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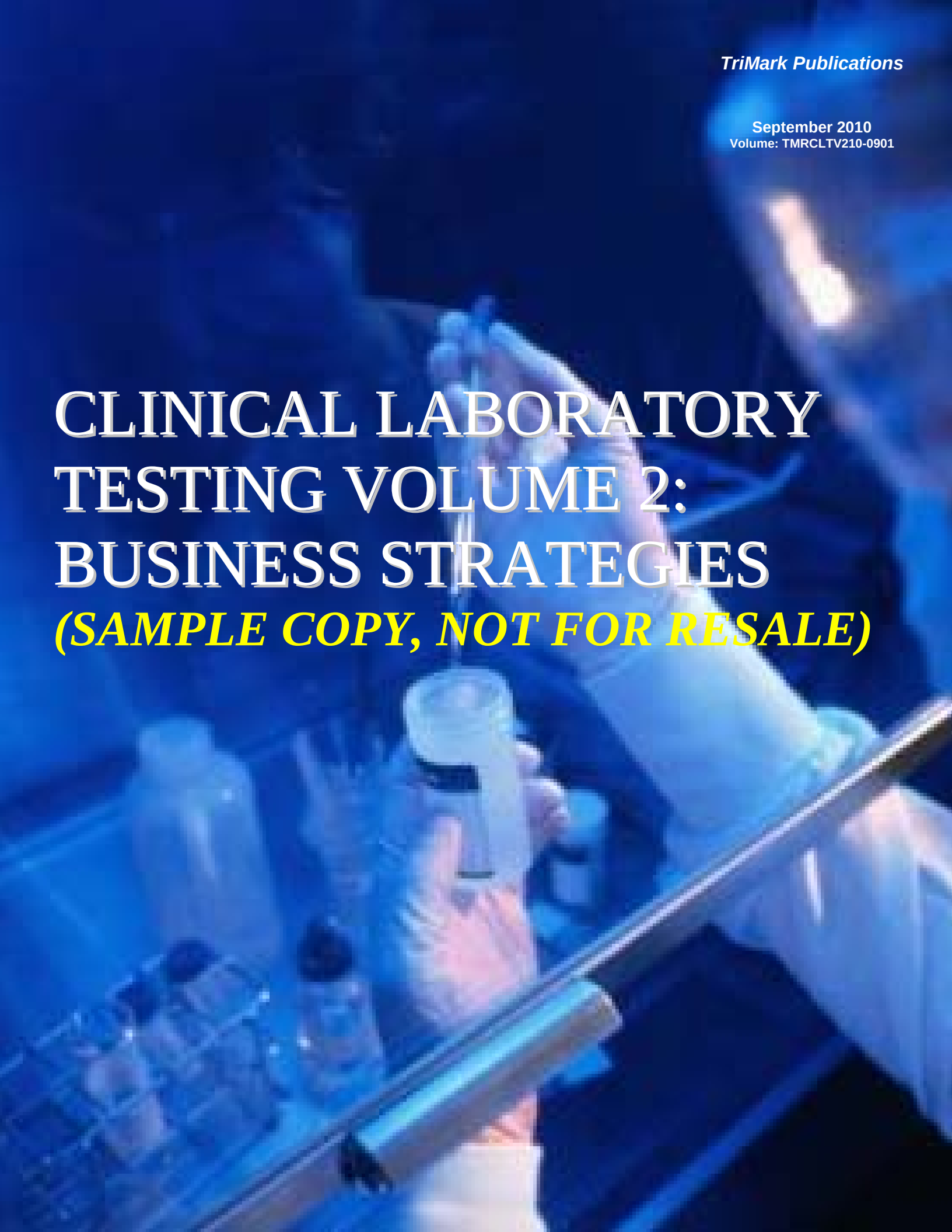

CLINICAL LABORATORY TESTING VOLUME 2: BUSINESS STRATEGIES

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1. Overview

Clinical laboratory analysis is one of the most important sections of medical care, generally involved in over [redacted]% of medical diagnoses, but accounting for less than [redacted]% of overall healthcare expenditures. By all accounts, clinical lab analysis is very mature, large and diverse. The term clinical laboratory analysis usually refers to determining the concentration or activity of a protein, carbohydrate, lipid, electrolyte, enzyme or small molecule in easily collected body fluids, such as blood, serum, plasma or urine.

Clinical laboratory analysis is not necessarily limited to these determinations. The analysis of virtually any biologically active substance—any place in the body—can loosely be defined as clinical laboratory. Traditional specialization barriers, such as microbiology, hematology, blood banking, immunology and even anatomical pathology are rapidly fading both operationally and instrumentally in the face of rapid technological innovation. But for the sake of defining the subject to a reasonable size, we here take the more traditional scope of clinical laboratory to be the subject of this report.

1.1 Objectives of the Report

The purpose of this report is to describe the specific segments of the clinical laboratory analysis business and the strategies used by laboratory companies to develop new business opportunities. Although there is mention of world testing business, the emphasis of this report is on the U.S. market. However, most of the trends and business practices of the clinical lab testing business apply very well to other parts of the world. In fact, this formerly parochial sector is rapidly becoming internationalized.

Within this area, the report covers those segments that are highly active in terms of innovation and growth. Specifically, this clinical laboratory business markets report examines the markets for small labs and highly automated, large labs, as well as hospital and doctor's office labs.

The emphasis in this analysis is on those companies that are actively analyzing and marketing laboratory data (as opposed to IVD manufacturers of lab equipment) for the clinical setting, which include hospitals, independent clinical labs, physician's offices and miscellaneous clinics. This study concentrates on the clinical laboratory industry in the U.S. To a lesser extent the report examines the laboratory testing business and the world. Particular attention is paid to those areas of the clinical laboratory instrumentation sector that are showing the greatest growth or the most innovation. The report attempts to answer the questions:

- What companies are the key players in clinical lab testing, and what are their business strategies?
- What are the best growth opportunities in clinical laboratory testing?
- What is happening with the information revolution, and how is it affecting clinical lab testing?
- What are the development trends, especially in acquisitions and mergers?
- Where are the new market growth areas?

This examination reviews the market for clinical laboratory data used in clinical practice. It defines the dollar volume of sales in each major market segment, and analyzes the factors that influence the size and the growth of the individual market segments. The report details market sizes and growth rates for the U.S. markets for testing procedures (rather than sales of reagents and equipment). The study surveys some of the key companies known to be marketing clinical laboratory data into the medical market. Each company is discussed in depth with a section on the history of the company, the product line, business and marketing analysis, and a subjective commentary of the position of the company in its market.

Unique Benefits of This Report Are:

- In-depth analysis of the major sectors of the clinical laboratory business sector, their size, growth rates and major drivers.
- Presentation of some of the emerging business practices, elucidating the potential areas that could gain traction in this market.
- Analysis of the partnerships and alliances the various key sector players have forged, as well as describing

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financings of these market participants, giving insight into potential market collaborations.
- Examination of new business methods for clinical laboratories to identify lead positions and potential future growth areas.
- The reader will gain an understanding of key areas of the clinical laboratory testing business.
- New ways to adapt technology innovations and create new revenue streams.
- Sales and marketing strategies that will improve net income.
- Which diagnostic tests are emerging as high profit drivers.
- Transition to a consumer-based lab model.
- Financial underpinnings of entrepreneurial labs.
- Networking opportunities.
- Insights into the boomer emerging market and their growing expenditures on healthcare.
- Increased mergers and acquisitions (M&As) activity.
- Shift to preventative medicine.
- Impact of point of care testing.
- Elements of personalized medicine, genetic testing and pharmacogenomics.

1.2 Methodology

The author of this report is a Ph.D. in biochemistry with many decades of experience in scientific writing and as a medical industry analyst. He has been a senior director of several large regional and national healthcare laboratories. Company-specific information is obtained mainly from industry trade publications, academic journals, news and research articles, press releases and corporate websites, as well as annual reports for publicly-held firms. Additionally, sources of information include the non-governmental organizations (NGOs) such as the World Health Organization (WHO) and governmental entities like the U.S. Department of Health and Human Services (HHS) and U.S. federal agencies such as the National Institutes of Health (NIH), the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). Where possible and practicable, the most recent data available have been used.

Some of the statistical information was taken from Biotechnology Associates' databases and from TriMark's private data stores. The information in this study was obtained from sources that we believe to be reliable, but we do not guarantee the accuracy, adequacy or completeness of any information or omission or for the results obtained by the use of such information. Key information from the business literature was used as a basis to conduct dialogue with and obtain expert opinion from market professionals regarding commercial potential and market sizes. Senior managers from major company players were interviewed for part of the information in this report.

Primary Sources

TriMark collects information from hundreds of Database Tables and many comprehensive multi-client research projects, as well as Sector Snapshots that we publish annually. We extract relevant data and analytics from TriMark's research as part of this data collection.

Secondary Sources

TriMark uses research publications, journals, magazines, newspapers, newsletters, industry reports, investment research reports, trade and industry association reports, government-affiliated trade releases and other published information as part of its secondary research materials. The information is then analyzed and translated by the Industry Research Group into a TriMark study. The Editorial Group reviews the complete package with product and market forecasts, critical industry trends, threats and opportunities, competitive strategies and market share determinations.

Market Forecasts and Modeling

The numerical data on market size, growth rates and sales forecasts are obtained from a well-examined model based upon quantitative market information obtained from the leading global companies in the sector, private seminar

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presentations by company experts and public SEC filings. Many industry experts are also consulted to confirm these market estimates.

TriMark Publications Report, Research and Data Acquisition Structure

The general sequence of research and analysis activity prior to the publication of every report in TriMark Publications includes the following items:

- Completing an extensive secondary research effort on an important market sector, including gathering all relevant information from corporate reporting, publicly-available data and proprietary databases.

- Formulating a study outline with the assigned writer, including important items, as follows:

    - Market and product segment grouping, and evaluating their relative significance.
    - Key competitors' evaluations, including their relative positions in the business and other relevant facts to prioritize diligence levels and assist in designing a primary research strategy.
    - End-user research to evaluate analytical significance in market estimation.
    - Supply chain research and analysis to identify any factors affecting the market.
    - New technology platforms and cutting-edge applications.

- Identifying the key technology and market trends that drive or affect these markets.

- Assessing the regional significance for each product and market segment for proper emphasis of further regional/national primary and secondary research.

- Completing a confirmatory primary research assessment of the report's findings with the assistance of expert panel partners from the industry being analyzed.

1.3 Scope of the Report

This report deals with the business of testing the chemical constituents of blood, plasma or serum of the patient by clinical labs. The two most important areas where such tests are measured are in the hospital and independent commercial clinical laboratories. The third place these tests are measured is in physician office laboratories (POLs). Newer areas of testing interest for these analytes can be satellite labs and pharmacies and corporate clinics.

The emphasis in this report is on those companies that are marketing clinical laboratory testing for analysis and data reporting to physicians for medical care of patients. 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 the *in vitro* diagnostics (IVD) market, such as molecular diagnostic testing, high-growth diagnostic test markets, blood gas and electrolytes over-the-counter (OTC) diagnostic testing markets and point of care testing (POCT), hematology testing and the reagent and instrument segment. A companion report, *Clinical Laboratory Testing Volume 1: Instruments and Reagents*, deals primarily with the IVD industry and the instruments and reagents that they market to clinical laboratories.

This analysis touches on the specialty testing areas in clinical laboratory diagnostic testing, such as POCT, genetic testing and cardiac markers, since these segments are frequently a part of the overall analytical focus of companies marketing general laboratory data. However, no effort is made to quantify the size of these individual markets. This is left to specific market reports on these subjects.

The report does not cover instruments and reagents markets or other diagnostic device markets, although many of the instruments, reagents and techniques in the clinical laboratory diagnostics market segment are intimately associated with these broader areas of the lab testing business. All of these subjects are treated thoroughly in other TriMark Publications reports.

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Although this examination mentions many common clinical laboratory testing procedures and analytes 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 analysis. This report reviews the clinical lab business market in the U.S. and worldwide. This market can be divided into four broad areas: the hospital market; the independent lab market; the doctor's office market; and, to a much lesser extent, the clinic market.

1.4 Executive Summary

Clinical laboratory testing is generally categorized as either of two general areas:

- Clinical testing.
- Anatomical pathology testing.

Clinical and anatomical pathology procedures are frequently ordered as part of regular physician office visits and hospital admissions in connection with the diagnosis and treatment of illnesses. Certain of these tests and procedures are used principally as tools in the diagnosis and treatment of a wide variety of medical conditions, such as cancer, AIDS, endocrine disorders, cardiac disorders and genetic disease.

Clinical lab testing is used in virtually every part of the health delivery system and end-users generally fall into one of five categories:

- Reference laboratories that conduct batteries of tests for physicians and hospitals.
- Hospital operating rooms, emergency rooms, laboratories, near-patient and patient bedside.
- Physician's offices, walk-in clinics and surgeries.
- Pharmacies and supermarkets that offer in-store testing.
- Individuals who purchase kits for self-testing.

The clinical laboratory testing sector consists primarily of three types of providers:

- Hospital-based laboratories.
- Physician office laboratories.
- Independent clinical laboratories.

The major clinical testing companies estimate the annual market for their services to be more than $[redacted]. The diagnostic equipment and reagent market serving this sector is currently valued at $[redacted] worldwide. The number of clinical laboratory tests carried out within hospitals in the U.S. was estimated to grow to [redacted] tests per annum by [redacted]. There are presently two major national independent commercial clinical laboratories which dominate the clinical testing business:

- LabCorp.
- Quest Diagnostics.

These laboratories dominate the independent clinical laboratory business. The clinical laboratory sector had total revenues of approximately $[redacted] in [redacted], and accounts for [redacted]% of the $[redacted] annually spent on healthcare services in the U.S. The industry is estimated to be growing at approximately [redacted]% to [redacted]% annually. Estimated revenue is predicted to be over $[redacted] by [redacted].

There are [redacted] clinical laboratories in the U.S. Routine tests account for [redacted]% of the clinical laboratory market and are growing at approximately [redacted]% annually. Anatomic pathology, including cytology, accounts for [redacted]% of the clinical laboratory market and is growing at between [redacted]% and [redacted]% annually. Esoteric tests account for [redacted]% of the clinical laboratory market and are growing at [redacted]% annually. Substance abuse tests account for [redacted]% of the clinical laboratory market and are declining at [redacted]% annually.

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In the U.S., approximately [redacted]% of clinical diagnostic testing is currently conducted in hospital-based and commercial laboratories. A total of $[redacted] was generated by all types of hospital-based clinical laboratories in the U.S. in [redacted]. A total of $[redacted] was generated by all types of independent clinical laboratories in the U.S. in [redacted]. The number of tests and revenue is highly concentrated in this industry. In the U.S., only [redacted] labs have revenue in excess of $[redacted], and the top ten labs control more than [redacted]% of the total testing dollars.

The POLs market was estimated to be about $[redacted] in U.S. sales in [redacted], or about [redacted]% of the total $[redacted] generated by all laboratories in the U.S. in [redacted]. Physician office laboratories comprise [redacted]% of the total number of reportable test results performed in the U.S. in [redacted]. The three most common (CLIA-waived and non-waived) tests performed at POLs are dipstick/tablet urinalysis, fecal occult blood, and urine pregnancy tests.

Hot sectors in the clinical lab testing market include:

- Workplace drugs-of-abuse testing.
- Clinical toxicology.
- Clinical testing for the pharmaceutical industry.
- Heavy metal, trace element and solvent analyses.
- Diabetes (glucose) testing.
- Molecular diagnostic testing.
- Cardiac markers.
- Blood bank screening.
- Genetic testing.
- Predictive medicine testing.
- Personalized medicine.
- Cancer testing.
- Cell-based cancer testing.
- Monitoring technologies.
- Anatomic pathology.

Worldwide M&A activity is high in the clinical laboratory sector. Consolidation in the clinical laboratory industry has continued its generally strong and aggressive pace in [redacted] and [redacted], as [redacted] mergers or acquisitions have been completed in the [redacted] period between [redacted] [redacted] and [redacted] [redacted]. In [redacted], M&A activity in the laboratory industry was characterized by larger acquisitions for greater sums and culminated in Quest Diagnostics' [redacted] acquisition of AmeriPath, Inc. Most striking about the [redacted] M&As was the relative lack of participation on the part of Quest. In the recession year of [redacted], M&As in the clinical lab sector still continued, albeit at a slower pace.

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