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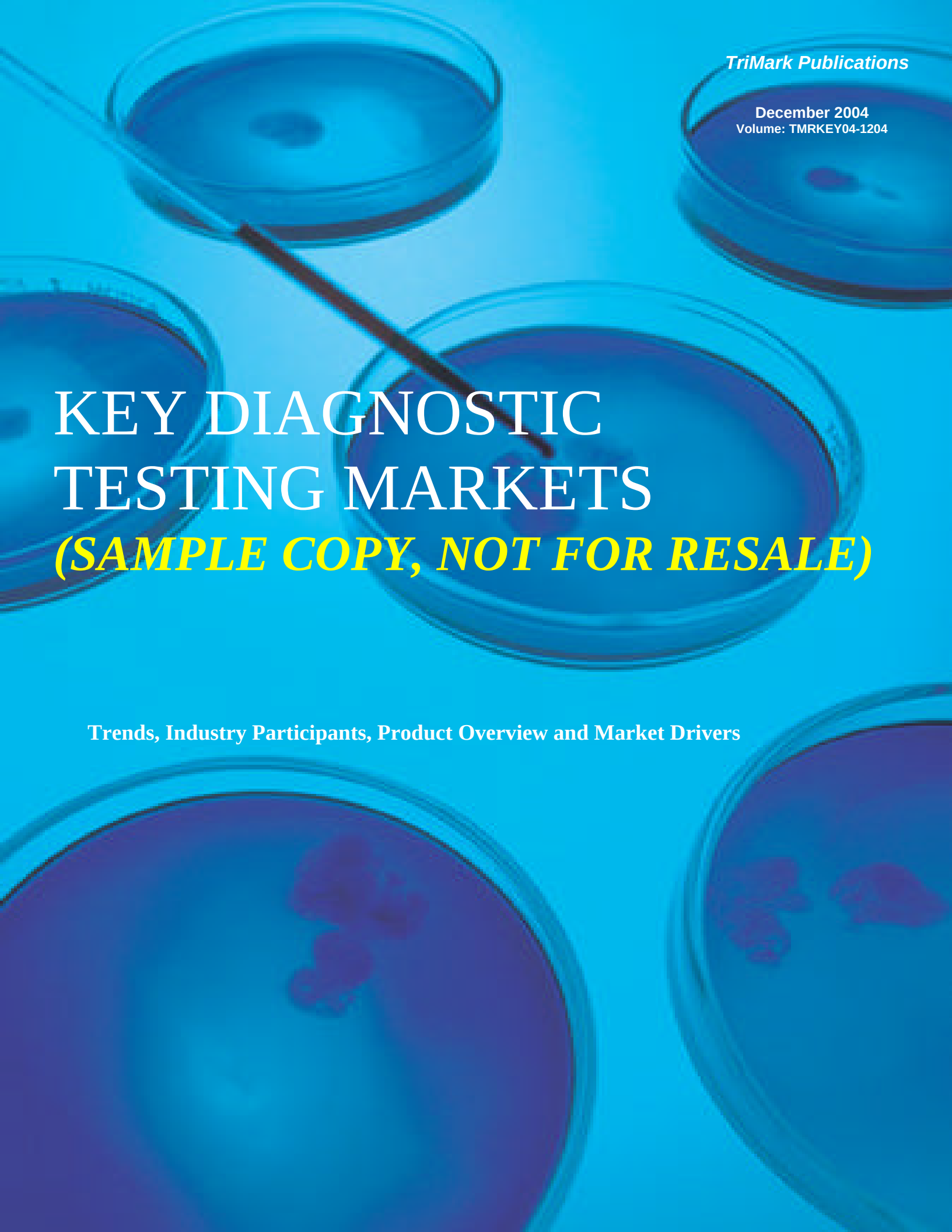

KEY DIAGNOSTIC TESTING MARKETS

(SAMPLE COPY, NOT FOR RESALE)

Trends, Industry Participants, Product Overview and Market Drivers

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1. Overview

1.1 Objectives

The purpose of this report is to describe the specific segments of the *in vitro* diagnostics market that are believed to have the potential for exceptionally high growth over the next five years. It examines those clinical measurement devices and their reagents and supplies that are utilized in hospitals, clinics and doctor's offices—as well as by patients—to diagnose and monitor disease.

1.2 Content and Scope

This report reviews the high-growth market segments for clinical laboratory testing equipment and supplies in the clinical hospital market, using screening reagents and instruments for analysis of individual components in blood, serum or plasma. Further, it examines the subsections of each market segment, including the clinical laboratory and research areas. Activity and trends in the clinical diagnostic market are discussed, including the numbers of institutions using this type of testing, and the factors that influence purchasing activity. Discussion details the trends that have developed that stimulate this market, and offers detailed comments on the patterns of information processing in point-of-care (POC) testing instruments.

The report surveys most of the important companies known to be marketing, manufacturing or developing instruments and reagents in the areas selected as high-growth diagnostic markets in the U.S. Each company is discussed in depth, with a section on its history, product line, business and marketing analysis, and a subjective commentary on the company's position in its market and its strategic direction.

Certain areas are only touched upon in this report. While these areas are related to the major elements of this report, they are in themselves an entirely different field or market. For example, the clinical chemistry testing market, or hematology, forms the foundation of much clinical screening testing today, but in the interest of brevity this area was not analyzed in depth.

The emphasis in this report is on those companies and products that are actively developing and marketing clinical laboratory instrumentation and reagents and supplies in market segments, and which have the potential for growth rates above 15% per year over the next five years. The reader should consult other TriMark Publications reports at http://www.trimarkpublications.com for a detailed discussion of the important individual market segments that are related to these high-growth markets, such as *POC Diagnostic Testing World Markets*, *Over The Counter Diagnostic Products World Markets* and *Cancer Diagnostic Testing World Markets*. The diagnostic markets that TriMark identified as candidates for exceptionally high annual growth rates over the next five years can be divided into eight general areas:

- Glucose monitoring.
- Rapid coagulation testing.
- Rapid cardiac markers.
- Drugs of abuse screening testing.
- Infectious disease testing.
- Cholesterol testing.
- Hepatitis testing.
- Tumor markers.

Concentration of this analysis is placed upon the overview of individual diagnostic markets that TriMark believes possess the elements that will lead to high and sustained growth rates for the foreseeable future. It assesses the current status of each market, makes five-year projections for market size, discusses the market strategies of the leading companies in each market segment, and evaluates the forces that underlie the high growth of each segment. Also presented is a brief description of the instruments, reagents and supplies marketed by major companies in each market segment. Discussion involves the market size, growth rate and market components for instruments, reagents, controls and consumables used in each high-growth area.

The report does not cover slower growing and relatively mature diagnostic markets such as hematology, although many of the instruments, reagents and techniques in the high-growth testing market segment are intimately associated with these broader areas. It does touch on the specialty testing areas in each high-growth market, since these segments are frequently a part of the overall analytical focus of companies marketing general laboratory automation equipment. However, no effort is made to quantify the size of this broader market; the report also doesn't focus on well-known companies that market and sell a limited number of instruments and equipment in a particular important diagnostic segment as a part of a much larger clinical laboratory product line. For example, Johnson & Johnson, Roche Diagnostics, Bayer Diagnostics and others who market many tests and instruments as part of their clinical line of reagents are discussed less in detail than some rather less well-known companies, which are smaller but market promising new *in vitro* diagnostic products.

In addition, there are a number of companies that market diagnostic testing devices, particularly urine test strips and occult blood test kits, which are primarily distributors of these products rather than the primary developer. These companies, although necessary and important to the diagnostic testing industry, are not covered in this report. This report discusses business tends, patient issues, technology trends and specific issues regarding growth drivers in diagnostic testing.

This report does not discuss clinical laboratory robotics and automation in detail. Although this report mentions recombinant proteins in passing, as well as techniques such as measuring the serum concentrations of therapeutic drugs and drugs of abuse, no extensive or in-depth treatment of this subject is presented. Such a discussion is outside the scope of this report but is covered in detail in TriMark's *Genomics World Markets* report and *Cancer Diagnostic Testing World Markets* reports. Each corporate profile includes the following elements:

- History.
- Unique company strengths.
- Corporate research and development strategy.
- Intellectual property assessment.
- Corporate collaborations.
- Products and developmental pipeline.
- Discovery-stage projects.
- Summary assessment of market prospect.
- Direct pipeline competition.
- Potential improvements over existing products.
- Financial details.
- Summary.

This report updates the current status and future potential of the market for *in vitro* diagnostics worldwide, concentrating on areas that are seeing significant change and substantial future growth worldwide. It is an invaluable source of competitor information for executives and decision-makers in diagnostic companies.

1.3 Methodology

The information in this report is based upon interviews with sales and marketing professionals of companies in the clinical laboratory market. People from virtually every company mentioned in this report were queried, some several times, about their company's products and marketing strategies, as well as their overall thoughts about their industry segment. Interviews with founders, CEOs and vice presidents of some of the companies discussed in the report also provided information. The structure of the hospital laboratories and near-patient facilities was derived from interviews with laboratory directors and medical technologists working in these areas.

Other sources of information included trade association publications and meetings, product brochures and catalogs, and company literature. When publicly-held companies were discussed, an examination of the annual reports, 10k filings and financial reports were used as the basis of the data reported. Some of the information obtained for the report was taken from TriMark's databases, Biotechnology Associates' data files and from the private data stores of the author. Much of the tabular data in this report have been developed from primary company sources with the help of a proprietary database calculator. The information set forth in this study was obtained from sources that TriMark

believes to be reliable, but it does not guarantee its accuracy, adequacy or completeness of any information or omission, or for the results obtained by the use of such information.

1.4 Executive Summary

TriMark estimated the worldwide *in vitro* medical diagnostic testing market to have been slightly more than $[redacted] in [redacted]. This figure encompasses all aspects of clinical laboratory testing, including central testing in hospitals and commercial labs, and alternate site testing (including POC, doctor's office, corporate and clinics), but excepting home care or over-the-counter (OTC) testing. The U.S. is the largest single market segment, with an annual product sales value estimated to be almost $[redacted].

Geographically, North America accounts for about [redacted]% of the total *in vitro* diagnostic (IVD) testing market of all types. The remaining diagnostic testing volume is generally divided between Europe at [redacted]%, Japan at [redacted]% and the rest of the world at [redacted]%. Total IVD revenues are growing at about [redacted]% per year worldwide, while the underlying test volume is growing at [redacted]% per year. The difference in these numbers suggests the price pressures in the industry.

In the market segment of general clinical chemistry, TriMark believes that the glucose whole blood testing segment is still a high-growth area despite its rather mature status in the hospital critical care areas. TriMark finds that there is still a substantial growth potential in the clinic and in-home testing, driven by the high prevalence of diabetes as a major health risk throughout the world.

In the U.S., the current glucose testing market is estimated to be $[redacted], with a worldwide market of $[redacted]. TriMark believes that the U.S. market is still growing at a rate of between [redacted]% and [redacted]%, primarily due to replacement units and more sophisticated data processing. Worldwide, there is still much room for expansion, and TriMark sees the market as growing by [redacted]% to [redacted]% over the next [redacted] years.

In [redacted], the worldwide market for immunoassays exceeded $[redacted], consisting primarily of testing related to infectious disease, endocrinology, therapeutic drug monitoring, drugs of abuse testing, immunology/allergy, tumor markers and blood typing. The global market for immunoassays continues to expand as new disease states are identified, new therapies become available, and worldwide standards of living and access to healthcare improve. Such tests are performed primarily in hospital-based laboratories and commercial laboratories, which account for approximately [redacted]% of all diagnostic tests performed annually. In recent years, diagnostic tests that can be performed nearer to the point of patient care have emerged as an important tool in disease diagnosis and management.

A relatively small share of this $[redacted] worldwide diagnostics market is represented by the high-growth areas selected for this report. The POC area certainly is, although much of this segment is still very closely tied to hospital practice. A substantial part of glucose testing might be included in this site segment, particularly the doctor's office and group practice markets. But much of the glucose testing still occurs in hospitals. In addition to the direct diagnostic utility of *in vitro* tests, some of the key major trends that will continue the growth of the industry are:

- Global demographics.
- Healthcare delivery and disease management.
- Technologic innovation.

In the U.S., approximately [redacted]% of clinical diagnostic testing is currently conducted in hospital-based and commercial laboratories. The alternate site diagnostic testing in [redacted] represented [redacted]% of the $[redacted] U.S. market for clinical diagnostic testing reagents, controls and equipment, and is projected to grow at an annual rate of [redacted]% through [redacted]. This estimate of the $[redacted] alternate site diagnostic testing market comprises both the traditional hospital-oriented POC testing and the newer elements of the free-standing clinic, doctor's office testing, doctor's group testing, corporate screening, but not home and OTC testing. This latter segment will become an increasingly larger and important part of the overall IVD testing picture in the next [redacted] years.

The IVD industry was estimated to grow to $[redacted] worldwide by the end of [redacted]. This figure encompasses all aspects of clinical laboratory testing, including central testing in hospitals and commercial labs, alternate site testing (including POC, doctor's office, corporate and clinics), except home care or OTC testing. Some areas of this industry are relatively stable (*e.g.*, serum enzyme testing), but others are due for explosive growth (*e.g.*, tumor

markers, hepatitis testing, drug testing, infectious disease testing and cardiac markers). The U.S. is the largest single market segment, with an annual product sales value estimated to be almost $[redacted]. Overall, the U.S. hospital-based POC market was estimated by TriMark to be about $[redacted] in sales. The total rapid, near-patient *in vitro* U.S. diagnostic testing market is $[redacted]. The second part of the alternate site diagnostic testing segment consists of physician office labs (POLs), nursing homes, pharmacies and other non-institutional settings in which healthcare providers perform diagnostic tests. This market segment is estimated to be about $[redacted]; clinics are $[redacted]; and miscellaneous other testing is $[redacted]. This market segment is growing at [redacted]% per year.

There were approximately [redacted] hospital labs certified for clinical laboratory improvement amendments (CLIA) in the U.S. in [redacted]. Since there are only [redacted] hospitals in the U.S., some of these are probably ancillary testing sites within the main facility. There are [redacted] independent labs in the U.S., and [redacted] POLs registered with CLIA. There are [redacted] labs of all types in the U.S. registered with CLIA. The difference between the number of "all types" and the number of POL, independent, hospital-registered labs and all types is [redacted], which includes clinics, drawing stations, corporate sites and other miscellaneous diagnostic testing providers in the U.S.

The third part of the alternate site diagnostic testing market is generally considered to be the at-home market. The OTC self-test market in the U.S. was estimated by TriMark to be north of $[redacted] in [redacted]. The OTC market is growing at a rate of [redacted]% per year. In the U.S., revenues from home diagnostic products and monitoring devices grew at a rate of [redacted]% compounded annually from $[redacted] in [redacted] to $[redacted] in total revenues in [redacted]. TriMark forecasts double-digit growth through [redacted] to $[redacted]. Much of this growth is expected to come from easy-to-use, POC diagnostic tests.

1.4.1 Glucose Monitoring

Worldwide sales of blood glucose self-monitoring products (home and OTC) were approximately $[redacted] in [redacted], which represented an increase of approximately [redacted]% over [redacted] levels. The finger-stick blood glucose testing market is estimated to be growing at [redacted]% annually. The blood glucose monitoring POC segment is by far the largest of the alternate site diagnostic testing market segments, and this is the driver for more growth. The world market is very mature, with annual sales in [redacted] of $[redacted], and growing at a rate of [redacted]% to [redacted]% per year. The market grew to $[redacted] by [redacted]. The annual growth of the glucose testing market is in the range of [redacted]% to [redacted]% annually. The POC glucose testing market is projected to grow to $[redacted] by [redacted].

1.4.2 Coagulation

This is a difficult market segment to evaluate. There are actually several markets for coagulation type testing (APTT, PTT, D-dimer, etc), as well as the large prothrombin time (PT) segment. Furthermore, there is a projected home or patient market and a professional segment in PT testing. This is further complicated by the different assumptions on frequency of testing that drives the potential market. The total coagulation testing market worldwide was estimated to be $[redacted] in [redacted], with the U.S. share at $[redacted]. The total coagulation market worldwide and in the U.S. is growing at [redacted]% per year, and is projected to reach $[redacted] by [redacted] (see Table 21). The total U.S. coagulation market is growing at [redacted]% per year and was $[redacted] in [redacted], growing to $[redacted] in [redacted].

TriMark estimates that the U.S. market for rapid, POC-type coagulation tests is approximately $[redacted] and growing at a rate of [redacted]% per year (see Table 21). The total sales for [redacted] were $[redacted], increasing to $[redacted] in the U.S. in [redacted]. This is the highest growth rate of all of the segments in the rapid test area, save cardiac tests, but moves from a much higher base of sales than the latter. There has been double-digit growth for these markers in the U.S. The market for D-dimer alone has been estimated by TriMark to be over $[redacted] in the U.S., and is expected to grow at [redacted]% per year.

