



2002/2003 MSPPSA SERIES

DNA AMPLIFICATION
REAGENTS &
METHODOLOGY

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 DNA amplification reagents and most common methodologies utilized in the U.S. This represents the attitudes and expectations of a cross-section of researchers who currently utilize DNA amplification in their work.

The survey was expanded this year to incorporate a dedicated section on real-time quantitative PCR and a more detailed examination of thermostable enzyme usage. Due to the larger size, the results regarding instrumentation used for DNA amplification has been presented separately. This companion report, DNA Amplification Instrumentation, was published on May 8th and includes an analysis of the real-time quantitative PCR platform market in addition to that for thermal cyclers.

The surveying was blind, with no reference made to any clients for the survey. To encourage respondents to express themselves freely, the survey was anonymous, and made frequent use of open-ended questions.

Several demographic screens have been used to characterize respondents, including scientific discipline, type of organization and length of experience with DNA amplification. Each respondent was also characterized by the applications for which he employs DNA amplification.

Early on in the survey, respondents were asked whether or not they currently use PCR, cycle sequencing, real-time PCR or other DNA amplification techniques in their work. Those respondents who answered positively were asked to provide the number of people in their group. These were then directed to the section regarding current usage of real-time quantitative PCR, a new addition for this year. This section, analyzed in the companion report on instrumentation, examines the applications currently in use, the monthly throughput, methods of monitoring assays (including multiplexing) and types of fluorophores used for real-time PCR. Based on the installed base, the historical growth and total size of the US market is estimated, in addition to an extensive evaluation of manufacturers' market shares.

Users were next asked a comparable series of questions regarding their usage of thermal cyclers for techniques other than real-time quantitative PCR. These results are also presented in the DNA Amplification Instrumentation report released recently. Similar, to the analysis for real-time PCR platforms, the market size and historical growth of this sector is examined, along with manufacturers' market shares. Respondents are also asked to provide their monthly throughput of reactions using thermal cyclers. Customer satisfaction with current instrumentation is also examined along with the reasons for selecting their most recently purchased model and the purchasing plans

within the next year. Respondents were also given an opportunity to suggest improvements to current offerings.

Respondents were next asked a series of questions regarding their usage of reagents for DNA amplification beginning with an open-ended question regarding the primary supplier of nucleotides. Next, respondents indicated their preference for the form of reagents, either kits or individual reagents, which is followed by a secondary question regarding whether they prefer to use master mixes or not. Specifically regarding thermostable enzyme usage, respondents are then asked to identify procedures currently used in the laboratory from a list of the eight options. These include standard PCR, high fidelity PCR, hot-start PCR, long range PCR, RT-PCR one-step, RT-PCR two step, quantitative PCR or RT-PCR and cycle sequencing.

Next, respondents were directed to a detailed audit question of thermostable enzymes purchased in a kit format. In particular, using the same list of procedures from the multiple choice question, researchers were asked to itemize the brand of thermostable enzyme kit, the consumption of kits on a monthly basis, the number of reactions per kit, the approximate kit price and the anticipated percent change in the throughput of reactions anticipated over the next 12 months. This information was requested for each procedure performed in the laboratory.

This is immediately followed by a comparable audit of separate thermostable enzymes used for DNA amplification. Here, for each of the procedures, respondents are requested to indicate the supplier, the monthly consumption in number of units, the price per unit and anticipated percent change in throughput of reactions over the coming 12 months.

Respondents were then asked why they chose these brands and whether there are any suppliers which they refuse to buy from and why. This is followed by a question asking them to rank nine leading U.S. reagent suppliers (and on optional 'other' category) in seven key areas. In particular, researchers choose the highest ranked supplier with regards to value for money, yield, results for long range PCR, highest specificity, highest fidelity, providing products for problematic PCR and for ease of optimization. Finally, respondents were asked to indicate which of eleven improvements would be most important to their work. Choices here include higher fidelity, higher yield, less cycling time, longer amplicons, better sensitivity, higher specificity, less set-up time, the capability to perform real-time analysis, less reagent consumption, room temperature assembly, or minimal optimization. Alternatively, researchers could write-in an unlisted improvement. This question, in addition to one regarding the type of PCR reaction container (0.5 ml thin walled, 0.5 ml standard, 0.2 ml thin walled, 0.2 ml standard, a slide, 96 well plate, a 384 well plate or 'other' type) used most often are both also found in the DNA Amplification Instrumentation report.

Major objectives of the survey were to estimate the present size of the thermostable enzyme market for kits and individual reagents. For each of these markets, we will also determine the present market share for leading companies in the U.S. based upon respondents' consumption and expenditure. We will also calculate the average monthly consumption and dollar spend for each type of reagents, as well as for those used for each procedure. In conjunction with the assessment of suppliers in the final series of questions, clients should be able to evaluate their present market positions, identify marketing strengths and weaknesses, and determine strategies to develop or improve sustainable competitive advantage.

This report is the second 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.

Reports scheduled to be released in the 2002/2003 series include the following U.S. topics:

DNA Amplification Instrumentation
DNA Amplification Reagents & Methodology
Microplate Reader & Equipment Market

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 over 5,000 U.S. life science researchers. After selection for appropriate areas of interest, invitations were sent to a random selection of 1,542 U.S. members of the panel who have been in contact with us in the last year. Customized e-mail invitations to the web site survey were sent to the selected individuals on February 26th, 2002.

Each participant received an e-mail 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 five prizes for completing the survey. These were a custom designed tee shirt, a chest of Ferrero Rocher chocolates, a laser pointer, a 120 minute MCI phonecard, an electronic stopwatch, a stainless steel folding knife, or a \$5 gift card good towards any purchase at Barnes & Noble.

The questionnaires were anonymous, using a combination of tabular entry, check-offs, and open-ended probes. 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 telephoning respondents, improving the overall confidence in the data.

Undeliverables to the PhorTech database mailing were measured at 89 or 5.8%. By the close of the survey on March 4th, 2002, we had received 438 responses to the first half of the survey on instrumentation and 386 responses to the reagent section. After removing duplicate responses and non-users, the final dataset contains a total of 412 valid responses regarding amplification instrumentation and 378 reporting thermostable enzyme data. This translates to an 30.1% response rate for the instrumentation section, and 26.6% for the reagent section. This exceeded our expectations.

We did not observe any survey fatigue in this questionnaire, and 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 DNA amplification users.

Based upon 378 respondents describing thermostable enzyme usage for DNA amplification, the overall statistical results presented in this report are accurate to within ± 5.0 percentage points at the 95% confidence level.

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 appropriate. Conveniently, 65% confidence levels are nearly exactly one half the size of the 95% level, thus our 65% levels would be $\pm 2.5\%$ for all respondents.

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 the 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 200 has a 95% confidence interval of $\pm 6.6\%$.

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%	$\pm 13.5\%$	$\pm 9.6\%$	$\pm 6.0\%$	$\pm 4.3\%$	$\pm 3.0\%$	$\pm 1.9\%$	$\pm 1.4\%$

II. DEMOGRAPHIC SEGMENTATION

QUESTION 3.

Question:

How would you best describe your organization (*Best single answer*): Academia, Hospital/med school, Biotech/pharma industry, Other industry, Government agency, or Private research foundation?

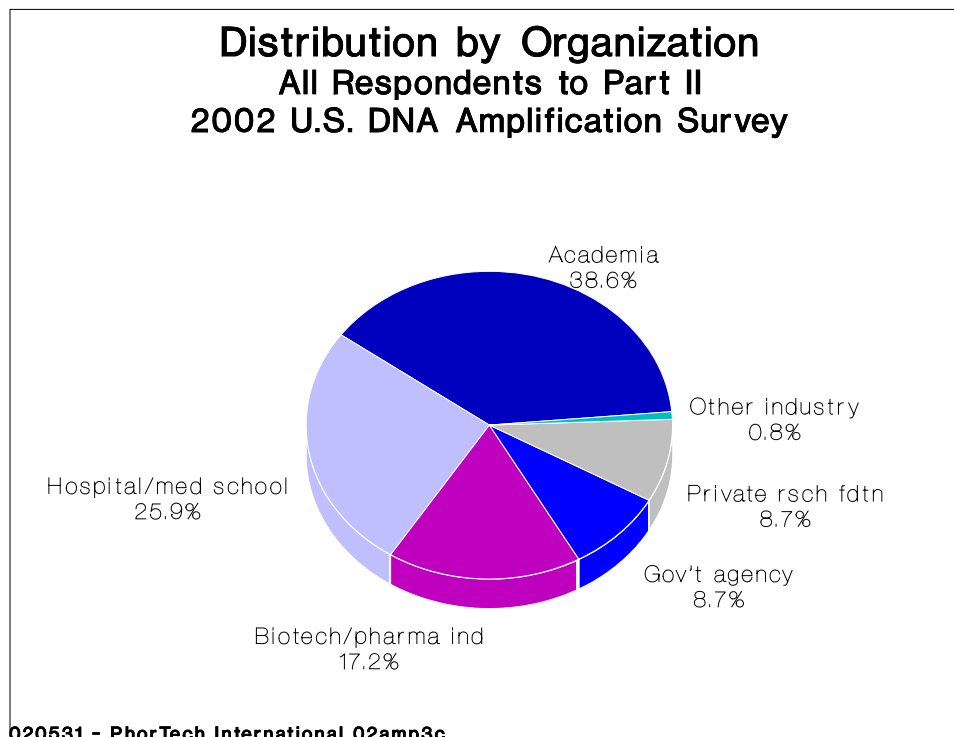
Rationale:

This question allows us to examine the distribution of respondents over the six types of organizations listed. This will identify where our respondents are located, and the primary sources of funding for current DNA amplification.

Results:

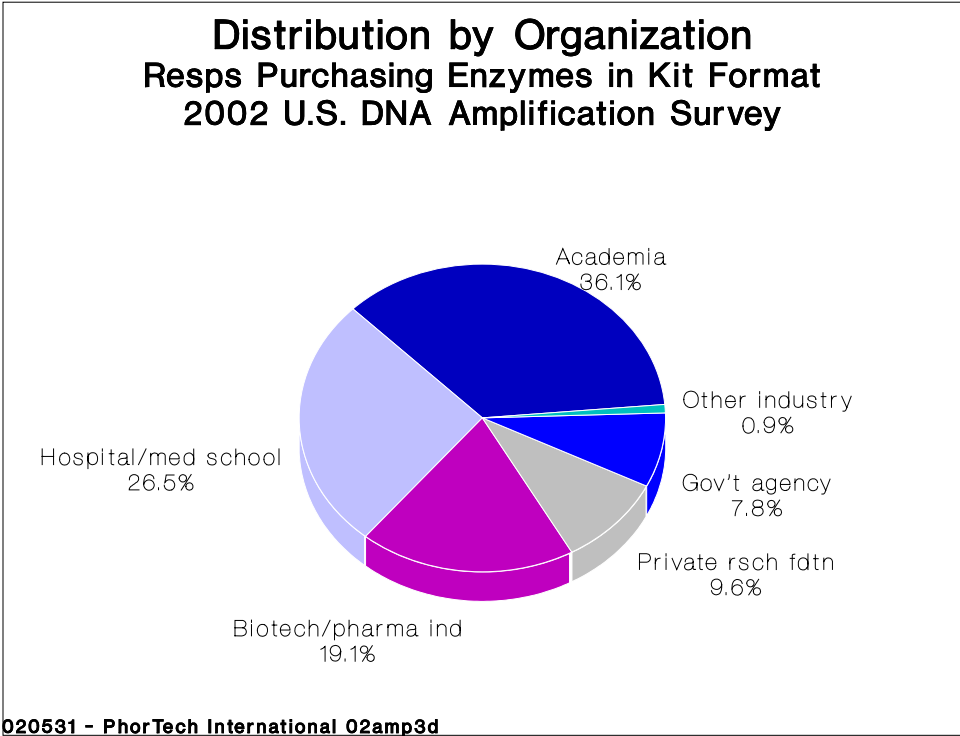
Before analyzing, the data required some editing to make the responses internally consistent. In order to reflect the source of funding, those working in a hospital, medical school or health science center have all been categorized as a hospital or medical school. Researchers working in private research foundations, many of which have an email ending in .org, and those receiving private funding from organizations such as HHMI, have been classified as private research foundations. VA Medical Centers and military organizations are considered to be government agencies.

The following pie chart shows the organizations from which our 378 DNA amplification users originate.

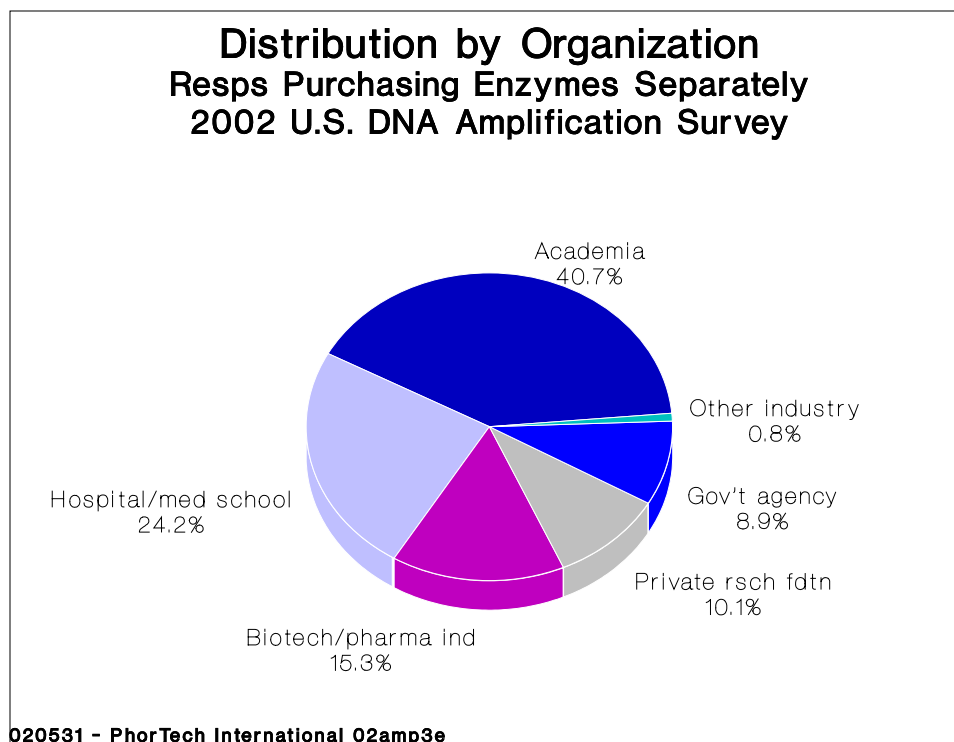


Close to 40% of the respondents are located in academia, with an additional 25% working in either a hospital or medical school. Of the remaining 35% of respondents, industry contributes 18%, of which nearly all are working in the biotechnology or pharmaceutical sectors, and government agencies and private research foundations each account for near 9%. Overall, this is remarkably similar to the results from our 1999 survey of respondents using this technique.

As seen in the following pie chart, the comparable distribution of the 230 researchers purchasing thermostable enzymes in kit format is not significantly different.



As seen at the top of the next page, the source of the 248 respondents reporting separate thermostable enzymes in the audit question is also not significantly different, despite small variations.



Analysis:

For completeness, we also present a list of the organizations represented by the respondents to this survey. These are presented in alphabetical order by type of organization with the largest sector, academia, listed first.

Organizations Represented by Respondents to this Survey

Academia
Ashland University
Auburn University
Boston University
Brandeis University
Bucks County Community College
California State University, Long Beach
Cancer Research Center of Hawaii
Columbia University
Cornell University
Creighton University
East Carolina University
Emory University
Harvard Dental School
Harvard University
Iowa State University
Johns Hopkins University
Louisiana State University
Marshall University
Massachusetts Institute of Technology
Miami University

Michigan Tech University
Montana State University
Moss Landing Marine Laboratories
North Carolina State University
Northwestern University
Ohio State University, Columbus
Ohio University
Oklahoma Animal Disease Diagnostic Laboratory
Oregon State University
Penn State University
Purdue University
Rockefeller University
Saint Louis University
San Diego State University
Southern Illinois University
Stanford University
State University of New York, Buffalo
SUNY at Buffalo
Tufts University
University of Alabama, Birmingham
University of Alberta
University of Arizona
University of Arkansas, Monticello
University of California, Davis
University of California, Los Angeles
University of California, San Diego
University of California, San Francisco
University of Chicago
University of Cincinnati
University of Connecticut
University of Delaware
University of Denver
University of Florida
University of Florida, McKnight Brain Institute
University of Georgia
University of Illinois, Chicago
University of Illinois, Urbana
University of Illinois, Urbana-Champaign
University of Iowa
University of Kentucky
University of Louisiana, Monroe
University of Maryland Biotechnology Institute
University of Miami, Biochem
University of Michigan
University of Minnesota
University of Missouri
University of Montreal
University of Nebraska, Lincoln
University of New Mexico
University of North Carolina, Chapel Hill

University of Pennsylvania
University of Pittsburgh
University of Puerto Rico
University of Rochester
University of Southern California
University of Southern Mississippi
University of Tennessee
University of Toronto
University of Vermont
University of Virginia
University of Washington
University of Wisconsin, Madison
Vanderbilt University
Virginia Tech
Washington University
Wayne State University
Williams College

Hospital/Medical School

AMC
Baylor College of Medicine
Beth Israel Deaconess Medical Center
Case Western Reserve University
Children's Hospital of The King's Daughters, Center for Pediatric Research
Clarian Health
Dana-Farber Cancer Institute
Duke University Medical Center
Emory University School of Medicine
Harvard Medical School
Hershey Medical Center
Hospital for Sick Children, Toronto
Institute of Human Virology, University of Maryland
Johns Hopkins Hospital
Johns Hopkins School of Medicine
Louisiana State University
LSU Health Sciences Center
LSU Health Sciences Center, Neuroscience Center
Mallory Institute of Pathology
Massachusetts General Hospital
Medical College of Ohio
Medical College of Virginia
Medical College of Wisconsin
Medical University of South Carolina
Memorial University of Newfoundland/Health Sciences Ctre
Michigan State University
New York University Medical Center
Northwestern University
Ohio State University Medical Center
Penn State Hershey Medical Center
Rush Medical Center

Saint Louis University
Southern Illinois University School of Medicine
SUNY Upstate Medical University
Texas A&M University College of Veterinary Medicine
University of Alabama Medical School
University of Arkansas for Medical Sciences
University of California, Davis School of Medicine
University of California, Los Angeles, Pediatric Endocrinology
University of California, San Diego
University of California, San Diego Medical Center
University of Cincinnati
University of Colorado Health Sciences Center
University of Florida
University of Georgia College of Veterinary Medicine
University of Louisville School of Medicine
University of Massachusetts Medical School
University of Medicine & Dentistry, New Jersey, RW Johnson Medical School
University of Minnesota
University of Mississippi Medical Center
University of North Carolina, Chapel Hill
University of Pennsylvania
University of Pittsburgh
University of Pittsburgh Medical School
University of Pittsburgh School of Medicine
University of South Dakota School of Medicine
University of South Florida
University of South Florida College of Medicine
University of Southern California
University of Tennessee
University of Texas Health Sciences Center, Houston
University of Texas Health Sciences Center, San Antonio
University of Texas Medical Branch
University of Wisconsin
UT Southwestern Medical School
Vanderbilt University Medical Center
Wake Forest University School of Medicine
Weill Cornell Medical College

Biotechnology/Pharmaceutical Industry

Abbott Laboratories
Acambis, Incorporated
Advanced Bioscience Laboratories
Astrazeneca R&D, Boston
Aventis Pharmaceuticals
Beckman Coulter, Inc.
Berkeley HeartLab, Inc.
Bioqual, Inc.
Bolder Biotechnology
Calgene
Cambria Biosciences

Chiron Corporation
Clingenix Inc.
Colgate-Palmolive
Eli Lilly and Company
ENZO Life Sciences
Essential Therapeutics
FDAH, Inc.
Fibrogen, Inc.
Gene Check, Inc.
GeneDx Inc.
Genetic Therapy Inc.
Genzyme Corporation
Genzyme Transgenics Corporation
GlaxoSmithKline
Heska Corporation
Hoffmann-LaRoche Inc.
Intervet, Inc.
ISTA Pharmaceuticals
Koronis Pharmaceuticals
Ligand Pharmaceuticals
Lynx Therapeutics Inc
Merck & Company, Rahway
Merck Research Labs, West Point
Millennium Pharmaceuticals
Monsanto, Davis
Monsanto, Chesterfield
NeoRx Corporation
Nestor Motria Associates
Neurocrine
Neurome, Inc.
Novozymes Biotech, Inc
Osiris Therapeutics
Protein Design Labs, Inc.
Pfizer Corp, Cambridge
Pfizer Global R&D, Groton
Pharmacia Corporation
Procter & Gamble
Sigma-Aldrich
Stratagene
Third Wave Technologies
Torrey Mesa Research Institute/Syngenta
Wyeth Ayerst Research
Wyeth Vaccines

Government Agency

Armed Forces Institute of Pathology
Brookhaven National Laboratory
Centers for Disease Control and Prevention, Anchorage
Centers for Disease Control and Prevention, Atlanta
Centers for Disease Control and Prevention/NIOSH

Federal Drug Administration
James A Haley VA Medical Center
National Cancer Institutes, Frederick
National Cancer Institutes, Rockville
National Center for Toxicology Research
National Institutes of Health
National Institutes of Health/NEI
National Institutes of Health/NIAID
National Institutes of Health/NIEHS
National Institutes of Health/NINDS
National Institutes of Health/NIOSH
National Research Council Canada, Plant Biotechnology Institute
USDA Forest Service
USDA/Center for Veterinary Biologics, Ames
USDA/University of Missouri
USDA-ARS ANRI
USDA-ARS HCRL
USDA-ARS, Beltsville
USDA-ARS, Mississippi State
USUHS
VA Medical Center, Memphis
Walter Reed Army Institute for Research

Private Research Foundation

BSCS
Burnham Institute
Cedars-Sinai Medical Center
Henry Ford Health System
Jackson Laboratories
John Wayne Cancer Institute
Lahey Clinic
Mayo Clinic, Jacksonville
Mayo Clinic, Rochester
Mayo Foundation
MD Anderson Cancer Center
MedStar Research Institute
Memorial Sloan-Kettering Cancer Center
National Jewish Medical & Research Center
Oklahoma Medical Research Foundation
Roswell Park Cancer Institute
Scripps Research Institute
Southwest Foundation for Biomedical Research
St. Jude Children's Research Hospital

Other Industry

Charles River Laboratories
IDNA Systems, Inc.
Nestle Purina Pet Care

QUESTION 2.

Question:

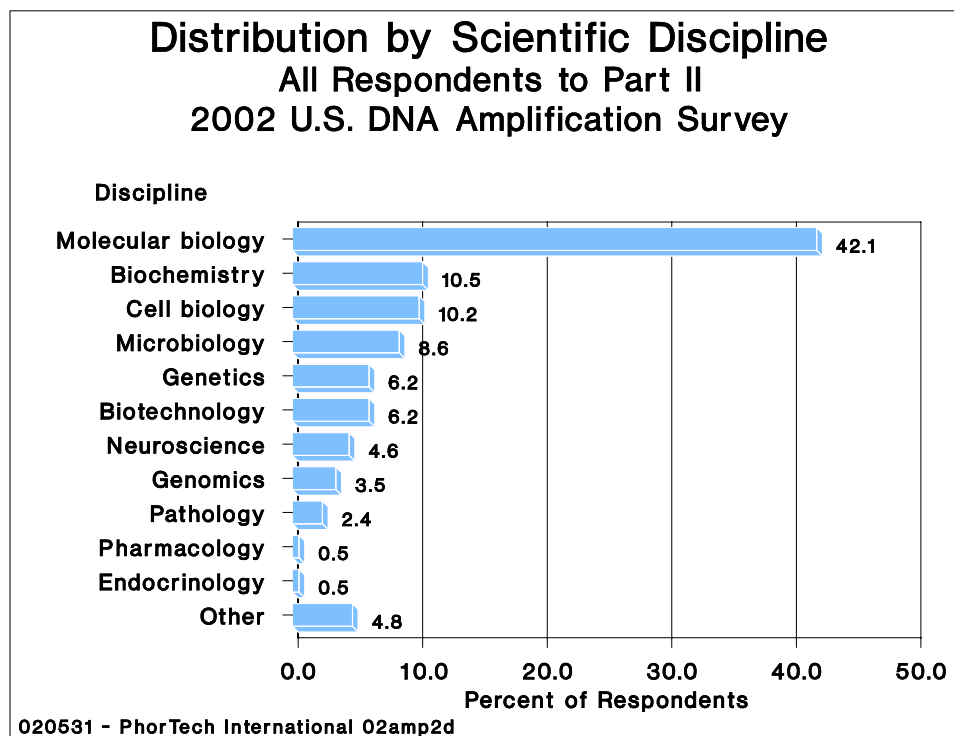
Please indicate below your primary scientific discipline: (*Best single answer*):
biochemistry, biotechnology, cell biology, endocrinology, genetics, genomics,
microbiology, molecular biology, neuroscience, pharmacology, pathology or
other?

Rationale:

The responses to this demographic screen will indicate the major disciplines of researchers performing DNA amplification. The choices reflect a balance between an exhaustive list of all possible life science categories and the most frequently-mentioned categories based upon previous work. Knowledge of the disciplines involved can give clients a good indication of the breadth of a particular technique.

Results:

In the horizontal bar chart below, we present the demographic profile of the 373 amplification users who answered this question.



As mentioned in the Amplification Instrumentation report, these results are consistent with previous studies in this area. Although molecular biology is by far the most common scientific discipline, it represents a slightly lower share than the 55% found in the previous 1999 study. At the same time, cell

biology and genomics double in share and biochemistry shows a small but insignificant increase. In spite of the fact that near one quarter of respondents are working in hospitals or medical schools, the combined share of those working in affiliated disciplines (neuroscience, pathology, pharmacology and endocrinology) is very small.

Analysis:

Molecular biology continues to be the primary discipline of researchers involved with DNA amplification, mentioned by four times as many respondents as any other area. Only two disciplines, biochemistry and cell biology represent at least 10% of respondents. Compared to our previous report in this area, published in 1999, the only significant difference is a small increase in those associated with cell biology.

QUESTION 4.

Question:

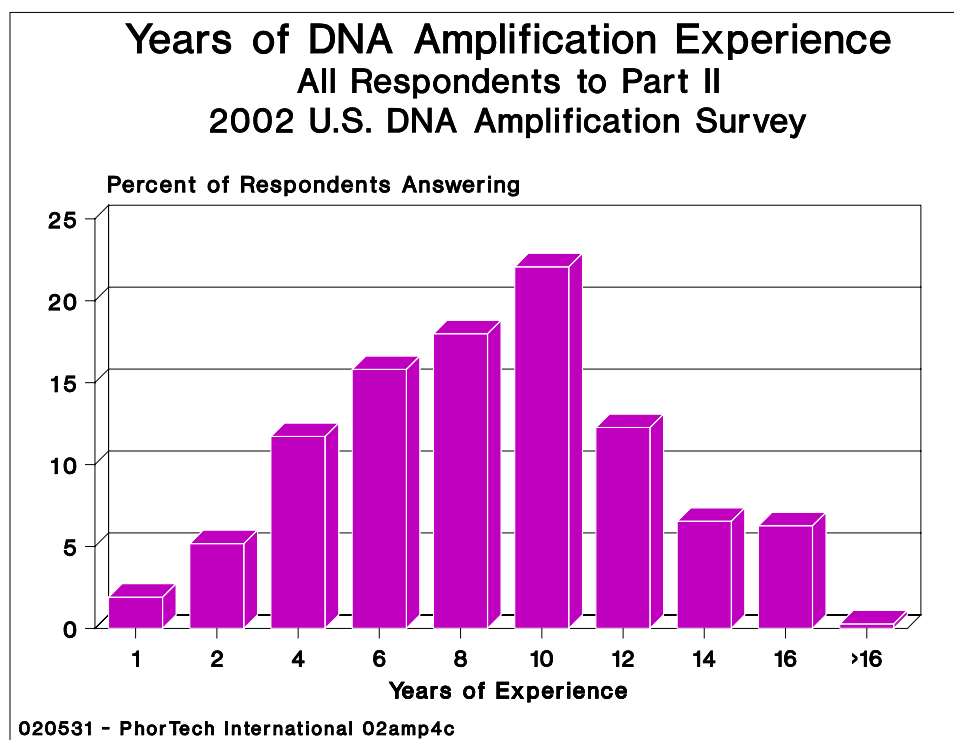
How long (*in years*) have you been using DNA amplification?

Rationale:

This question allows us to determine respondents' level of experience with DNA amplification, as well as to investigate the expansion of this technique. Depending upon the results, we may be able to generate meaningful cross-tabulations for new versus highly experienced users.

Results:

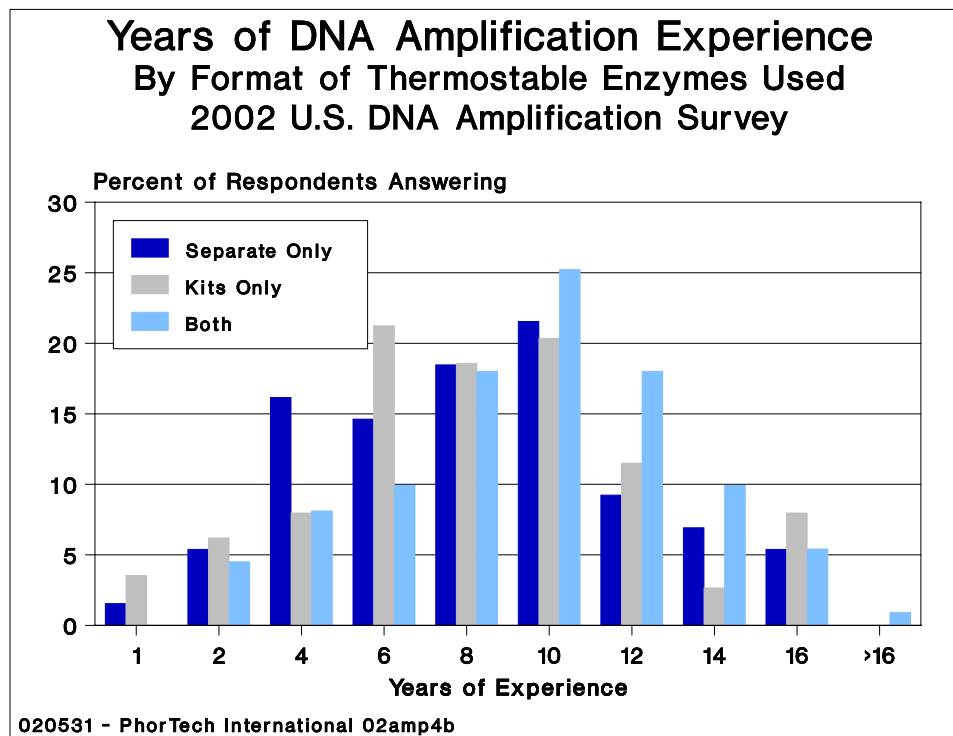
In the vertical bar chart below, we present the demographic profile for all 367 respondents who answered this question, rounded up to the next year.



We received a wide variety of responses ranging from just 1 or 2 years of experience with DNA amplification up to 20 years for a combined total of 3,010 years. With a mean value of 8.2 years, a median of 8 years and 10 year mode, it is not surprising that fully 55% of the respondents report from 5 to 10 years of experience in this field.

For completeness, we also present the results according to the format of thermostable enzymes purchased. According to the responses to the audit data, we find that there are 116 respondents report thermostable enzyme kits

or master mixes only, 134 respondents exclusively purchasing enzymes separately and an additional 114 researchers who indicate purchasing both forms, separate enzymes and kits. The distribution for each of these populations is shown below.



Although there are some variations in the distribution, the statistical values summarized in the following table indicate no significant difference in the level of experience of respondents in these three groups.

Level of Experience for Respondents by Form of Thermostable Enzymes Purchased,
Statistical Values

Format	Mean	Median	Mode
Separate enzymes	7.8	8	10
Enzyme kits	7.9	8	10
Both	9.2	10	10
All	8.2	8	10

Analysis:

The overall mean of 8.2 years of experience is relatively similar to the 7.8 year mean reported in our 1999 study, which was nearly double the 4.7 year mean found in 1995. Looking at those selecting kits vs separate thermostable enzymes, we have found no significant difference in the number of years these two groups of respondents have been working with amplification. Finally, based on these results, we believe that these researchers are well-qualified to provide knowledgeable responses to the questions on this survey.