



1997/8 US MSPPSA SERIES

MOLECULAR DIAGNOSTICS SYSTEMS

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

September 30, 1997

Copyright 1997 by PhorTech International, 238 Crestview Drive, San Carlos CA 94070. All rights reserved. No material contained in this report may be reproduced in whole or in part without the written permission of the publisher. This report is not intended to be, and should not be construed as a recommendation for the purchase or sale of any securities mentioned herein. The information has been derived from statistical and other sources which we deem reliable but their completeness cannot be guaranteed. Opinions expressed herein are based upon our interpretation of available information and are subject to change.

TABLE OF CONTENTS

I. BACKGROUND	9
A. Survey Objectives.....	10
B. Survey Methodology.....	13
II. OVERALL MOLECULAR DIAGNOSTICS USAGE.....	15
#1. Current Use of Molecular Diagnostics Procedures	16
#2. Planned Molecular Diagnostics Usage.....	19
#0. Geographical Distribution of Respondents & Users	21
#3. Applications Currently Targeted.....	26
#20. Other Assays Requested	29
#21. Desired Improvements in Molecular Diagnostics Assays.	33
#22. New Developments Affecting Molecular Diagnostics	37
#23. Features for an Automated Amplification Assay System .	42
III: CANCER GENE ANALYSIS	47
#26. Professional Laboratory Position of Respondents	48
#27. Area of Involvement for Cancer Gene Researchers	50
#28. Scientific Field of Interest for Cancer Gene Researchers..	52
#29. Type of Laboratory for Cancer Gene Researchers	54
#3. Cancer Gene Applications Currently Targeted	57
#4. Purpose of Molecular Diagnostic Tests	61
#5. Primary Source of DNA.....	63
#6. Proteinase K / SDS Digestion Usage	64
#7. DNA Purification Methods	65
#8. DNA Concentration Determination Method	66
#17. Anatomical Areas of Interest	68
#24. Laboratory Techniques in Use	70
#25. Methods for Analysis of PCR Products	72
#18. Tumor Marker Samples Analyzed Annually	74
#18+. Forecast Change in Tumor Marker Usage	79
IV. INFECTIOUS DISEASE ANALYSIS	81
#26. Professional Laboratory Position of Respondents	82
#27. Area of Involvement for Infectious Disease Researchers .	84
#28. Scientific Interests of Infectious Disease Researchers.....	86
#29. Type of Laboratory for Infectious Disease Researchers ...	88
#3. Infectious Disease Applications Currently Targeted	91
#4. Purpose of Molecular Diagnostic Tests	97
#5. Primary Source of DNA.....	98
#6. Proteinase K / SDS Digestion Usage	100
#7. DNA Purification Methods	102

#8.	DNA Concentration Determination Method	103
#10.	Types of Probes Used	105
#11.	Means of Acquiring DNA Probes	107
#24.	Laboratory Techniques in Use	109
#25.	Methods of Analysis for PCR Products	111
#9.	Population Size Estimates, Infectious Disease Rschrs	113
#12.	Estimated Market Size for DNA Probe Assays	115
#12+.	DNA Probe Assay Suppliers' Unit & Market Shares	121
#12++.	Forecast Change in DNA Probe Assay Usage	126
#13.	Reasons for Selecting DNA Probe Assay Supplier	128
#14.	Customer Satisfaction with DNA Probe Assays.....	132
#15.	Desired Improvements in DNA Probe Assays	134
#16.	Ranked Supplier Performance: DNA Probe Assays	136

V: GENETIC DISEASE TESTING 141

#26.	Professional Laboratory Position of Respondents	142
#27.	Area of Involvement for Genetic Disease Researchers	145
#28.	Scientific Interests of Genetic Disease Researchers	147
#29.	Type of Laboratory for Genetic Disease Researchers	149
#3.	Genetic Disease Applications Currently Targeted	152
#4.	Purpose of Molecular Diagnostic Tests	157
#5.	Primary Source of DNA.....	158
#6.	Proteinase K / SDS Digestion Usage	159
#7.	DNA Purification Methods	160
#8.	DNA Concentration Determination Method	161
#24.	Laboratory Techniques in Use	163
#25.	Methods of Analysis for PCR Products	165
#19.	Genetic Disease Assay Audit	167
#19+.	Forecast Changes in Genetic Disease Assay Usage.....	174

VI: FORENSIC/IDENTITY TESTING 177

#26.	Professional Laboratory Position of Respondents	178
#27.	Area of Involvement for Forensic Testing Researchers ...	180
#28.	Scientific Interests of Forensic Testing Researchers	181
#29.	Type of Laboratory for Forensic Testing Researchers	182
#3.	Targeted Forensic/Identity Testing Applications.....	185
#4.	Purpose of Molecular Diagnostic Tests	186
#5.	Primary Source of DNA.....	187
#6.	Proteinase K / SDS Digestion Usage	188
#7.	DNA Purification Methods	189
#8.	DNA Concentration Determination Method	190
#24.	Laboratory Techniques in Use	191
#25.	Methods of Analysis for PCR Products	193

VII. QUESTIONNAIRE..... 195

LIST OF TABLES & GRAPHS

I. BACKGROUND	9
Survey Objectives	10
Survey Methodology.....	13
Survey Response Rates.....	13
II. OVERALL MOLECULAR DIAGNOSTICS USAGE.....	15
Molecular Diagnostics Participation Rates, By Source of Name.....	16
Population Estimate of Molecular Diagnostics Professionals, By Source...	17
Total U.S. Population Estimate of Molecular Diagnostics Users	18
Planned Molecular Diagnostic Usage	19
Projected U.S. Population Estimate of Users In 12 Months	20
Geographical Distribution of Five Sources of Names.....	21
Geographical Distribution of All Survey Respondents, by Source.....	22
Geographical Distribution, Molecular Diagnostics Users	24
Geographical Distribution, Original Sources of Names	24
Currently Targeted Applications, All Molecular Diagnostic Users.....	26
Currently Targeted Applications, By Source of Name	27
Projected Population of U.S. Scientists Using Each Targeted Application	28
Other Assays Requested, Sorted by Application Area	29
Desired Improvements in Comm'l. Products, By Application Area	33
Developments Affecting Clinical DNA Diagnostics, By App. Area.....	37
Requested Features for Automated System for Clinical Service, App. Area	42
III. CANCER GENE ANALYSIS.....	47
Professional Laboratory Positions, Cancer Gene Researchers	48
Area of Involvement, Cancer Gene Researchers	50
Scientific Field of Interest, Cancer Gene Researchers.....	52
Scientific Field of Interest, Assoc. of Molecular Pathologists.....	53
Type of Laboratory, Cancer Gene Researchers.....	54
Type of Hospital Laboratory, Cancer Gene Researchers	55
Type of Independent Laboratory, Cancer Gene Researchers.....	55
Current Cancer Genetics Applications and Tests Performed Weekly	57
Currently Targeted Cancer Gene Applications, Share of Mentions.....	60
Purpose of Molecular Diagnostics Tests, Cancer Gene Researchers	61
Test Purpose vs. Laboratory Type, Cancer Gene Researchers.....	62
Primary Source of DNA, Cancer Gene Researchers	63
Proteinase K/SDS Digestion Usage, Cancer Gene Researchers.....	64
DNA Purification Method, Cancer Gene Researchers	65
DNA Concentration Determination Method, Cancer Gene Researchers..	66
Anatomical Areas of Interest, Cancer Gene Researchers.....	68
‘Other’ Anatomical Areas for Oncology Research	69
Laboratory Technique Utilization, Cancer Gene Researchers.....	70
Methods for Analysis of PCR Products, Cancer Gene Researchers.....	72
Tumor Marker Samples Analyzed Yearly, Cancer Gene Researchers	74
Tumor Market Audit, % of Cancer Geneticists Analyzing.....	75
Tumor Market Audit, Unit Share by Marker Type.....	76

Tumor Market Audit, Adjusted Unit Share by Marker Type	76
Tumor Market Audit, Average Number of Samples Analyzed Annually....	77
Extrapolated Market Size for U.S. Tumor Marker Analysis	78
Forecast Change in Tumor Market Use Over the Next 12 Months	80
Calculated Increase in Tumor Marker Use Over the Next 12 Months.....	80
Estimated Increase in Samples Analyzed With Tumor Markers	80
IV. INFECTIOUS DISEASE ANALYSIS	81
Professional Laboratory Position, Infectious Disease Researchers.....	82
Verbatim Description of 'Other' Professional Positions.....	83
Area of Involvement, Infectious Disease Researchers.....	84
Scientific Field of Interest, Infectious Disease Researchers	86
Verbatim Description of 'Other' Fields of Interest.....	87
Scientific Field of Interest, ASM Clinical Microbiology Members	87
Type of Laboratory, Infectious Disease Researchers	88
Type of Hospital Laboratory, Infectious Disease Researchers.....	89
Type of Independent Laboratory, Infectious Disease Researchers	90
Currently Targeted Infectious Disease Applications, Tests/Week.....	91
Currently Targeted Infectious Disease Applications, Share of Mentions ...	95
Average Tests per Week, Infectious Disease Assays	96
Purpose of Molecular Diagnostics Tests, Infectious Disease Researchers...	97
Primary Source of DNA, Infectious Disease Researchers	98
Description of 'Other' Bodily Fluid Sources of DNA	99
Proteinase K/SDS Digestion Usage, Infectious Disease Researchers.....	100
Description of Alternative Methods to Proteinase K/SDS Digestion.....	101
DNA Purification Method, Infectious Disease Researchers.....	102
DNA Concentration Determination Method, Infectious Disease Rschrs..	103
Description of 'Other' Methods for DNA Concentration Determination.	104
Types of Probes Used, Infectious Disease Researchers.....	105
Means of Acquiring DNA Probes, Infectious Disease Researchers	107
Laboratory Technique Utilization, Infectious Disease Researchers.....	109
Methods for Analysis of PCR Products, Infectious Disease Researchers....	111
Use of DNA Probes for Infectious Disease Diagnosis, Usage by Source....	113
Population Estimate of U.S. Infectious Disease Researchers.....	114
Population Estimate of Infectious Disease Rschrs Using DNA Probes.....	114
DNA Probe Assays Used Annually, Infectious Disease Researchers.....	115
Median & Mean Assays Performed Annually, Infectious Disease Rschrs...	116
Annual Expenditure on DNA Probe Assays, Infectious Disease Rschrs.....	116
Median & Mean Annual Expenditure on DNA Probe Assays.....	116
Comm'l DNA Probe Usage By Application, Infectious Disease Rschrs.....	117
Comm'l DNA Probe Unit Share By Assay Type, Infectious Dis Rschrs....	118
Comm'l DNA Probe \$ Share By Assay Type, Infectious Disease Rschrs...	119
Extrapolated Annual U.S. Market Size for DNA Probe Assays.....	119
Extrapolated Annual U.S. Expenditure for DNA Probe Assays.....	119
Extrapolated Annual Market Size for DNA Probe Assays, By Assay Type.	120
Unit Market Share for Major Suppliers, DNA Probe Assays.....	121
Dollar Market Share for Major Suppliers, DNA Probe Assays	122
Dollar Market Share for Major Suppliers, Chlamydia Trachomatis Assays	123
Dollar Market Share for Major Suppliers, N Gonorrhoeae Assays	124

Dollar Market Share for Major Suppliers, M Tuberculosis Assays	124
Dollar Market Share for Major Suppliers, Hepatitis C Virus Assays	125
Forecast Change in DNA Probe Assay Use Over the Next 12 Months	127
Calculated Increase in DNA Probe Assay Use Over the Next 12 Months	127
Estimated Annual Dollar Market Size for DNA Probe Assays, 12 Months	127
Verbatim Comments Regarding Choice of DNA Probe Assay Supplier	128
Customer Satisfaction Rate with DNA Probe Assays	132
Verbatim Comments Regarding Reason for Dissatisfaction with Supplier	133
Desired Improvements in DNA Probe Assays, Infectious Disease Rschrs..	134
Ranked Supplier's Performance: Best Value for Money	136
Ranked Supplier's Performance: Most Consistent Quality.....	137
Ranked Supplier's Performance: Fastest Delivery.....	138
Ranked Supplier's Performance: Best Application Support.....	138
Ranked Supplier's Performance: Widest Product Range	139

V. GENETIC DISEASE TESTING 141

Professional Laboratory Position, Genetic Disease Researchers	142
Description of 'Other' Professional Positions, Genetic Disease Rschrs.....	143
Professional Laboratory Position, Resp for ASHG & Nature Genetics	144
Area of Involvement, Genetic Disease Researchers.....	145
Scientific Field of Interest, Genetic Disease Researchers.....	147
Description of 'Other' Fields of Interest, Genetic Disease Researchers.....	148
Type of Laboratory, Genetic Disease Researchers	149
Type of Hospital Laboratory, Genetic Disease Researchers	150
Type of Independent Laboratory, Genetic Disease Researchers.....	151
Current Genetic Disease Applications and Tests Performed Weekly.....	152
Currently Targeted Genetic Disease Applications, Share of Mentions	155
Average Tests per Week, Genetic Disease Assays.....	156
Purpose of Molecular Diagnostics Tests, Genetic Disease Researchers.....	157
Primary Source of DNA, Genetic Disease Researchers.....	158
Proteinase K/SDS Digestion Usage, Genetic Disease Researchers	159
DNA Purification Method, Genetic Disease Researchers.....	160
DNA Concentration Determination Method, Genetic Disease Rschrs	161
Laboratory Technique Utilization, Genetic Disease Researchers	163
Methods for Analysis of PCR Products, Genetic Disease Researchers	165
Genetic Disease & Other Assays, Samples Analyzed Annually	167
Genetic Disease Assay Audit, % Researchers Analyzing Diseases.....	168
Verbatim Comments Regarding Other Molecular Diagnostics Assays	168
Genetic Disease & Other Assay Usage, Unit Share by Assay Type.....	170
Assay Name & Annual Consumption for 'Other' Category	170
Major Genetic Disease Assay Usage, Unit Share for DNA/RNA Analytes	172
Total DNA/RNA Analytes Reported for Genetic Disease Assays	172
Average Consumption Values for Genetic Disease Diagnostics.....	173
Extrapolated Annual U.S. Market Size for Genetic Disease Diagnostics ...	173
Forecast Change in Genetic Disease Assays, All Genetic Disease Rschrs..	174
Forecast Change in All 'Other' Assays, All Genetic Disease Rschrs.....	175
Weighted Average Forecast Change, Genetic Disease Rschrs.....	176
Calculated Increase in Genetic Disease Analysis Over the Next 12 Mths..	176
Estimated Increase in Samples for Genetic Disease Analysis.....	176

VI. FORENSIC/IDENTITY TESTING	177
Professional Laboratory Position, Forensic/Identity Testing Researchers ..	179
Area of Involvement, Forensic/Identity Testing Researchers	180
Scientific Field of Interest, Forensic/Identity Testing Researchers	181
Type of Laboratory, Forensic/Identity Testing Researchers.....	182
Type of Hospital Laboratory, Forensic/Identity Testing Researchers	183
Type of Independent Laboratory, Forensic/Identity Testing Researchers..	184
Currently Targeted Forensic/Identity Testing Applicat'ns & Tests/Week.	185
Purpose of Molecular Diagnostics Tests,Forensic/Identity Testing Rschrs	186
Primary Source of DNA, Forensic/Identity Testing Researchers	187
Proteinase K/SDS Digestion Usage, Forensic/Identity Testing Rschrs	188
DNA Purification Method, Forensic/Identity Testing Researchers	189
DNA Conc Determination Method, Forensic/Identity Testing Rschrs.....	190
Laboratory Technique Utilization, Forensic/Identity Testing Researchers.	191
Methods for Analysis of PCR Products, Forensic/Identity Testing Rschrs	193
VII. QUESTIONNAIRE.....	195