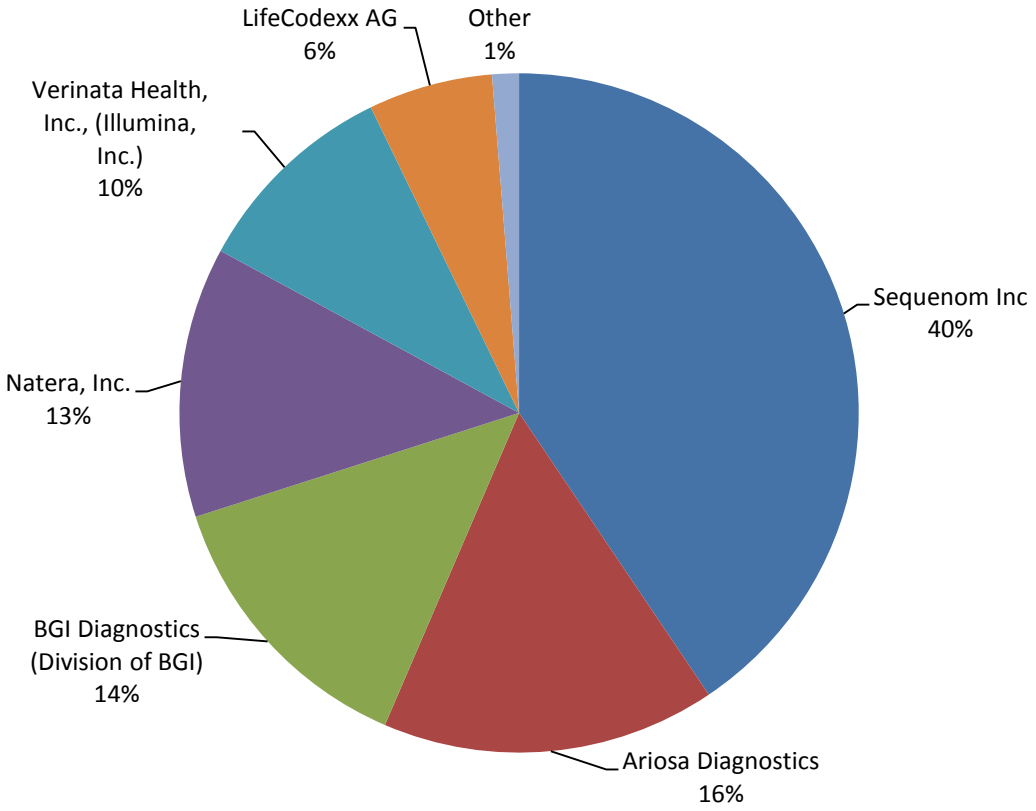
Exhibit E.S. 1: Global Market Share Analysis – Non-invasive Prenatal Diagnostic Products (2013)

Company	Market Share (%)
Sequenom Inc	40.6
Ariosa Diagnostics	15.9
BGI Diagnostics (Division of BGI)	13.6
Natera, Inc.	12.9
Verinata Health, Inc., (Illumina, Inc.)	9.9
LifeCodexx AG	5.9
Other	1.3
Total	100.0

Others include: Berry Genomics Co., Ltd

Source: Veracity Health

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



Others include: Berry Genomics Co., Ltd

Source: Veracity Health

ES.5 Company Profiles

This chapter provides the profiles of the leading 9 companies involved in the research and development, manufacture and marketing of devices which incorporate the technologies used for the detection of CNAs used in prenatal diagnostics. It provides a review of their historical development, key product areas including products in developments as well as short reviews of their key proprietary technologies.

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The Author

The author is an independent market analyst for the medical industry with a BSc and PhD in Biochemistry from the University of Liverpool and an MBA from Oxford Brookes University. The author has worked in the medical industry as a senior marketing executive for 20 years creating and implementing strategic business and marketing plans for major multinational medical device companies before establishing himself as an independent research analyst.

For the last ten years the author has focused on the structure, organization and functioning of the global health care systems with particular focus on reimbursement systems, analyzing specific product global market segments and advising/preparing strategic business and marketing plans for international pharmaceutical, medical devices and healthcare technology companies.