

## RENAL BIOMARKERS: TECHNOLOGIES AND GLOBAL MARKETS



**BIO138A**  
**January 2015**

Cheng-Yuk Lee  
***Project Analyst***

ISBN: 1-62296-003-3



**BCC Research**  
**49 Walnut Park, Building 2**  
**Wellesley, MA 02481 USA**  
**866-285-7215 (toll-free within the USA),**  
**or (+1) 781-489-7301**  
**[www.bccresearch.com](http://www.bccresearch.com)**  
**[information@bccresearch.com](mailto:information@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	2
INTENDED AUDIENCE	3
METHODOLOGY AND INFORMATION SOURCES	4
ANALYST'S CREDENTIALS	4
RELATED BCC RESEARCH REPORTS	4
BCC RESEARCH WEBSITE	5
DISCLAIMER	5
CHAPTER 2 SUMMARY	7
<i>SUMMARY TABLE RENAL BIOMARKER MARKET BY REGION, THROUGH 2019 (\$ MILLIONS)</i>	7
<i>SUMMARY FIGURE A RENAL BIOMARKER MARKET BY REGION, 2013-2019 (\$ MILLIONS)</i>	7
<i>SUMMARY FIGURE B ESTIMATED GLOBAL POPULATION WITH RENAL DISEASE, 2013-2019 (NO. OF CASES)</i>	8
CHAPTER 3 OVERVIEW	10
BACKGROUND OF RENAL DISEASE	10
<i>FIGURE 1 CLASSIFICATION OF ACUTE KIDNEY INJURY</i>	10
SYMPTOMS	11
DIAGNOSIS	12
CLASSIFICATION OF KIDNEY INJURY AND DISEASE	12
<i>TABLE 1 DEFINITION CRITERIA FOR KIDNEY INJURY/DISEASE</i>	13
TREATMENT FOR ACUTE KIDNEY FAILURE	13
RELATIONSHIP BETWEEN ACUTE KIDNEY INJURY AND CHRONIC KIDNEY DISEASE	14
<i>FIGURE 2 POTENTIAL OUTCOMES OF ACUTE KIDNEY INJURY</i>	14
CONNECTION BETWEEN CARDIOVASCULAR AND RENAL DISEASE	15
EPIDEMIOLOGY OF RENAL DISEASE	16
DECREASED ESTIMATED GFR	17
<i>TABLE 2 STAGES OF CHRONIC KIDNEY DISEASE</i>	17
<i>FIGURE 3 NUMBER OF HOSPITALIZATIONS WITH ACUTE KIDNEY INJURY, FROM 1979-2002</i>	21
<i>FIGURE 4 TRENDS OF KIDNEY DISEASE INCIDENT RATE IN THE U.S., FROM 1980-2005</i>	21
<i>TABLE 3 INCIDENCE OF ESRD BY COUNTRY, 2011 (PER MILLION POPULATION)</i>	22
<i>TABLE 4 PREVALENCE OF ESRD BY COUNTRY, 2011</i>	23
<i>TABLE 5 PERCENTAGE OF INCIDENT ESRD PATIENTS DUE TO DIABETES BY COUNTRY, 2011 (%)</i>	24
<i>TABLE 6 KIDNEY TRANSPLANT RATES BY COUNTRY, 2011 (RATE IN PATIENTS PER MILLION)</i>	25
REVENUE ANALYSIS OF THE GLOBAL RENAL DIALYSIS EQUIPMENT AND ACCESSORIES MARKET	26
GLOBAL MARKET SUMMARY	26

<b>TOPIC</b>	<b>PAGE NO.</b>
<i>TABLE 7 GLOBAL MARKET FOR RENAL DIALYSIS EQUIPMENT AND ACCESSORIES, THROUGH 2018 (\$ MILLIONS)</i>	27
<i>TABLE 8 SHARE OF THE RENAL DIALYSIS EQUIPMENT AND ACCESSORIES MARKET BY PRODUCT SEGMENT, 2013 AND 2018 (%)</i>	27
<i>TABLE 9 SHARE OF THE TOTAL DIALYSIS EQUIPMENT AND ACCESSORIES MARKET BY REGION, 2013 AND 2018 (%)</i>	28
ARTIFICIAL KIDNEYS FOR GRADUAL REPLACEMENT OF DIALYSIS	29
PORTABLE, CARTRIDGE-BASED HEMODIALYSIS DEVICE	29
WEARABLE PERITONEAL DIALYSIS DEVICE	30
PRICING AND REIMBURSEMENT TRENDS	30
<i>TABLE 10 REIMBURSEMENT OF DIALYSIS SERVICES PER WEEK BY SELECTED COUNTRIES, 2011-2013 (\$)</i>	30
THE U.S.	30
CANADA	31
JAPAN	31
GERMANY	31
FRANCE	32
ITALY	32
THE U.K.	32
BRAZIL	33
OTHER COUNTRIES-CHINA, INDIA AND SPAIN	33
FUTURE DIRECTION OF RENAL BIOMARKERS	33
CLINICAL VALUES OF RENAL BIOMARKERS	34
Alpha-1/Beta2-microglobulin	34
Alanine-aminopeptidase (Ala-AP)	34
Alkaline Phosphatase (ALP)	35
Albumin	35
Calprotectin	36
Clusterin	37
Creatinine	38
Cystatin C	39
FGF23	39
Hepcidin	40
Interleukin-18 (IL-18)	40
Kidney Injury Molecule-1 (KIM-1)	41
Liver Fatty Acid-Binding Protein (L-FABP)	42
N-acetyl-beta-D-Glucosaminidase (NAG)	42
Netrin	43
Neutrophil Gelatinase-Associated Lipocalin (NGAL)	43
Retinol Binding Protein (RBP)	44
Sodium/Hydrogen Exchanger Isoform 3 (NHE3)	44
Tissue Inhibitors of Metalloproteinases-2 (TIMP-2)	44
Trefoil Factor 3 (TFF3)	45
Gamma-Glutamyl Transpeptidase	45
CLINICAL EVALUATION OF BIOMARKERS	46
Glomerular Filtration Rate (GFR)	46
CHAPTER 4 INDUSTRY STRUCTURE AND COMPETITIVE ANALYSIS	53

<b>TOPIC</b>	<b>PAGE NO.</b>
INDUSTRY STRUCTURE	53
DIAGNOSTIC METHODS	53
Immunoassay	53
Radioimmunoassay	54
ELISA	54
Chemiluminescent Enzyme Immunoassay	55
Light Scattering	55
Turbidimetry	56
Nephelometry	56
Particle Counting	56
New Developments	56
Liquid Chromatography-Mass Spectrometry	56
NEWLY ISSUED PATENTS	57
<i>TABLE 11 RENAL BIOMARKER DIAGNOSIS ASSAY PATENT TRENDS, 2010-2014 (NO. OF PATENTS)</i>	57
BY BIOMARKERS	57
<i>TABLE 12 PATENTS BY BIOMARKERS, 2010-2014</i>	57
BY MANUFACTURER/RESEARCH INSTITUTE	58
<i>TABLE 13 PATENTS BY COMPANY/INSTITUTION, 2010-2014 (NO. OF PATENTS/%)</i>	58
<i>TABLE 14 PATENTS FOR RENAL BIOMARKER DIAGNOSIS ASSAY, 2014</i>	59
<i>TABLE 15 RENAL BIOMARKER DIAGNOSIS PATENT ORIGIN, FROM 2012-MAY 2014 (NO. OF PATENTS/%)</i>	59
NEW PATENT APPLICATIONS	59
<i>TABLE 16 PATENT APPLICATIONS BY BIOMARKERS, 2012-MAY 2014 (NO. OF PATENT APPLICATIONS/%)</i>	60
<i>TABLE 17 EXAMPLES OF PATENT APPLICATION BY COMPANY, JAN-MAY 2014</i>	60
<i>TABLE 18 RENAL BIOMARKER DIAGNOSIS PATENT ORIGIN, FROM 2012-MAY 2014 (NO. OF PATENTS/%)</i>	61
BY SECTOR	61
<i>TABLE 19 PATENT APPLICATIONS BY COMPANY, AUG-OCT, 2013</i>	61
GOVERNMENT REGULATION	62
U.S. FDA 510(K) APPROVAL	62
Division Acceptance and Review	62
CE MARKING IN EUROPE	63
OTHER INTERNATIONAL REGULATORY AGENCIES	64
TRENDS IN PRICE AND PRICE/PERFORMANCE	64
GENERAL TECHNOLOGY ISSUES	65
SELECTIVITY AND SPECIFICITY	65
POSITIVE AND NEGATIVE PREDICTIVE VALUES	65
RECEIVER OPERATOR CHARACTERISTIC CURVES	65
CHAPTER 5 MARKET BY ASSAYS	68
SUMMARY OF MARKET BY ASSAYS	68
<i>TABLE 20 GLOBAL RENAL BIOMARKER MARKET BY ASSAY, THROUGH 2019 (\$ MILLIONS)</i>	68
<i>TABLE 21 GLOBAL RENAL BIOMARKER MARKET BY INSTRUMENT, THROUGH 2019 (\$ MILLIONS)</i>	69
<i>TABLE 22 GLOBAL CREATININE BIOMARKER MARKET BY RENAL DISEASE, THROUGH 2019 (\$ MILLIONS)</i>	69

<b>TOPIC</b>	<b>PAGE NO.</b>
CHAPTER 6 MARKET BY REGION	71
SUMMARY OF MARKET BY REGION	71
TABLE 23 ACUTE KIDNEY INJURY BIOMARKER MARKET BY REGION, THROUGH 2019 (\$ MILLIONS)	71
TABLE 24 CHRONIC KIDNEY DISEASE BIOMARKER MARKET BY REGION, THROUGH 2019 (\$ MILLIONS)	71
U.S. MARKET	72
TABLE 25 U.S. PATIENT POPULATION WITH RENAL DISEASE, THROUGH 2019 (CASES)	73
TABLE 26 U.S. MARKET BY RENAL DISEASE, THROUGH 2019 (\$ MILLIONS)	73
TABLE 27 U.S. RENAL BIOMARKER MARKET BY ASSAY, THROUGH 2019 (\$ MILLIONS)	73
TABLE 28 U.S. CREATININE BIOMARKER MARKET BY RENAL DISEASE, THROUGH 2019 (\$ MILLIONS)	74
EUROPEAN MARKET	74
TABLE 29 EUROPE PATIENT POPULATION WITH RENAL DISEASE, THROUGH 2019 (CASES)	74
TABLE 30 EUROPE MARKET BY RENAL DISEASE, THROUGH 2019 (\$ MILLIONS)	75
TABLE 31 EUROPE RENAL BIOMARKER MARKET BY ASSAY, THROUGH 2019 (\$ MILLIONS)	76
TABLE 32 EUROPE CREATININE BIOMARKER MARKET BY RENAL DISEASE, THROUGH 2019 (\$ MILLIONS)	76
CHINESE MARKET	76
TABLE 33 CHINA PATIENT POPULATION WITH RENAL DISEASE, THROUGH 2019 (CASES)*	77
TABLE 34 CHINA MARKET BY RENAL DISEASE, THROUGH 2019 (\$ MILLIONS)	77
TABLE 35 CHINA RENAL BIOMARKER MARKET BY ASSAY, THROUGH 2019 (\$ MILLIONS)	77
TABLE 36 CHINA CREATININE BIOMARKER MARKET BY RENAL DISEASE, THROUGH 2019 (\$ MILLIONS)	78
CENTRAL AND SOUTH AMERICA MARKET	78
TABLE 37 CENTRAL AND SOUTH AMERICA PATIENT POPULATION WITH RENAL DISEASE, THROUGH 2019 (CASES)	79
TABLE 38 CENTRAL AND SOUTH AMERICA MARKET BY RENAL DISEASE, THROUGH 2019 (\$ MILLIONS)	79
TABLE 39 CENTRAL AND SOUTH AMERICA RENAL BIOMARKER MARKET BY ASSAY, THROUGH 2019 (\$ MILLIONS)*	79
TABLE 40 CENTRAL AND SOUTH AMERICA CREATININE BIOMARKER MARKET BY RENAL DISEASE, THROUGH 2019 (\$ MILLIONS)	79
REST OF THE WORLD (ROW) MARKET	80
TABLE 41 REST OF THE WORLD PATIENT POPULATION WITH RENAL DISEASE, THROUGH 2019 (CASES)	81
TABLE 42 REST OF THE WORLD MARKET BY RENAL DISEASE, THROUGH 2019 (\$ MILLIONS)	81
TABLE 43 REST OF THE WORLD RENAL BIOMARKER MARKET BY ASSAY, THROUGH 2019 (\$ MILLIONS)	81
TABLE 44 REST OF THE WORLD CREATININE BIOMARKER MARKET BY RENAL DISEASE, THROUGH 2019 (\$ MILLIONS)	82
CHAPTER 7 COMPANY PROFILES	84
MAJOR COMPANIES AND MARKET SHARE	84

<b>TOPIC</b>	<b>PAGE NO.</b>
<i>TABLE 45 MANUFACTURERS OF DIAGNOSTICS ASSAYS GLOBAL SALES, 2012 (\$ MILLIONS/%)</i>	84
<i>TABLE 46 MANUFACTURERS OF DIAGNOSTICS ASSAYS, NORTH AMERICA SALES, 2012 (\$ MILLIONS/%)</i>	84
<i>TABLE 47 MANUFACTURERS OF DIAGNOSTICS ASSAYS, EUROPE SALES, 2012 (\$ MILLIONS)</i>	85
<i>TABLE 48 MANUFACTURERS OF DIAGNOSTICS ASSAYS ASIA SALES, 2012 (\$ MILLIONS/%)</i>	86
<i>TABLE 49 MANUFACTURERS OF DIAGNOSTICS ASSAYS REST OF THE WORLD SALES, 2012 (\$ MILLIONS/%)</i>	86
ABBOTT DIAGNOSTICS	86
KEY PRODUCTS	87
COMPANY STRATEGY	87
AFFYMETRIX INC.	87
KEY PRODUCTS	87
ALERE	88
KEY PRODUCTS	88
ASTUTE MEDICAL INC.	88
KEY PRODUCT	89
BECKMAN COULTER	89
KEY PRODUCTS	89
BECTON, DICKINSON AND CO.	89
BG MEDICINE INC.	90
KEY PRODUCTS	90
COMPANY STRATEGY	90
BIOMERIEUX	91
BIOPHYSICAL CORP.	91
KEY PRODUCTS	92
COMPANY STRATEGY	92
BIOPORTO DIAGNOSTICS	92
KEY PRODUCTS	92
CMIC HOLDINGS CO. LTD.	93
CORRELOGIC SYSTEMS INC.	93
KEY PRODUCTS	93
COMPANY STRATEGY	93
RADIOMETER MEDICAL	94
KEY PRODUCT	94
RANDOX LABORATORY	94
KEY PRODUCTS	95
RESPONSE BIOMEDICAL CORP.	95
KEY PRODUCTS	95
ROCHE HOLDING AG	95
KEY PRODUCTS	96
COMPANY STRATEGY	96
SIEMENS HEALTHCARE	96
KEY PRODUCTS	97
SINGULEX	97
KEY PRODUCT	97

<b>TOPIC</b>	<b>PAGE NO.</b>
THERMO FISHER SCIENTIFIC	97
KEY PRODUCTS	98

**LIST OF TABLES**

<b>TABLE HEADING</b>	<b>PAGE NO.</b>
SUMMARY TABLE RENAL BIOMARKER MARKET BY REGION, THROUGH 2019 (\$ MILLIONS)	7
TABLE 1 DEFINITION CRITERIA FOR KIDNEY INJURY/DISEASE	13
TABLE 2 STAGES OF CHRONIC KIDNEY DISEASE	17
TABLE 3 INCIDENCE OF ESRD BY COUNTRY, 2011 (PER MILLION POPULATION)	22
TABLE 4 PREVALENCE OF ESRD BY COUNTRY, 2011	23
TABLE 5 PERCENTAGE OF INCIDENT ESRD PATIENTS DUE TO DIABETES BY COUNTRY, 2011 (%)	24
TABLE 6 KIDNEY TRANSPLANT RATES BY COUNTRY, 2011 (RATE IN PATIENTS PER MILLION)	25
TABLE 7 GLOBAL MARKET FOR RENAL DIALYSIS EQUIPMENT AND ACCESSORIES, THROUGH 2018 (\$ MILLIONS)	27
TABLE 8 SHARE OF THE RENAL DIALYSIS EQUIPMENT AND ACCESSORIES MARKET BY PRODUCT SEGMENT, 2013 AND 2018 (%)	27
TABLE 9 SHARE OF THE TOTAL DIALYSIS EQUIPMENT AND ACCESSORIES MARKET BY REGION, 2013 AND 2018 (%)	28
TABLE 10 REIMBURSEMENT OF DIALYSIS SERVICES PER WEEK BY SELECTED COUNTRIES, 2011-2013 (\$)	30
TABLE 11 RENAL BIOMARKER DIAGNOSIS ASSAY PATENT TRENDS, 2010-2014 (NO. OF PATENTS)	57
TABLE 12 PATENTS BY BIOMARKERS, 2010-2014	57
TABLE 13 PATENTS BY COMPANY/INSTITUTION, 2010-2014 (NO. OF PATENTS/%)	58
TABLE 14 PATENTS FOR RENAL BIOMARKER DIAGNOSIS ASSAY, 2014	59
TABLE 15 RENAL BIOMARKER DIAGNOSIS PATENT ORIGIN, FROM 2012-MAY 2014 (NO. OF PATENTS/%)	59
TABLE 16 PATENT APPLICATIONS BY BIOMARKERS, 2012-MAY 2014 (NO. OF PATENT APPLICATIONS/%)	60
TABLE 17 EXAMPLES OF PATENT APPLICATION BY COMPANY, JAN-MAY 2014	60
TABLE 18 RENAL BIOMARKER DIAGNOSIS PATENT ORIGIN, FROM 2012-MAY 2014 (NO. OF PATENTS/%)	61
TABLE 19 PATENT APPLICATIONS BY COMPANY, AUG-OCT, 2013	61
TABLE 20 GLOBAL RENAL BIOMARKER MARKET BY ASSAY, THROUGH 2019 (\$ MILLIONS)	68
TABLE 21 GLOBAL RENAL BIOMARKER MARKET BY INSTRUMENT, THROUGH 2019 (\$ MILLIONS)	69
TABLE 22 GLOBAL CREATININE BIOMARKER MARKET BY RENAL DISEASE, THROUGH 2019 (\$ MILLIONS)	69
TABLE 23 ACUTE KIDNEY INJURY BIOMARKER MARKET BY REGION, THROUGH 2019 (\$ MILLIONS)	71
TABLE 24 CHRONIC KIDNEY DISEASE BIOMARKER MARKET BY REGION, THROUGH 2019 (\$ MILLIONS)	71
TABLE 25 U.S. PATIENT POPULATION WITH RENAL DISEASE, THROUGH 2019 (CASES)	73
TABLE 26 U.S. MARKET BY RENAL DISEASE, THROUGH 2019 (\$ MILLIONS)	73
TABLE 27 U.S. RENAL BIOMARKER MARKET BY ASSAY, THROUGH 2019 (\$ MILLIONS)	73
TABLE 28 U.S. CREATININE BIOMARKER MARKET BY RENAL DISEASE, THROUGH 2019 (\$ MILLIONS)	74
TABLE 29 EUROPE PATIENT POPULATION WITH RENAL DISEASE, THROUGH 2019 (CASES)	74
TABLE 30 EUROPE MARKET BY RENAL DISEASE, THROUGH 2019 (\$ MILLIONS)	75



<b>TABLE HEADING</b>	<b>PAGE NO.</b>
TABLE 31 EUROPE RENAL BIOMARKER MARKET BY ASSAY, THROUGH 2019 (\$ MILLIONS)	76
TABLE 32 EUROPE CREATININE BIOMARKER MARKET BY RENAL DISEASE, THROUGH 2019 (\$ MILLIONS)	76
TABLE 33 CHINA PATIENT POPULATION WITH RENAL DISEASE, THROUGH 2019 (CASES)*	77
TABLE 34 CHINA MARKET BY RENAL DISEASE, THROUGH 2019 (\$ MILLIONS)	77
TABLE 35 CHINA RENAL BIOMARKER MARKET BY ASSAY, THROUGH 2019 (\$ MILLIONS)	77
TABLE 36 CHINA CREATININE BIOMARKER MARKET BY RENAL DISEASE, THROUGH 2019 (\$ MILLIONS)	78
TABLE 37 CENTRAL AND SOUTH AMERICA PATIENT POPULATION WITH RENAL DISEASE, THROUGH 2019 (CASES)	79
TABLE 38 CENTRAL AND SOUTH AMERICA MARKET BY RENAL DISEASE, THROUGH 2019 (\$ MILLIONS)	79
TABLE 39 CENTRAL AND SOUTH AMERICA RENAL BIOMARKER MARKET BY ASSAY, THROUGH 2019 (\$ MILLIONS)*	79
TABLE 40 CENTRAL AND SOUTH AMERICA CREATININE BIOMARKER MARKET BY RENAL DISEASE, THROUGH 2019 (\$ MILLIONS)	79
TABLE 41 REST OF THE WORLD PATIENT POPULATION WITH RENAL DISEASE, THROUGH 2019 (CASES)	81
TABLE 42 REST OF THE WORLD MARKET BY RENAL DISEASE, THROUGH 2019 (\$ MILLIONS)	81
TABLE 43 REST OF THE WORLD RENAL BIOMARKER MARKET BY ASSAY, THROUGH 2019 (\$ MILLIONS)	81
TABLE 44 REST OF THE WORLD CREATININE BIOMARKER MARKET BY RENAL DISEASE, THROUGH 2019 (\$ MILLIONS)	82
TABLE 45 MANUFACTURERS OF DIAGNOSTICS ASSAYS GLOBAL SALES, 2012 (\$ MILLIONS/%)	84
TABLE 46 MANUFACTURERS OF DIAGNOSTICS ASSAYS, NORTH AMERICA SALES, 2012 (\$ MILLIONS/%)	84
TABLE 47 MANUFACTURERS OF DIAGNOSTICS ASSAYS, EUROPE SALES, 2012 (\$ MILLIONS)	85
TABLE 48 MANUFACTURERS OF DIAGNOSTICS ASSAYS ASIA SALES, 2012 (\$ MILLIONS/%)	86
TABLE 49 MANUFACTURERS OF DIAGNOSTICS ASSAYS REST OF THE WORLD SALES, 2012 (\$ MILLIONS/%)	86

**LIST OF FIGURES**

<b>FIGURE TITLE</b>	<b>PAGE NO.</b>
SUMMARY FIGURE A RENAL BIOMARKER MARKET BY REGION, 2013-2019 (\$ MILLIONS)	7
SUMMARY FIGURE B ESTIMATED GLOBAL POPULATION WITH RENAL DISEASE, 2013-2019 (NO. OF CASES)	8
FIGURE 1 CLASSIFICATION OF ACUTE KIDNEY INJURY	10
FIGURE 2 POTENTIAL OUTCOMES OF ACUTE KIDNEY INJURY	14
FIGURE 3 NUMBER OF HOSPITALIZATIONS WITH ACUTE KIDNEY INJURY, FROM 1979-2002	21
FIGURE 4 TRENDS OF KIDNEY DISEASE INCIDENT RATE IN THE U.S., FROM 1980-2005	21