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DRUGS OF ABUSE TESTING MARKETS

(SAMPLE COPY, NOT FOR RESALE)

Trends, Industry Participants, Product Overviews and Market Drivers

TABLE OF CONTENTS

INDEX OF FIGURES

INDEX OF TABLES

1. Overview

1.1 Statement of Report

This report describes the specific segment of the *in vitro* diagnostics (IVD) market known as drugs of abuse testing. This term is used to distinguish it from testing for therapeutic drugs. In the current medical diagnostics market, drugs of abuse testing offers promise for growth and innovation. The development of this sector of the diagnostics industry has been driven by:

- The use mass spec instrumentation for drug-screening confirmation.
- The development of a wide variety of mass spectrometry and other separation-based technology platforms.
- The rise of drug profiling.
- New developments in diagnosis and treatment of drug dependence.
- The need for screening both therapeutic and illicit drug content.
- Improved detection levels.
- The use of computer assisted data analysis and multiplexing.

This review analyzes the size and growth of the drugs of abuse testing market, including the factors that influence the various market segments within it, the dollar volume of sales, both in the United States and worldwide. Also examined are:

- Drug analysis technology platforms.
- Clinical applications of drugs of abuse testing.
- The market for quantitative diagnostic drug tests.
- Companies participating in this sector.
- New instrumentation.
- Trends in the industry.
- The internal structure of the drugs of abuse testing sector.

1.2 About This Report

This report includes the following features:

- It examines all of the generally-accepted clinical analytical activities in use today in the drugs of abuse testing sector. It includes the prevalent clinical measurement devices and the accompanying reagents and supplies as utilized in hospitals and large reference laboratories.
- It discusses the potential benefits of the drugs of abuse testing market for various sectors of the medical and scientific communities, and it assesses the market drivers and bottlenecks from the perspective of these communities.
- It establishes the current total market size and future growth of the drugs of abuse testing market and analyzes the current size and growth of various segments.
- It assesses various business models in drugs of abuse testing and provides strategic recommendations for near-term business opportunities.
- It examines the products offered and roles played by companies that have invested significantly in this market, and it provides current and forecasted market shares by these companies.

The main objectives of this analysis are:

- Identifying viable technology drivers through a comprehensive look at platform technologies for drugs of abuse testing, including gas chromatography-quadrupole mass spectrometry, automated laboratory chemistry instruments, and point of care systems and reagents.
- Obtaining a complete understanding of the drugs of abuse tests—*i.e.*, predictive, screening, prognostic, monitoring, pharmacogenomic and theranostic—from their basic principles to their applications.

- Discovering feasible market opportunities by identifying high-growth applications in different clinical diagnostic areas and by focusing on expanding markets, such as employee drug screening, emergency medicine, opiate testing and defense and security work.
- Focusing on global industry development through an in-depth analysis of the major world markets for drugs of abuse testing, including growth forecasts.
- How can drug testing contribute to laboratory growth plans?
- Which tests are the most likely candidates for migration to MS platforms?
- How to understand the business issues that go into justifying mass spec?

1.3 Scope of the Report

The goal of this study is to review the market for drugs of abuse testing equipment and supplies using reagents and instruments for analysis of individual components in body tissues and fluids (particularly blood and urine). Toward this goal, this review answers the following key questions:

- Which companies are utilizing cutting-edge technologies to develop, validate and market drugs of abuse tests for clinical use?
- What are the current impediments to incorporating promising drugs of abuse tests in clinical practice?
- Which new drugs of abuse tests show the most promise for approval?
- What are the economic challenges to gaining approval?
- How can regulatory oversight drive approval and adoption of new technologies?
- Which alliances show the greatest synergy in bringing drugs of abuse testing to market?
- Which shared technologies are driving the most encouraging development?

This examination surveys most of the instrument companies known to be currently marketing, manufacturing or developing instruments and reagents for the drugs of abuse testing market, in both the U.S. and the world. Each leading company is discussed in depth, with sections on its history, product line, business and marketing analysis, and a subjective commentary of the company's market position.

The U.S., Europe and Japan—the world's three largest drugs of abuse testing markets—are the focus of this report. Primary attention is paid to the hospital market segment and, separately, to the instruments, reagents and supplies marketed by the major companies in this segment. Drugs of abuse are also prominent features of parallel markets such as: workplace drug testing, prescription drug abuse, and sports medicine. Indeed, it has been reported that over [redacted]% of U.S. employers have a drug testing policy in place. Market size, growth rates and market components for instruments, reagents, controls and consumables used in this area are also analyzed.

This analysis examines the companies that are actively developing and marketing mass spectrometry clinical laboratory instrumentation, reagents and supplies for performing drugs of abuse tests. The emphasis in this report is on the clinical use of drugs of abuse tests.

The reader should consult other TriMark Publications reports at www.trimarkpublications.com for detailed discussions of important individual market segments related to the drugs of abuse testing market, such as clinical chemistry testing and high-growth diagnostic tests markets,. Diagnostics drug tests marketed primarily as qualitative or quantitative reagents are generally included in this report, although there is inevitably some overlap. TriMark's *Point of Care Diagnostic Testing World Markets* report discusses near patient drug testing.

1.4 Objectives

The emphasis in this report is on the clinical use of drugs of abuse tests and their development into the instrument mixture of clinical laboratory testing space. One goal of this study is to review the market for drugs of abuse testing equipment and supplies using reagents and instruments for analysis of individual components in blood, serum or plasma. The report also defines the dollar volume of sales, both worldwide and in the U.S., and analyzes the factors that influence the size and the growth of the market segments. The subsections of the drugs of abuse testing market segment are examined in detail, including: major drugs of abuse, clinical testing markets, trends, analysis, challenges, government regulations, reimbursement and billing, and business decisions. The use of drugs of abuse testing in commercial, hospital and specialty laboratories is examined. Additionally, the factors that influence purchases are also discussed.

The focus of this report is to:

- Assess the drugs of abuse testing market drivers and bottlenecks from the perspective of the medical and scientific communities.
- Discuss the potential benefits of the drugs of abuse testing market for various sectors of the medical and scientific community.
- Establish the current total market size and future growth of the drugs of abuse testing market and analyze the current size and growth of various segments.
- Provide current and forecasted market shares by the company.
- Provide strategic recommendations for near-term business opportunities.
- Assess current commercial uses of the drugs of abuse testing market.
- Review the drugs of abuse testing business models.

On a more technical level, we:

- Discuss the problems of using indirect methods such as immunoassays for analyzing complex biological fluids when making diagnostic decisions and their replacement with MS technology platforms.
- Review the strategies available for sample preparation.
- Contrast the optimal methods for quantification when employing LC/MS/MS techniques.
- Differentiate the strategies of toxicology analysis to best fit the clinical requirements.
- Appraise the use of mass spectrometry for applications of drugs of abuse testing.
- Evaluate the applications of new technologies to the clinical laboratory assessment of drugs of abuse.
- Review the dynamic regulatory environment (FDA) and assess how drugs of abuse testing may play a role in the clinical laboratory.

This review answers the following key questions:

- Which companies are utilizing cutting-edge technologies to develop, validate and implement drug tests for clinical use?
- What impediments still exist to incorporating promising drug tests into clinical practice?
- Which new drug of abuse test shows the most promise for approval?
- What are the economic challenges to approval?
- How can regulatory oversight drive approval and adoption of new technologies?
- Which alliances show the greatest synergy in bringing drugs of abuse tests to market?
- Which shared technologies are driving the most encouraging development?
- How are businesses entering the clinical lab testing space by leveraging drugs of abuse testing?

1.5 Methodology

The author of this report holds a Ph.D. in medicine/immunology from the Royal College Surgeons of Ireland and has completed post-doctoral studies and lecturing in Trinity College Dublin and University College Cork. She has over ten years of experience as a director in laboratory testing and instrument and reagent development technology, as well as extensive experience in senior level positions in biotech and medical service companies. The senior editor has a Ph.D. in chemistry from the University of Minnesota, with more than 30 years of experience as a clinical laboratory director, as well as editing and writing articles in science and technology. A contributor to this report is a clinical lab director certified in virtually all states in the U.S. for drug testing. He is has been laboratory director of a large institution whose lab specializes in prescription drug abuse analysis.

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. Additional sources of information include non-governmental organizations (NGOs) such as the World Health Organization

(WHO) and governmental entities such as the U.S. Department of Health and Human Services (HHS), 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 it publishes annually. TriMark extracts relevant data and analytics from its 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.

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.

1.6 Executive Summary

Globalization has increased both the supply and the demand for illicit drugs around the world. Drug abuse is no longer the concern of only the developed world. Countries without histories of drug use, especially developing countries, are now reporting problems of abuse because they have become transit points for international drug trafficking. Because the problem is now worldwide, a global strategy is needed for identifying, analyzing and developing strategies to deal with drug abuse and the associated problems for health and safety.

The National Survey on Drug Use and Health has reported the following findings:

- About [redacted] Americans are estimated to be current illicit drug abusers in [redacted]—or [redacted]% of the population.
- The most commonly abused illicit drugs were marijuana, cocaine (including crack), heroin, hallucinogens, inhalants, or prescription-type psychotherapeutics.

The average age of first time illicit drug abuse was [redacted] years in [redacted]—slightly down from [redacted] years the previous year. The National Survey on Drug Use and Health estimated that three million U.S. citizens became first time users in [redacted] ([redacted] years or older), which equates to [redacted] people per day. Of these users, [redacted]% were less than [redacted] years old and [redacted]% were female.

The first drug of abuse that the majority ([redacted]%) of first time users sampled was marijuana. This was followed by psychotherapeutics at [redacted]%, inhalants at [redacted]% and hallucinogens at [redacted]%. Marijuana was the most common illicit drug used, with [redacted] users—[redacted]% of the population in [redacted]. Psychotherapeutic drug use in [redacted] was estimated at [redacted] in the U.S., or [redacted]% of the population.

The main five drugs of abuse that SAMHSA requires an employer to test for are:

- Cannabinoids.
- Cocaine.
- Amphetmines.
- Opiates.
- Phencyclidine.

A number of human samples can be obtained to determine illicit drug use and these include:

- Urine.
- Hair follicles.
- Oral fluid.
- Sweat.
- Blood.

DoA assays can be performed on a number of sample types other than the above, for example Randox Laboratories DoA assays can be used on the following samples:

- Post-mortem blood.
- Vitrous humor.
- Forensic specimens.
- Meconium.
- Tissue.

However, urine testing is the gold standard and federal regulated and most private sector organizations will only test urine for the presence of drugs of abuse. Urine testing is widely used as it is accurate and reliable. Saliva testing is becoming more popular and costs are similar to urine testing. Immunoassay based detection methods are initially used to determine if a sample is positive for a drug of abuse. If found positive, the result is confirmed by using gas chromatography (GC) or mass spectrometry (MS). The drugs of abuse (DOA) testing market is incorporated within the clinical diagnostic testing market. This market is forecast to be worth over $[redacted] by [redacted]. Growth factors for the clinical diagnostic testing market include:

- Increases in consumer driven healthcare.

- An aging population with better healthcare services.
- Demand for esoteric testing.
- Demand for genetic testing.

Almost $[redacted] was generated from the DOA testing market in [redacted], up from $[redacted] in [redacted], and $[redacted] in [redacted]. By [redacted], the global drugs of abuse (DOA) testing market will be worth upwards of $[redacted] according to industry experts. Between [redacted] and [redacted], a compound annual growth rate (CAGR) of [redacted]% is expected.

As for the geographic distribution of DOA testing, the U.S. has the largest market share and was worth an estimated $[redacted] in [redacted], a growth from $[redacted] in [redacted]. By [redacted], DOA testing in the U.S. is predicted to bring in revenues of $[redacted]—with a CAGR of [redacted]%. The second largest market share is held by the European Union (E.U.) which was worth an estimated $[redacted] in [redacted]. This is predicted to grow to nearly $[redacted] by [redacted] with a CAGR of [redacted]%. With an estimated $[redacted] in revenue in [redacted], the Rest of the World market is the least dominant sector. However, this sector is still forecast to increase in revenue to $[redacted] in [redacted] with a CAGR of [redacted]%.

The predominant drivers for this market overall are an increasing population involved in illicit drug abuse, government crackdown on illicit and prescription drug abuse, the availability of rapid and cost effective DOA tests and a global requirement for the reduction of drug abuse in the workplace and sports. The drugs of abuse testing market is dominated by urine analysis; however, oral fluid/saliva testing is gaining ground. With respect to the urine testing segment, the main competitors are:

- Roche Diagnostics.
- Abbott Laboratories.
- Siemens.
- Thermofisher.
- Beckman Coulter.
- Randox.
- American BioMedica.
- Alpha Scientific.
- First Check Medical.
- Orasure.
- Avitar.
- Biophor.
- Princeton BioMeditech.
- Inverness Medical Innovations (BioSite).
- Bioscan Screening Systems.

The top companies in the drugs of abuse oral testing market are:

- Avitar.
- OraSure.
- Alpha Scientific.
- Bioscan Screening Systems.
- American BioMedica.

Diagnostic testing will tend to be dominated by company consolidation in the near future, with more stringent reimbursement policies and a greater emphasis on cost conscious customers. Therefore, future diagnostic test market customers will require:

- Lower costs.
- Automation.
- Service discounts.

- Volume discounts.
- Reduced inventory levels.

Specific strengths of the drugs of abuse market include high level sales in the chemical analyzer market, professional diagnostics and immunoassay demand are also key drivers of this market. The DOA testing market is also strengthened by U.S. Federal Government mandatory testing regimes. Within the private sector, hospital laboratories and clinical testing facilities also promote sales.

A key advantage of this market is the ability of drug testing companies to self-propagate the market. Such companies pre-empt SAMHSA guidelines and develop emerging drugs of abuse kits. Another key driver of the DOA testing market is the current increase in oral fluid testing, as opposed to traditional urine testing. This also has the advantage of being cost effective and samples can be obtained straight from the individual. Point of care tests are similarly driving the DOA test market.

Interestingly, the number of prescriptions for potentially addictive prescription drugs such as OxyContin has increased over the last few years and this has increased the need for workplace testing. Out-of-competition testing for performance enhancing drugs in sport is also on the increase and will lead to an increase in the market. Technology advancements such as the increase in knowledge of pharmacogenetics is also predicted to propel this industry in the near future.

The main weaknesses of the current DOA testing market include ongoing problems with reimbursement and retrenchment within the hospital field. Also, as the global economy is generally weak, this has a knock-on effect on this field. The geographic combination of product sales will be affected by fluctuating exchange rates and so weakens the market further.

The European market, although strong is significantly below that of the U.S. Therefore, there is great potential here to grow the DOA testing market further. This of course will depend on each specific countries Government regulations and also the requirement by end users. Within Emerging markets, the following points must be considered:

- Changing patterns of opiate use in Asia, particularly in China's Yunnan province.
- The recent surge of injection drug use among drug users in Pakistan.
- Substantial increases of injection drug use in African countries, particularly Egypt, Kenya, Mauritius, Nigeria, South Africa and Tanzania.
- Growing trends in production, trafficking and consumption of methamphetamine and cocaine in Mexico.
- Ecstasy use in South Africa.
- Rising drug abuse in Brazil.

The emergence of new drugs and poly drug use and the prevalence of methamphetamine and amphetamine abuse in North America are not only a cause for concern but also an opportunity to grow the DOA testing market further. Multi-drug testing opportunities are also growing in the U.S. with concurrent use of methamphetamine, MDMA, LSD, ketamine, GHB and flunitrazepam among American youths. There are also significant opportunities within the alternative specimen testing sector within DOA testing. Saliva and oral fluid tests are increasing in usage and parallel urine test sensitivities.

There are noteworthy threats to the DOA testing markets and this includes a crack-down by the U.S. government on addictive drug prescribing. OxyContin sales reduced from $[redacted] in the U.S. in [redacted] to $[redacted] in [redacted], a trend that this is set to decrease in coming years. Consequently, over the next decade the level of positive DOA test positives are predicted to reduce, and so restrict the buying power of end-testers.

Competition within the market will also intensify with respect to chemical and immunodiagnostic analyzers. As technology within these systems increases, the market will flood with hi-spec facilities which could drive sales prices down. Global economic retraction has restricted the number of new-hires to the workplace. This in turn has reduced the number of pre-employment DOA tests. Expiration of patents and intellectual property claims also threaten this market place.