

## GLOBAL MARKETS FOR RAPID MEDICAL DIAGNOSTIC KITS



HLC007H  
June 2013

Peggy Lehr  
*Project Analyst*

ISBN: 1-56965-434-4

**bcc** | Research  
Market Forecasting

**BCC Research**  
49 Walnut Park, Building 2  
Wellesley, MA 02481  
866-285-7215, 781-489-7301  
[www.bccresearch.com](http://www.bccresearch.com)  
Custom Reports:  
[carol.laverty@bccresearch.com](mailto:carol.laverty@bccresearch.com)

**TABLE OF CONTENTS**

<b>TOPIC</b>	<b>PAGE NO.</b>
CHAPTER 1 INTRODUCTION	2
STUDY GOALS AND OBJECTIVES	2
REASONS FOR DOING THE STUDY	2
SCOPE OF REPORT	3
INTENDED AUDIENCE	3
METHODOLOGIES AND INFORMATION SOURCES	3
ANALYST CREDENTIALS	4
RELATED BCC REPORTS	4
BCC ONLINE SERVICES	4
DISCLAIMER	5
CHAPTER 2 SUMMARY	7
<i>SUMMARY TABLE GLOBAL MARKET FOR RAPID MEDICAL DIAGNOSTIC KITS, THROUGH 2017 (\$ MILLIONS)</i>	8
<i>SUMMARY FIGURE GLOBAL MARKET FOR RAPID DIAGNOSTIC KITS BY REGION, 2012 AND 2017 (%)</i>	9
CHAPTER 3 OVERVIEW OF MDK AND RAPID MDK MARKETS	11
COMPONENTS OF MDK	11
<i>FIGURE 1 COMPONENTS OF AN MDK</i>	11
ADVANTAGES OF RAPID MDK	12
MARKETS FOR RAPID MDK	12
CLINICAL TESTING	13
Clinical Diagnostic Testing	13
Monitoring	13
Screening	13
Confirmatory Testing	13
HOME USE	14
VETERINARY DIAGNOSIS	14
EXCLUSION OF RESEARCH MARKET IN THIS REPORT	14
INTERNAL AND EXTERNAL MARKET FORCES	14
INTERNAL MARKET FORCES	14
Trade Practices	14
Promotion	14
Pricing	15
Sales Tie-ins	15
Industry Channels of Distribution	15
Strategies in Consumer Advertising	15
EXTERNAL FORCES	16
TYPES OF RAPID MDK SCREENING	16
<i>TABLE 1 CHARACTERISTICS OF TWO RAPID TESTING TECHNOLOGIES</i>	17
RAPID MDK MARKET DRIVERS	17
GLOBALLY AGING POPULATION	17
SPREADING INFECTIOUS DISEASES	17
TRENDS CONTRIBUTING TO INCREASE IN INFECTIOUS DISEASE PROBLEMS	18
<i>TABLE 2 SELECTED MAJOR GLOBAL INFECTIOUS DISEASES, 2006*</i>	19

<b>TOPIC</b>	<b>PAGE NO.</b>
INFECTIOUS DISEASE TRANSMISSION	19
ANTIBIOTIC-RESISTANT ORGANISMS	20
IMPLICATIONS OF CLIMATE CHANGE ON INFECTIOUS DISEASES	20
CHRONIC DISEASE TREATMENT	20
<i>TABLE 3 TOP 10 CAUSES OF DEATH BY INCOME GROUP, 2004*</i>	21
RAPID MDK MARKET SIZE	21
<i>TABLE 4 PROJECTED RAPID MDK MARKET BY END-USE SEGMENT, THROUGH 2017 (\$ MILLIONS)</i>	22
ALTERNATIVE METHODS	22
<i>TABLE 5 ALTERNATIVE METHODS TO MDKS AND AREAS OF PRIMARY USE</i>	22
CULTURE	23
MICROSCOPY	23
BIOLOGICAL ASSAY	23
CHROMATOGRAPHIC SEPARATION	24
MERGERS AND ACQUISITIONS	24
<i>TABLE 6 SELECTED MERGERS AND ACQUISITIONS IN THE RAPID MDK MARKET, JANUARY 2007-FEBRUARY 2013</i>	24
CHAPTER 4 THE TECHNOLOGICAL ASPECTS OF RAPID MDK	26
<i>TABLE 7 MAJOR MDK APPLICATIONS BY TYPE OF TECHNOLOGY AND ITS USES</i>	26
CHEMICAL ANALYSIS	26
ENZYMATIC ANALYSIS	27
IMMUNOLOGICAL ANALYSIS	27
ENZYLE IMMUNOASSAY (EIA)	27
LATERAL FLOW TECHNIQUE	28
Components of a Lateral Flow Test	28
FLOW-THROUGH TECHNIQUE	28
Colloid Gold Technology	29
LATEX AGGLUTINATION (LA)	29
IMMUNOPRECIPITATION/AGGLUTINATION	30
TYPES OF RAPID MDKS FOR INFECTIOUS DISEASE TESTING	30
IMMUNODIAGNOSTIC KITS	30
DIPSTICKS	30
MICROBIAL AND RAPID MDK	30
MDK FEATURES AFFECTING MARKETABILITY	31
RELIABILITY AND ACCURACY	31
RANGE OF MEASUREMENT AND SENSITIVITY	31
STORAGE STABILITY	31
EASE OF USE	31
RAPID MDK MARKET SHARE BY TYPE	32
<i>TABLE 8 MARKET SHARE FOR RAPID MDK, BY TEST TYPE (%)</i>	32
TRENDS IN RAPID MDK MANUFACTURE	32
CLINICAL RAPID TESTING	32
VETERINARY RAPID TESTING	33
PAPER-BASED DIAGNOSTICS	33
CHAPTER 5 CLINICAL RAPID MDK APPLICATIONS	35

<b>TOPIC</b>	<b>PAGE NO.</b>
<i>TABLE 9 PROJECTED GLOBAL MARKET FOR RAPID MDK IN CLINICAL SETTINGS BY TEST, THROUGH 2017 (\$ MILLIONS)</i>	35
<i>FIGURE 2 RAPID CLINICAL MDK MARKET BY CONDITION, 2012 AND 2017 (%)</i>	36
INFECTIOUS DISEASE TESTING	37
BACTERIA	37
<i>TABLE 10 SELECTED LISTING OF BACTERIA FOUND IN CLINICAL SPECIMENS, THE DISEASES THEY CAUSE AND RAPID MDK MANUFACTURERS</i>	38
FUNGI	38
VIRUSES	39
<i>TABLE 11 SELECTED LISTING OF VIRUSES FOUND IN CLINICAL SPECIMENS, THE DISEASES THEY CAUSE AND RAPID MDK MANUFACTURERS</i>	39
PROTOZOA	39
IMPORTANCE OF TESTING	39
CLINICAL TESTING METHODS	40
INFECTIOUS DISEASE RAPID TESTS	40
GASTROINTESTINAL DISEASES (GAS)	40
<i>TABLE 12 SELECTED LISTING OF RAPID MDK GASTROINTESTINAL TESTS, 2012</i>	41
<i>TABLE 13 SELECTED LISTING OF RAPID STREP TESTS BY TEST NAME, MANUFACTURER AND PROCESS TIME, 2012</i>	42
MONONUCLEOSIS	42
<i>TABLE 14 SELECTED LISTING OF RAPID MONONUCLEOSIS TESTS BY TEST NAME, MANUFACTURER AND PROCESS TIME, 2012</i>	43
HEPATITIS	43
<i>TABLE 15 RAPID MDK FOR HEPATITIS</i>	44
<i>TABLE 16 PROJECTED GLOBAL MARKET FOR RAPID MDK FOR HEPATITIS TESTING, THROUGH 2017 (\$ MILLIONS)</i>	45
HUMAN IMMUNODEFICIENCY VIRUS (HIV)	45
TESTING TYPES	45
<i>TABLE 17 RAPID MDK FOR HIV TEST NAME, MANUFACTURER AND PROCESS TIME</i>	46
<i>TABLE 18 PROJECTED GLOBAL MARKET FOR RAPID MDK FOR HIV TESTING, THROUGH 2017 (\$ MILLIONS)</i>	46
H. PYLORI BLOOD TEST	47
<i>TABLE 19 PROJECTED GLOBAL MARKET FOR RAPID MDK FOR H. PYLORI TESTING, THROUGH 2017 (\$ MILLIONS)</i>	47
<i>TABLE 20 SELECTED LISTING OF RAPID H. PYLORI BLOOD TESTS BY TEST NAME, MANUFACTURER AND PROCESS TIME, 2012</i>	48
SEXUALLY TRANSMITTED DISEASES	48
IMPLICATIONS FOR WOMEN	48
SEXUALLY TRANSMITTED DISEASES IN THE U.S.	48
<i>TABLE 21 PROJECTED GLOBAL MARKET FOR RAPID MDK FOR SEXUALLY TRANSMITTED DISEASES TESTING, THROUGH 2017 (\$ MILLIONS)</i>	49
<i>TABLE 22 SELECTED LISTING OF RAPID MDK TESTS TO DETECT SEXUALLY TRANSMITTED DISEASES, 2012</i>	49
MALARIA	50
<i>TABLE 23 PROJECTED MARKET FOR RAPID MALARIA MDK, THROUGH 2017 (\$ MILLIONS)</i>	50
MALARIA RAPID DETECTION PRODUCTS	50
<i>TABLE 24 SELECTED LISTING OF RAPID MALARIA MDK TESTS BY TEST NAME, MANUFACTURER AND PROCESS TIME, 2012</i>	51
INFLUENZA A & B	51

<b>TOPIC</b>	<b>PAGE NO.</b>
<i>TABLE 25 SELECTED LISTING OF RAPID INFLUENZA A, B TESTS BY DISEASE, TEST NAME, MANUFACTURER AND PROCESS TIME, 2012</i>	52
CARDIOVASCULAR DISEASE/CHOLESTEROL	52
<i>TABLE 26 PROJECTED GLOBAL MARKET FOR CARDIOVASCULAR AND CHOLESTEROL RAPID MDK, THROUGH 2017 (\$ MILLIONS)</i>	53
<i>TABLE 27 SELECTED LISTING OF RAPID CARDIAC MARKER MDK, 2012</i>	53
CHOLESTEROL	54
<i>TABLE 28 SELECTED LISTING OF RAPID MDK CHOLESTEROL TESTS, 2012</i>	54
DRUG/SUBSTANCE ABUSE TESTING	54
THERAPEUTIC MONITORING	54
DIAGNOSING OVERDOSES	55
DIFFERENTIAL DIAGNOSIS	55
DETECTING DRUG ABUSE	55
<i>TABLE 29 PROJECTED GLOBAL MARKET FOR RAPID MDK FOR SUBSTANCE ABUSE TESTING, THROUGH 2017 (\$ MILLIONS)</i>	55
PRODUCTS FOR SUBSTANCE ABUSE TESTING	55
<i>TABLE 30 RAPID MDK FOR SUBSTANCE ABUSE TESTING</i>	56
PREGNANCY/OVULATION/HORMONAL CONDITIONS	57
HORMONAL CONDITIONS	57
Diagnostic Benefits of Hormone Analysis	57
<i>TABLE 31 PROJECTED MARKET FOR RAPID CLINICAL PREGNANCY, OVULATION, MENOPAUSE MDK, THROUGH 2017 (\$ MILLIONS)</i>	57
TYPES OF HORMONE MDK TESTS	57
Hypothalamus	58
Pituitary	58
Thyroid	58
Parathyroid	58
Adrenal Glands	58
Pancreas	59
Brain Peptides	59
HORMONE TESTING MARKET	59
<i>TABLE 32 RAPID MDK FOR CLINICAL HORMONE TESTING</i>	59
CLINICAL CONFIRMATION OF PREGNANCY	59
<i>TABLE 33 RAPID MDK FOR PREGNANCY/OVULATION</i>	60
TUMOR MARKERS	61
MARKET SIZE AND STRUCTURE	61
<i>TABLE 34 PROJECTED GLOBAL MARKET FOR RAPID TUMOR MARKER MDK, THROUGH 2017 (\$ MILLIONS)</i>	61
INCIDENCE OF NEW CANCER CASES ANNUALLY	61
Risk Factors	61
Detection Methods	62
<i>TABLE 35 SELECTED LISTING OF RAPID CANCER MDK, 2012</i>	63
OTHER TESTS	63
BLOOD/URINE CHEMISTRY	63
Market Size and Structure	63
<i>TABLE 36 PROJECTED MARKET FOR OTHER RAPID MDK, THROUGH 2017 (\$ MILLIONS)</i>	64
<i>TABLE 37 SELECTED LISTING OF RAPID BLOOD/URINE MDK TESTS, 2012</i>	64
AUTOIMMUNE DISEASE	65

<b>TOPIC</b>	<b>PAGE NO.</b>
<i>TABLE 38 SELECTED LISTING OF RAPID AUTOIMMUNE TESTS, 2012</i>	65
BLOOD GLUCOSE TESTING IN CLINICAL SETTINGS	66
FECAL OCCULT BLOOD TEST	66
<i>TABLE 39 SELECTED LISTING OF RAPID FECAL OCCULT BLOOD TESTS BY TEST NAME, MANUFACTURER AND PROCESS TIME, 2012</i>	67
REGIONAL ANALYSIS	67
<i>TABLE 40 PROJECTED GLOBAL MARKET FOR RAPID CLINICAL MDK BY GEOGRAPHIC REGION, THROUGH 2017</i>	67
<i>FIGURE 3 GLOBAL MARKET FOR RAPID CLINICAL MDK BY GEOGRAPHIC REGION, 2012 AND 2017 (%)</i>	68
<i>TABLE 41 PROJECTED GLOBAL RAPID CLINICAL MDK MARKET BY GEOGRAPHIC REGION AND DISEASE CATEGORY, THROUGH 2017 (\$ MILLIONS)</i>	69
AMERICAS	69
<i>TABLE 42 PROJECTED AMERICAS MARKET FOR RAPID CLINICAL MDK BY REGION, THROUGH 2017 (\$ MILLIONS)</i>	70
<i>FIGURE 4 PROJECTED MARKET SHARE FOR RAPID CLINICAL MDK IN THE AMERICAS BY REGION, 2012 AND 2017 (%)</i>	70
EMRA	71
<i>TABLE 43 PROJECTED EMRA MARKET FOR RAPID CLINICAL MDK BY REGION, THROUGH 2017 (\$ MILLIONS)</i>	71
<i>FIGURE 5 PROJECTED MARKET SHARE FOR RAPID CLINICAL MDK IN THE EMRA BY REGION, 2012 AND 2017 (%)</i>	71
ASIA	73
<i>TABLE 44 PROJECTED ASIAN MARKET FOR RAPID CLINICAL MDK BY REGION, THROUGH 2017 (\$ MILLIONS)</i>	73
<i>FIGURE 6 PROJECTED MARKET SHARE FOR RAPID CLINICAL MDK IN ASIA BY REGION, 2012 AND 2017 (%)</i>	73
CHAPTER 6 HOME-USE TESTING MARKET	76
<i>TABLE 45 PROJECTED HOME-USE RAPID MDK MARKET, THROUGH 2017 (\$ MILLIONS)</i>	76
ALLERGIES	77
ALLERGY TESTING PRODUCTS	77
<i>TABLE 46 SELECTED LISTING OF RAPID HOME-USE MDK ALLERGY TESTS, 2012</i>	77
BLOOD GLUCOSE MONITORING	77
DIABETES IN INDIA	78
BLOOD GLUCOSE MONITORING MARKET	78
<i>FIGURE 7 GLOBAL HOME-USE BLOOD GLUCOSE MONITORING MARKET BY MANUFACTURER, 2011 (%)</i>	78
<i>TABLE 47 PROJECTED GLOBAL MARKET FOR RAPID HOME-USE BLOOD GLUCOSE MONITORING MDK, THROUGH 2017 (\$ MILLIONS)</i>	79
BLOOD GLUCOSE MONITORING PRODUCTS	79
<i>TABLE 48 RAPID HOME-USE MDK FOR BLOOD GLUCOSE MONITORING</i>	80
CHOLESTEROL	80
CHOLESTEROL MONITORING	81
<i>TABLE 49 PROJECTED GLOBAL MARKET FOR RAPID HOME-USE RAPID CHOLESTEROL MDK, THROUGH 2017 (\$ MILLIONS)</i>	81
CHOLESTEROL MONITORING PRODUCTS	81
<i>TABLE 50 SELECTED LISTING OF RAPID HOME-USE MDK CHOLESTEROL TESTS, 2012</i>	82

TOPIC	PAGE NO.
DRUG SCREENING	82
THE GROWTH OF THE HOME-USE DRUG SCREENING MDK MARKET	82
TABLE 51 PROJECTED GLOBAL MARKET FOR RAPID HOME-USE MDK FOR DRUG SCREENING, THROUGH 2017 (\$ MILLIONS)	83
DRUG SCREENING PRODUCTS	83
TABLE 52 SELECTED LISTING OF RAPID HOME-USE DRUG SCREENING TESTS BY TEST NAME, MANUFACTURER AND PROCESS TIME, 2012	83
FECAL OCCULT BLOOD	85
FECAL OCCULT BLOOD TEST PRODUCTS	85
TABLE 53 SELECTED LISTING OF RAPID MDK HOME-USE FECAL OCCULT BLOOD TESTS, 2012	86
PREGNANCY/OVULATION/MENOPAUSE	86
TABLE 54 PROJECTED GLOBAL MARKET FOR RAPID HOME-USE MDK FOR PREGNANCY, OVULATION AND MENOPAUSE PRODUCTS, THROUGH 2017 (\$ MILLIONS)	86
PREGNANCY/OVULATION/MENOPAUSE PRODUCTS	86
TABLE 55 SELECTED LISTING OF HOME-USE RAPID PREGNANCY, OVULATION AND MENOPAUSE TESTS, 2012	87
INFECTIOUS DISEASES	87
HEPATITIS	88
TABLE 56 PROJECTED GLOBAL MARKET FOR HOME-USE RAPID HEPATITIS MDK, THROUGH 2017 (\$ MILLIONS)	88
Hepatitis Home-Use Test Products	88
TABLE 57 SELECTED LISTING OF RAPID HOME-USE MDK HEPATITIS C TESTS, 2012	88
H. PYLORI	89
TABLE 58 PROJECTED GLOBAL MARKET FOR HOME-USE H. PYLORI RAPID MDK, THROUGH 2017 (\$ MILLIONS)	89
H. pylori Home-Use Rapid Test MDK	89
TABLE 59 SELECTED LISTING OF HOME-USE RAPID MDK H. PYLORI TESTS, 2012	89
HUMAN IMMUNODEFICIENCY VIRUS (HIV)	90
HIV Rapid Home-Use Test	90
TABLE 60 SELECTED LISTING OF HOME-USE RAPID MDK HIV TESTS, 2012	90
REGIONAL ANALYSIS	90
TABLE 61 PROJECTED MARKET FOR RAPID HOME-USE MDK BY REGION, THROUGH 2017 (\$ MILLIONS)	91
FIGURE 8 MARKET SHARE FOR RAPID HOME-USE MDK BY REGION, 2012 AND 2017 (%)	91
THE AMERICAS	92
Diabetes in North America	92
Diabetes in the Central and South America	92
TABLE 62 PROJECTED AMERICAS MARKET FOR RAPID HOME-USE MDK BY REGION, THROUGH 2017 (\$ MILLIONS)	93
FIGURE 9 MARKET SHARE FOR RAPID HOME-USE MDK IN THE AMERICAS, 2012 AND 2017 (%)	93
TABLE 63 PROJECTED AMERICAS MARKET FOR RAPID HOME-USE MDK BY DISEASE, THROUGH 2017 (\$ MILLIONS)	94
EMRA	94
Blood Glucose Monitoring Reimbursement in Europe	94
Diabetes in Africa	95
Diabetes in Europe, Eastern Europe and Russia	95

<b>TOPIC</b>	<b>PAGE NO.</b>
Diabetes in the Middle East	95
Pregnancy Home-Use MDK in EMRA	96
MARKET IN THE EMRA BY REGION	96
<i>TABLE 64 PROJECTED EMRA MARKET FOR RAPID HOME-USE MDK BY REGION, THROUGH 2017 (\$ MILLIONS)</i>	96
<i>FIGURE 10 MARKET SHARE FOR RAPID HOME-USE MDK IN THE EMRA, 2012 AND 2017 (%)</i>	96
<i>TABLE 65 PROJECTED EMRA MARKET FOR RAPID HOME-USE MDK BY DISEASE, THROUGH 2017 (\$ MILLIONS)</i>	98
ASIA	98
Diabetes in Japan	98
Diabetes in Southeast Asia	99
Diabetes in the Western Pacific Region	99
<i>TABLE 66 PROJECTED ASIAN MARKET FOR RAPID HOME-USE MDK BY REGION, THROUGH 2017 (\$ MILLIONS)</i>	99
<i>FIGURE 11 MARKET SHARE FOR RAPID HOME-USE MDK IN ASIA, 2012 AND 2017 (%)</i>	99
<i>TABLE 67 PROJECTED ASIAN MARKET FOR RAPID HOME-USE MDK BY DISEASE, THROUGH 2017 (\$ MILLIONS)</i>	101
CHAPTER 7 VETERINARY RAPID MDK APPLICATIONS	103
THE VETERINARY PRACTITIONER AND CHANGING VETERINARY PRACTICE	103
VIRAL INFECTIOUS AGENTS	103
<i>TABLE 68 MAJOR VIRAL INFECTIOUS AGENTS</i>	104
BACTERIAL INFECTIOUS AGENTS	105
<i>TABLE 69 MAJOR BACTERIAL INFECTIOUS AGENTS, THE DISEASES THEY CAUSE AND THE AVAILABLE RAPID MDK</i>	106
PARASITIC INFECTIOUS AGENTS	106
<i>TABLE 70 MAJOR PARASITIC INFECTIOUS AGENTS</i>	106
COMPANION ANIMALS	107
LEISHMANOSIS	107
BORDETELLA	107
CANINE CORONAVIRUS (CCV)	107
CANINE INFLUENZA VIRUS (CIV)	107
CANINE PARVOVIRUS TYPE 2 (CPV2)	107
FELINE IMMUNODEFICIENCY VIRUS (FIV)	108
FELINE LEUKEMIA VIRUS (FELV)	108
GIARDIA	108
HEARTWORM	108
DIAGNOSTIC METHODS FOR ANIMAL DISEASES	108
<i>TABLE 71 DIAGNOSTIC METHODS FOR SELECTED VIRAL, BACTERIAL, PARASITIC AND OTHER CONDITIONS OF COMPANION ANIMALS</i>	108
LIVESTOCK ANIMALS	110
AVIAN INFLUENZA	110
BOVINE TUBERCULOSIS	111
BOVINE VIRAL DIARRHEA	111
FOOT AND MOUTH DISEASE	111
PORCINE REPRODUCTIVE, RESPIRATORY SYNDROME VIRUS (PRRSV)	111
JOHNE'S DISEASE	111



<b>TOPIC</b>	<b>PAGE NO.</b>
<i>TABLE 72 DIAGNOSTIC METHODS FOR SELECTED VIRAL, BACTERIAL AND OTHER CONDITIONS OF LIVESTOCK ANIMALS</i>	112
VETERINARY RAPID MDK TECHNOLOGY	112
LATERAL FLOW IMMUNOASSAY	113
LATEX AGGLUTINATION (LA)	113
ENZYME IMMUNOASSAY (EIA)	113
VETERINARY RAPID MDK MARKET SIZE AND STRUCTURE	113
<i>TABLE 73 PROJECTED GLOBAL VETERINARY RAPID MDK TESTING MARKET, THROUGH 2017 (\$ MILLIONS)</i>	114
LEADING RAPID MDK KITS	114
<i>TABLE 74 REVENUES FOR VETERINARY RAPID DIAGNOSTICS BY TYPE, THROUGH 2017 (\$ MILLIONS)</i>	115
MARKET SHARE BY PARTICIPANT	115
<i>FIGURE 12 GLOBAL MARKET SHARE FOR MAJOR PARTICIPANTS IN THE COMPANION INFECTIOUS DISEASE MDK MARKET, 2011 (%)</i>	115
<i>FIGURE 13 GLOBAL MARKET SHARE FOR MAJOR PARTICIPANTS IN THE LIVESTOCK INFECTIOUS DISEASE MDK MARKET, 2011 (%)</i>	116
REGIONAL ANALYSIS	117
<i>TABLE 75 MAJOR COMPANION ANIMAL INFECTIOUS DISEASES, BY REGION</i>	117
<i>TABLE 76 PROJECTED MARKET FOR RAPID MDK FOR COMPANION AND LIVESTOCK ANIMALS BY GEOGRAPHIC REGION, THROUGH 2017 (\$ MILLIONS)</i>	117
<i>FIGURE 14 GLOBAL MARKET SHARE FOR RAPID MDK FOR COMPANION AND LIVESTOCK ANIMALS BY REGION, 2012 AND 2017 (%)</i>	117
REGIONAL MARKETS FOR RAPID INFECTIOUS DISEASE MDK FOR COMPANION ANIMALS	118
<i>FIGURE 15 PROJECTED REGIONAL MARKETS FOR RAPID INFECTIOUS DISEASE MDK FOR COMPANION ANIMALS, 2012 AND 2017 (%)</i>	119
REGIONAL MARKETS FOR RAPID INFECTIOUS DISEASE MDK FOR LIVESTOCK ANIMALS	120
<i>FIGURE 16 PROJECTED REGIONAL MARKETS FOR RAPID INFECTIOUS DISEASE MDK FOR LIVESTOCK ANIMALS, 2012 AND 2017 (%)</i>	120
AMERICAS	121
Heartworm in North America	121
Canine Influenza in North America	121
FelV	121
<i>TABLE 77 PROJECTED MARKET FOR RAPID MDK IN THE AMERICAS, THROUGH 2017 (\$ MILLIONS)</i>	121
EMRA	122
Heartworm in EMRA	122
FelV	122
<i>TABLE 78 PROJECTED MARKET FOR RAPID MDK IN THE EMRA, THROUGH 2017 (\$ MILLIONS)</i>	122
ASIA	123
FelV in Asia	123
MDK in China	123
Declining Japanese Market	123
<i>TABLE 79 PROJECTED MARKET FOR RAPID MDK IN ASIA, THROUGH 2017 (\$ MILLIONS)</i>	123
VETERINARY RAPID MDK	124
<i>TABLE 80 VETERINARY RAPID MDK BY ANIMAL TYPE, 2012</i>	124

<b>TOPIC</b>	<b>PAGE NO.</b>
CHAPTER 8 EMERGING TECHNOLOGY/PATENTS/REGULATIONS	130
EMERGING TECHNOLOGIES	130
MICROFLUIDIC PAPER-BASED PRODUCTS	130
MALARIA	130
Fyodor Biotechnologies	130
Foundation for Innovative New Diagnostics	131
CHEMBIO DIAGNOSTICS	131
DPP Hepatitis-C (HCV) Test	131
DPP Tuberculosis	132
ROCHE DIAGNOSTICS	132
RECENTLY GRANTED PATENTS FOR RAPID DIAGNOSTIC TESTS	132
<i>TABLE 81 SELECTED LISTING OF RECENTLY GRANTED PATENTS FOR RAPID DIAGNOSTIC TESTS, 2008-2012</i>	132
REGULATIONS	133
FDA REGULATION	133
510(K) CLEARANCE PATHWAY	133
PMA APPROVAL PATHWAY	133
BLA APPROVAL PATHWAY	134
CLINICAL STUDIES	134
POST-MARKET REGULATION	134
CLIA CLASSIFICATION	135
Selected CLIA Approved Rapid Tests	135
<i>TABLE 82 CLIA-WAIVED TESTS</i>	136
GOOD MANUFACTURING PRACTICE	137
<i>TABLE 83 PERTINENT PARAMETERS OF GMP AFFECTING MDK</i>	138
COST CONTAINMENT EFFORTS	138
United States	138
Diagnosis Related Groups (DRGs)	138
Medicare	138
Third-Party Payers	139
REGULATION OUTSIDE THE UNITED STATES	139
CHAPTER 9 HUMAN RAPID MDK COMPANY DIRECTORY	141
ABBOTT LABORATORIES	141
ACCUTECH, LLC	141
ALERE	141
ALFA SCIENTIFIC DESIGNS	142
ANI BIOTECH OY	142
AGAMATRIX	142
APEX BIOTECHNOLOGY	143
ARKRAY USA, INC.	143
ATLAS LINK BIOTECH CO, LTD.	143
BTNX, INC.	144
BECKMAN COULTER/DANAHER	144
BECTON DICKINSON	144
BIOCARE DIAGNOSTICS, LTD	145
BIOMERICA	145

<b>TOPIC</b>	<b>PAGE NO.</b>
BIOMERIEUX	145
CHEMATICS	146
CHEMBIO DIAGNOSTIC SYSTEMS	146
DIAGNOSTIC AUTOMATION/CORTEZ DIAGNOSTICS, INC.	146
DIASORIN	147
ENZO LIFE SCIENCES	147
FIRST DIAGNOSTIC LLC	147
FIRSTVUE CORP.	147
GERMAINE LABORATORIES	148
GLUCO PLUS	148
HENRY SCHEIN, INC	148
HOME DIAGNOSTICS, INC. (SEE NIPRO DIAGNOSTICS)	149
IMMUNOSTICS, INC.	149
INBIOS INTERNATIONAL, INC.	149
IND DIAGNOSTIC, INC.	149
JANT PHARMACAL CORP.	150
LIFESCAN (JOHNSON & JOHNSON DIABETES CARE)	150
LIFESIGN	150
MEDMIRA, INC.	150
MERIDIAN BIOSCIENCE	151
NIPRO DIAGNOSTICS (FORMERLY HOME DIAGNOSTICS)	151
ORASURE TECHNOLOGIES	151
PHAMATECH	151
PRINCETON BIOMEDITECH	152
QUIDEL	152
REDWOOD TOXICOLOGY	152
REMEL (THERMOFISHER SCIENTIFIC)	152
ROCHE DIAGNOSTICS	153
RUNBIO BIOTECH CO., LTD	153
SA SCIENTIFIC, INC.	153
SCI INTERNATIONAL	153
SEIKISUI DIAGNOSTICS	154
SHANGHAI KEHUA BIO-ENGINEERING CO, LTD.	154
STANBIO LABORATORY	154
STANDARD DIAGNOSTICS	154
TAIDOC	155
TRINITY BIOTECH PLC	155
UCP BIOSCIENCES	155
CHAPTER 10 VETERINARY COMPANY DIRECTORY	157
AGROLABO SPA	157
ABAXIS	157
BIOGAL-GALED LABORATORIES	157
BIONOTE/ALERE	158
CHEMBIO (SEE HUMAN MDK)	158
DIACHEMIX, LLC	158
IDEXX LABORATORIES	158

<b>TOPIC</b>	<b>PAGE NO.</b>
HESKA	159
MEGACOR DIAGNOSTIK, GMBH	159
SA SCIENTIFIC (SEE HUMAN MDK MANUFACTURERS)	159
SHENZHEN LVSHIYUAN BIOTECHNOLOGY CO. LTD	159
ZOETIS (FORMERLY PFIZER ANIMAL HEALTH AND SYNBIOTICS)	160

**LIST OF TABLES**

<b>TABLE HEADING</b>	<b>PAGE NO.</b>
SUMMARY TABLE GLOBAL MARKET FOR RAPID MEDICAL DIAGNOSTIC KITS, THROUGH 2017 (\$ MILLIONS)	8
TABLE 1 CHARACTERISTICS OF TWO RAPID TESTING TECHNOLOGIES	17
TABLE 2 SELECTED MAJOR GLOBAL INFECTIOUS DISEASES, 2006*	19
TABLE 3 TOP 10 CAUSES OF DEATH BY INCOME GROUP, 2004*	21
TABLE 4 PROJECTED RAPID MDK MARKET BY END-USE SEGMENT, THROUGH 2017 (\$ MILLIONS)	22
TABLE 5 ALTERNATIVE METHODS TO MDKS AND AREAS OF PRIMARY USE	22
TABLE 6 SELECTED MERGERS AND ACQUISITIONS IN THE RAPID MDK MARKET, JANUARY 2007-FEBRUARY 2013	24
TABLE 7 MAJOR MDK APPLICATIONS BY TYPE OF TECHNOLOGY AND ITS USES	26
TABLE 8 MARKET SHARE FOR RAPID MDK, BY TEST TYPE (%)	32
TABLE 9 PROJECTED GLOBAL MARKET FOR RAPID MDK IN CLINICAL SETTINGS BY TEST, THROUGH 2017 (\$ MILLIONS)	35
TABLE 10 SELECTED LISTING OF BACTERIA FOUND IN CLINICAL SPECIMENS, THE DISEASES THEY CAUSE AND RAPID MDK MANUFACTURERS	38
TABLE 11 SELECTED LISTING OF VIRUSES FOUND IN CLINICAL SPECIMENS, THE DISEASES THEY CAUSE AND RAPID MDK MANUFACTURERS	39
TABLE 12 SELECTED LISTING OF RAPID MDK GASTROINTESTINAL TESTS, 2012	41
TABLE 13 SELECTED LISTING OF RAPID STREP TESTS BY TEST NAME, MANUFACTURER AND PROCESS TIME, 2012	42
TABLE 14 SELECTED LISTING OF RAPID MONONUCLEOSIS TESTS BY TEST NAME, MANUFACTURER AND PROCESS TIME, 2012	43
TABLE 15 RAPID MDK FOR HEPATITIS	44
TABLE 16 PROJECTED GLOBAL MARKET FOR RAPID MDK FOR HEPATITIS TESTING, THROUGH 2017 (\$ MILLIONS)	45
TABLE 17 RAPID MDK FOR HIV TEST NAME, MANUFACTURER AND PROCESS TIME	46
TABLE 18 PROJECTED GLOBAL MARKET FOR RAPID MDK FOR HIV TESTING, THROUGH 2017 (\$ MILLIONS)	46
TABLE 19 PROJECTED GLOBAL MARKET FOR RAPID MDK FOR H. PYLORI TESTING, THROUGH 2017 (\$ MILLIONS)	47
TABLE 20 SELECTED LISTING OF RAPID H. PYLORI BLOOD TESTS BY TEST NAME, MANUFACTURER AND PROCESS TIME, 2012	48
TABLE 21 PROJECTED GLOBAL MARKET FOR RAPID MDK FOR SEXUALLY TRANSMITTED DISEASES TESTING, THROUGH 2017 (\$ MILLIONS)	49
TABLE 22 SELECTED LISTING OF RAPID MDK TESTS TO DETECT SEXUALLY TRANSMITTED DISEASES, 2012	49
TABLE 23 PROJECTED MARKET FOR RAPID MALARIA MDK, THROUGH 2017 (\$ MILLIONS)	50
TABLE 24 SELECTED LISTING OF RAPID MALARIA MDK TESTS BY TEST NAME, MANUFACTURER AND PROCESS TIME, 2012	51
TABLE 25 SELECTED LISTING OF RAPID INFLUENZA A, B TESTS BY DISEASE, TEST NAME, MANUFACTURER AND PROCESS TIME, 2012	52
TABLE 26 PROJECTED GLOBAL MARKET FOR CARDIOVASCULAR AND CHOLESTEROL RAPID MDK, THROUGH 2017 (\$ MILLIONS)	53
TABLE 27 SELECTED LISTING OF RAPID CARDIAC MARKER MDK, 2012	53
TABLE 28 SELECTED LISTING OF RAPID MDK CHOLESTEROL TESTS, 2012	54
TABLE 29 PROJECTED GLOBAL MARKET FOR RAPID MDK FOR SUBSTANCE ABUSE TESTING, THROUGH 2017 (\$ MILLIONS)	55
TABLE 30 RAPID MDK FOR SUBSTANCE ABUSE TESTING	56

<b>TABLE HEADING</b>	<b>PAGE NO.</b>
TABLE 31 PROJECTED MARKET FOR RAPID CLINICAL PREGNANCY, OVULATION, MENOPAUSE MDK, THROUGH 2017 (\$ MILLIONS)	57
TABLE 32 RAPID MDK FOR CLINICAL HORMONE TESTING	59
TABLE 33 RAPID MDK FOR PREGNANCY/OVULATION	60
TABLE 34 PROJECTED GLOBAL MARKET FOR RAPID TUMOR MARKER MDK, THROUGH 2017 (\$ MILLIONS)	61
TABLE 35 SELECTED LISTING OF RAPID CANCER MDK, 2012	63
TABLE 36 PROJECTED MARKET FOR OTHER RAPID MDK, THROUGH 2017 (\$ MILLIONS)	64
TABLE 37 SELECTED LISTING OF RAPID BLOOD/URINE MDK TESTS, 2012	64
TABLE 38 SELECTED LISTING OF RAPID AUTOIMMUNE TESTS, 2012	65
TABLE 39 SELECTED LISTING OF RAPID FECAL OCCULT BLOOD TESTS BY TEST NAME, MANUFACTURER AND PROCESS TIME, 2012	67
TABLE 40 PROJECTED GLOBAL MARKET FOR RAPID CLINICAL MDK BY GEOGRAPHIC REGION, THROUGH 2017	67
TABLE 41 PROJECTED GLOBAL RAPID CLINICAL MDK MARKET BY GEOGRAPHIC REGION AND DISEASE CATEGORY, THROUGH 2017 (\$ MILLIONS)	69
TABLE 42 PROJECTED AMERICAS MARKET FOR RAPID CLINICAL MDK BY REGION, THROUGH 2017 (\$ MILLIONS)	70
TABLE 43 PROJECTED EMRA MARKET FOR RAPID CLINICAL MDK BY REGION, THROUGH 2017 (\$ MILLIONS)	71
TABLE 44 PROJECTED ASIAN MARKET FOR RAPID CLINICAL MDK BY REGION, THROUGH 2017 (\$ MILLIONS)	73
TABLE 45 PROJECTED HOME-USE RAPID MDK MARKET, THROUGH 2017 (\$ MILLIONS)	76
TABLE 46 SELECTED LISTING OF RAPID HOME-USE MDK ALLERGY TESTS, 2012	77
TABLE 47 PROJECTED GLOBAL MARKET FOR RAPID HOME-USE BLOOD GLUCOSE MONITORING MDK, THROUGH 2017 (\$ MILLIONS)	79
TABLE 48 RAPID HOME-USE MDK FOR BLOOD GLUCOSE MONITORING	80
TABLE 49 PROJECTED GLOBAL MARKET FOR RAPID HOME-USE RAPID CHOLESTEROL MDK, THROUGH 2017 (\$ MILLIONS)	81
TABLE 50 SELECTED LISTING OF RAPID HOME-USE MDK CHOLESTEROL TESTS, 2012	82
TABLE 51 PROJECTED GLOBAL MARKET FOR RAPID HOME-USE MDK FOR DRUG SCREENING, THROUGH 2017 (\$ MILLIONS)	83
TABLE 52 SELECTED LISTING OF RAPID HOME-USE DRUG SCREENING TESTS BY TEST NAME, MANUFACTURER AND PROCESS TIME, 2012	83
TABLE 53 SELECTED LISTING OF RAPID MDK HOME-USE FECAL OCCULT BLOOD TESTS, 2012	86
TABLE 54 PROJECTED GLOBAL MARKET FOR RAPID HOME-USE MDK FOR PREGNANCY, OVULATION AND MENOPAUSE PRODUCTS, THROUGH 2017 (\$ MILLIONS)	86
TABLE 55 SELECTED LISTING OF HOME-USE RAPID PREGNANCY, OVULATION AND MENOPAUSE TESTS, 2012	87
TABLE 56 PROJECTED GLOBAL MARKET FOR HOME-USE RAPID HEPATITIS MDK, THROUGH 2017 (\$ MILLIONS)	88
TABLE 57 SELECTED LISTING OF RAPID HOME-USE MDK HEPATITIS C TESTS, 2012	88
TABLE 58 PROJECTED GLOBAL MARKET FOR HOME-USE H. PYLORI RAPID MDK, THROUGH 2017 (\$ MILLIONS)	89
TABLE 59 SELECTED LISTING OF HOME-USE RAPID MDK H. PYLORI TESTS, 2012	89
TABLE 60 SELECTED LISTING OF HOME-USE RAPID MDK HIV TESTS, 2012	90
TABLE 61 PROJECTED MARKET FOR RAPID HOME-USE MDK BY REGION, THROUGH 2017 (\$ MILLIONS)	91

<b>TABLE HEADING</b>	<b>PAGE NO.</b>
TABLE 62 PROJECTED AMERICAS MARKET FOR RAPID HOME-USE MDK BY REGION, THROUGH 2017 (\$ MILLIONS)	93
TABLE 63 PROJECTED AMERICAS MARKET FOR RAPID HOME-USE MDK BY DISEASE, THROUGH 2017 (\$ MILLIONS)	94
TABLE 64 PROJECTED EMRA MARKET FOR RAPID HOME-USE MDK BY REGION, THROUGH 2017 (\$ MILLIONS)	96
TABLE 65 PROJECTED EMRA MARKET FOR RAPID HOME-USE MDK BY DISEASE, THROUGH 2017 (\$ MILLIONS)	98
TABLE 66 PROJECTED ASIAN MARKET FOR RAPID HOME-USE MDK BY REGION, THROUGH 2017 (\$ MILLIONS)	99
TABLE 67 PROJECTED ASIAN MARKET FOR RAPID HOME-USE MDK BY DISEASE, THROUGH 2017 (\$ MILLIONS)	101
TABLE 68 MAJOR VIRAL INFECTIOUS AGENTS	104
TABLE 69 MAJOR BACTERIAL INFECTIOUS AGENTS, THE DISEASES THEY CAUSE AND THE AVAILABLE RAPID MDK	106
TABLE 70 MAJOR PARASITIC INFECTIOUS AGENTS	106
TABLE 71 DIAGNOSTIC METHODS FOR SELECTED VIRAL, BACTERIAL, PARASITIC AND OTHER CONDITIONS OF COMPANION ANIMALS	108
TABLE 72 DIAGNOSTIC METHODS FOR SELECTED VIRAL, BACTERIAL AND OTHER CONDITIONS OF LIVESTOCK ANIMALS	112
TABLE 73 PROJECTED GLOBAL VETERINARY RAPID MDK TESTING MARKET, THROUGH 2017 (\$ MILLIONS)	114
TABLE 74 REVENUES FOR VETERINARY RAPID DIAGNOSTICS BY TYPE, THROUGH 2017 (\$ MILLIONS)	115
TABLE 75 MAJOR COMPANION ANIMAL INFECTIOUS DISEASES, BY REGION	117
TABLE 76 PROJECTED MARKET FOR RAPID MDK FOR COMPANION AND LIVESTOCK ANIMALS BY GEOGRAPHIC REGION, THROUGH 2017 (\$ MILLIONS)	117
TABLE 77 PROJECTED MARKET FOR RAPID MDK IN THE AMERICAS, THROUGH 2017 (\$ MILLIONS)	121
TABLE 78 PROJECTED MARKET FOR RAPID MDK IN THE EMRA, THROUGH 2017 (\$ MILLIONS)	122
TABLE 79 PROJECTED MARKET FOR RAPID MDK IN ASIA, THROUGH 2017 (\$ MILLIONS)	123
TABLE 80 VETERINARY RAPID MDK BY ANIMAL TYPE, 2012	124
TABLE 81 SELECTED LISTING OF RECENTLY GRANTED PATENTS FOR RAPID DIAGNOSTIC TESTS, 2008-2012	132
TABLE 82 CLIA-WAIVED TESTS	136
TABLE 83 PERTINENT PARAMETERS OF GMP AFFECTING MDK	138

**LIST OF FIGURES**

<b>FIGURE TITLE</b>	<b>PAGE NO.</b>
SUMMARY FIGURE GLOBAL MARKET FOR RAPID DIAGNOSTIC KITS BY REGION, 2012 AND 2017 (%)	9
FIGURE 1 COMPONENTS OF AN MDK	11
FIGURE 2 RAPID CLINICAL MDK MARKET BY CONDITION, 2012 AND 2017 (%)	36
FIGURE 3 GLOBAL MARKET FOR RAPID CLINICAL MDK BY GEOGRAPHIC REGION, 2012 AND 2017 (%)	68
FIGURE 4 PROJECTED MARKET SHARE FOR RAPID CLINICAL MDK IN THE AMERICAS BY REGION, 2012 AND 2017 (%)	70
FIGURE 5 PROJECTED MARKET SHARE FOR RAPID CLINICAL MDK IN THE EMRA BY REGION, 2012 AND 2017 (%)	71
FIGURE 6 PROJECTED MARKET SHARE FOR RAPID CLINICAL MDK IN ASIA BY REGION, 2012 AND 2017 (%)	73
FIGURE 7 GLOBAL HOME-USE BLOOD GLUCOSE MONITORING MARKET BY MANUFACTURER, 2011 (%)	78
FIGURE 8 MARKET SHARE FOR RAPID HOME-USE MDK BY REGION, 2012 AND 2017 (%)	91
FIGURE 9 MARKET SHARE FOR RAPID HOME-USE MDK IN THE AMERICAS, 2012 AND 2017 (%)	93
FIGURE 10 MARKET SHARE FOR RAPID HOME-USE MDK IN THE EMRA, 2012 AND 2017 (%)	96
FIGURE 11 MARKET SHARE FOR RAPID HOME-USE MDK IN ASIA, 2012 AND 2017 (%)	99
FIGURE 12 GLOBAL MARKET SHARE FOR MAJOR PARTICIPANTS IN THE COMPANION INFECTIOUS DISEASE MDK MARKET, 2011 (%)	115
FIGURE 13 GLOBAL MARKET SHARE FOR MAJOR PARTICIPANTS IN THE LIVESTOCK INFECTIOUS DISEASE MDK MARKET, 2011 (%)	116
FIGURE 14 GLOBAL MARKET SHARE FOR RAPID MDK FOR COMPANION AND LIVESTOCK ANIMALS BY REGION, 2012 AND 2017 (%)	117
FIGURE 15 PROJECTED REGIONAL MARKETS FOR RAPID INFECTIOUS DISEASE MDK FOR COMPANION ANIMALS, 2012 AND 2017 (%)	119
FIGURE 16 PROJECTED REGIONAL MARKETS FOR RAPID INFECTIOUS DISEASE MDK FOR LIVESTOCK ANIMALS, 2012 AND 2017 (%)	120