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MOLECULAR BIOLOGY REAGENT SYSTEMS

VOLUME 2.
AMPLIFICATION, SEQUENCING,
CDNA SYNTHESIS, LABELING, DETECTION
& OTHER KITS

AN ANALYSIS OF
MARKET SIZE & GROWTH,
MARKET SHARE, PURCHASE PLANS &
SUPPLIER ASSESSMENT FOR
THE U.S. LIFE SCIENCE RESEARCH MARKET

A Multi-Client Report

by
PhorTech International
San Carlos, California

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I. BACKGROUND

A. SURVEY OBJECTIVES

The purpose of this survey was to provide the management of our client companies with an analysis of the current market for molecular biology reagent systems (including the present consumption of kits for nucleic acid labeling, nucleic acid detection, DNA sequencing, amplification and other applications) in the United States and of the attitudes of a cross section of researchers who utilize these kits in their work. Because the data from this survey was so extensive, we performed a completely separate survey and analysis of the nucleic acid isolation and purification market with the results presented in a companion report, Volume 1. This second volume deals with the analysis of molecular biology reagent systems designed for amplification, sequencing, synthesis, labeling and detection of nucleic acids from various sources.

A random cross-section of U.S. researchers from the PhorTech panel of life science researchers was used for this survey. The surveying was blind, with no reference made to any clients for the survey. To encourage respondents to express themselves freely and without bias, the survey was anonymous, and made frequent use of open-ended questions.

The two demographic screens used to characterize respondents included years of experience with molecular biology techniques and the respondents' type of organization.

Early in the survey, respondents were asked whether or not they currently used molecular biology reagents or procedures in their work and whether they used reagents in kit format as opposed to purchasing all reagents individually. Those who indicated that they did use kits were then asked to indicate the smallest group of people that shares the most reagents and equipment in the lab group. Respondents were then directed to detailed audit questions.

Users were also asked to itemize the commercial kits they utilized for DNA sequencing, including the brand and type of kit, number of kits used annually, approximate price per kit and the forecast percent change over the next 12 months for radioactive manual sequencing kits, non-isotopic manual sequencing kits and automated sequencing kits.

Respondents were then queried regarding their usage of thermostable enzymes. They were first requested to identify current applications from a list of 17 options including automated cycle sequencing, cloning PCR products, disease diagnosis, distinguish alleles, fingerprinting, genetic mapping, GMO detection, in vitro labeling, in-situ PCR, LA PCR, manual cycle sequencing, presence of sequencing, quantitative PCR, quantitative RT-PCR, RT-PCR, site-directed mutagenesis or an 'other' option for those performing an

unlisted application. Respondents were also asked to provide detailed audit information regarding their thermostable enzyme kit usage by itemizing the brand and type of kit, annual kit consumption, the number of preps per kit, cost and percent change over the coming 12 months. The next audit requested detailed information about separate thermostable enzyme purchases, including the brand, product name, consumption of units per year, the price per unit and anticipated change over the next year. Respondents were also asked to provide audit information on commercial kits for ribonuclease protection assays.

After completing a multiple choice question regarding the types of nucleic acid labeling kits currently in use (from a list including random primer, nick translation, in vitro transcription, 5' end labeling, and direct enzyme labeling of oligos), respondents were then asked to complete an audit of these kits. They were specifically asked to identify the type of kit from the above list, the brand, name, number of kits consumed annually, the price per kit and the anticipated percent change over the coming 12 months.

Respondents were then directed to a multiple choice question identifying which of the following six cloning kit applications they currently perform: cDNA cloning, Expression cloning (bacterial), Expression cloning (eukaryotic), Genomic DNA, PCR product cloning, or an 'Other' category where respondents could write-in an unlisted application.

This was immediately followed by an audit of molecular biology kits for cDNA synthesis and cloning. Furthermore, specific questions requested respondents performing cDNA synthesis to identify the reverse transcriptase used. Choices included AMV-RT, MMLV-RT, MMLV-RT RNAse H-, Tth or a write-in category.

The final series of questions refers to respondents' usage of other types of commercial kits. Consistent with the previous section, this begins with a multiple choice question identifying other types of commercial kits currently in use from the following list of seven options: Differential display, Genotyping/fingerprinting, In vitro transcription (RNA production), In vitro translation, RACE, Site-directed mutagenesis and Transfection. This is followed by an audit question requesting product details in each of these kit categories.

Finally, respondents were also asked what improvements they would like to see in molecular biology kits and if there were any additional applications in which they would like to see a commercial molecular biology reagent system.

Major objectives of the survey were to estimate the present size and growth rate for the molecular biology kit market as a whole and for major segments within this market. Secondly, we wanted to determine the present market share for major kit categories among leading companies in the US and to

project which supplier has the best prospects for growth in the coming year. Lastly, profiles of respondents most likely to purchase the various kits will be carefully examined.

The audit should permit the evaluation of our clients' present market positions, identify marketing strengths and weaknesses, and suggest strategies to develop or improve sustainable competitive advantage.

This report is the fourth and final 2001/2002 study in a growing series of market research analyses that began in 1993. We plan to continue the series, adding titles and alternating between U.S. and international markets, depending upon our clients' suggestions and support.

Topics in the U.S. series published in 2001/2002 include:

Electrophoretic Instrumentation & Reagents
Molecular Biology Reagent Systems, Vol. 2

This series also includes the following reports covering international markets:

Densitometers & Image Analysis in Europe
DNA Sequencing in the Far East.

The 2000/2001 series covered the following three reports:

U.S. DNA Amplification
U.S. Molecular Biology Reagent Systems, Vol. 1
Molecular Biology Reagent Systems, Vol. 1 in the Far East.

In the 1999/2000 series, we have released three reports examining the following markets. These are:

Microplate Equipment in Europe
DNA Sequencing in the U.S.
Monoclonal Antibodies in the U.S.

The following nine titles have been released in the series for 1998/1999:

Cell & Tissue Culture in the U.S.
Cytokines & Growth Factors in the U.S.
DNA Amplification in the Far East
DNA Sequencing in Europe
Electrophoretic Gel Media in Europe
HPLC in the Life Sciences in the U.S.
Molecular Biology Reagent Systems, Vol. 1
Molecular Biology Reagent Systems, Vol. 2 in the Far East
Protein Expression Systems in the U.S.

The following titles have been released in the U.S. series for 1997/8:

DNA Sequencing
Molecular Biology Reagent Systems, Vol. 1
Molecular Biology Reagent Systems, Vol. 2
Molecular Diagnostics.

Clients are reminded that additional copies of any of these reports that have been purchased in the past are available at a modest cost. Please contact us for further details. Those wishing to know publication dates for any of these reports, or wanting to read summaries of the 72+ reports in this series are invited to visit our Web site at: www.phortech.com.

B. SURVEY METHODOLOGY

E-mail invitations to take part in the survey were sent to a selected cross-section of life science researchers from our panel of 5,000 U.S. life science researchers. After selection for appropriate areas of interest, invitations were sent to 1,395 U.S. members of the panel who have been in contact with us in the last year and previously indicated their involvement in work with nucleic acids, amplification or sequencing techniques. Customized email invitations to the web site survey were sent on October 16th. The survey was kept open until October 25th at which time nearly 500 responses had been received.

Each participant received an email invitation including the web address of the survey and a unique validation code.

To improve response rates, respondents were able to select from a choice of six prizes for completing the survey. These were a custom designed tee-shirt, a \$5 gift card towards any purchase at a Barnes & Noble bookstore, a box of Ferrero Rocher chocolates, a laser pointer, a AAA mini-Maglite flashlight or 1 pound of Starbuck's coffee.

No reference was made to any of our clients as sponsors of the survey. The questionnaires were anonymous, a combination of tabular entry, check-offs, and open-ended probes. Apart from the prizes, no inducements were employed. However, the majority of respondents did identify themselves by filling in the prize form. This made it possible for us to double-check the responses to some questions by contacting respondents, which improved the accuracy of the data.

By the close of the survey, 492 responses had been received for an overall response rate of 35.3%, which was significantly better than expected.

We felt that respondents spent considerable time explaining their positions on the open-ended questions. We have no reason not to believe that the survey is representative of the entire U.S. population of molecular biology kit and reagent users. We have found that, within the limits of experimental error for sample size we have obtained, no demonstrable bias could be detected that could affect our results.

Based upon these responses, the overall statistical results presented in this report are accurate to within ± 4.4 percentage points at the 95% confidence level. In cases where we only calculate the percentages of respondents that use kits, the results are accurate to $\pm 4.8\%$. In our experience, 95% confidence levels are appropriate primarily for scientific experiments. Most business people making decisions are content to be right more often than they are wrong. In this case, a 65% confidence level, (in which you would be right twice as often as you would be wrong) is more appropriate. Conveniently,

65% confidence levels are nearly exactly one half the size of the 95% level, thus our 65% levels would be $\pm 2.2\%$ for all respondents and 2.4% for all kit users.

According to the binomial distribution theory, these values are valid when the measured event has about a 50% probability. When the measured event is considerably more rare than this, the corresponding confidence intervals get smaller. On the other hand, these confidence intervals are valid for answers based upon the complete pool of respondents. When analyzing data for a group that includes only a small segment of respondents, the answers are less certain and confidence intervals are correspondingly larger.

In this report, we will calculate more exact individual confidence intervals when appropriate. In our comments, we will note whether given differences are significant at either the 65% or 95% level. To aid our clients in determining the appropriate confidence interval for various combinations of sample size and measurements, we have created the following table. Just read the closest percentage on the left and find the closest sample size column. The intersection will show the confidence interval for that combination. For example, a measured 35% value with a sample size of 500 has a 95% confidence interval of $\pm 4.2\%$.

95% Confidence Intervals for Various Percentages & Sample Sizes

Percent	n=10	n=20	n=50	n=100	n=200	n=500	n=1000
5%	$\pm 13.5\%$	$\pm 9.6\%$	$\pm 6.0\%$	$\pm 4.3\%$	$\pm 3.0\%$	$\pm 1.9\%$	$\pm 1.4\%$
10%	$\pm 18.6\%$	$\pm 13.1\%$	$\pm 8.3\%$	$\pm 5.9\%$	$\pm 4.2\%$	$\pm 2.6\%$	$\pm 1.9\%$
20%	$\pm 24.8\%$	$\pm 17.5\%$	$\pm 11.1\%$	$\pm 7.8\%$	$\pm 5.5\%$	$\pm 3.5\%$	$\pm 2.5\%$
35%	$\pm 29.6\%$	$\pm 20.9\%$	$\pm 13.2\%$	$\pm 9.3\%$	$\pm 6.6\%$	$\pm 4.2\%$	$\pm 3.0\%$
50%	$\pm 31.0\%$	$\pm 21.9\%$	$\pm 13.9\%$	$\pm 9.8\%$	$\pm 6.9\%$	$\pm 4.4\%$	$\pm 3.1\%$
65%	$\pm 29.6\%$	$\pm 20.9\%$	$\pm 13.2\%$	$\pm 9.3\%$	$\pm 6.6\%$	$\pm 4.2\%$	$\pm 3.0\%$
80%	$\pm 24.8\%$	$\pm 17.5\%$	$\pm 11.1\%$	$\pm 7.8\%$	$\pm 5.5\%$	$\pm 3.5\%$	$\pm 2.5\%$
90%	$\pm 18.6\%$	$\pm 13.1\%$	$\pm 8.3\%$	$\pm 5.9\%$	$\pm 4.2\%$	$\pm 2.6\%$	$\pm 1.9\%$
95%	$\pm 13.5\%$	$\pm 9.6\%$	$\pm 6.0\%$	$\pm 4.3\%$	$\pm 3.0\%$	$\pm 1.9\%$	$\pm 1.4\%$

