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Information

30-Country In Vitro Diagnostics (IVD) Market Atlas, 2025

SAMPLE

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Table of Contents

CHAPTER 1: WORLDWIDE IVD MARKET	1
IVD MARKET DEMAND AND GROWTH.....	1
SCOPE AND METHODOLOGY	2
MARKET SEGMENTATION	4
<i>Country Atlas Scope</i>	<i>9</i>
Table 1-1: Key Interest Countries (30-Country Atlas) for IVD Markets, 2024.....	9
Table 1-2: Global IVD Market by Leading Countries, Estimated 2024-2029 (\$ million)	
[Australia, Austria, Belgium, Brazil, Canada, Chile, China, Egypt, France, Germany, India, Indonesia, Italy, Japan, Mexico, Netherlands, Poland, Romania, Russia, Saudi Arabia, South Africa, South Korea, Spain, Sweden, Switzerland, Turkey, UAE, U.K., U.S., Vietnam]	10
Figure 1-1: Global IVD Market by Leading Countries, Estimated 2024 (\$ million)	
[Australia, Austria, Belgium, Brazil, Canada, Chile, China, Egypt, France, Germany, India, Indonesia, Italy, Japan, Mexico, Netherlands, Poland, Romania, Russia, Saudi Arabia, South Africa, South Korea, Spain, Sweden, Switzerland, Turkey, UAE, U.K., U.S., Vietnam]	12
Figure 1-2: Global IVD Market by Leading Countries, Estimated 2029 (\$ million)	
[Australia, Austria, Belgium, Brazil, Canada, Chile, China, Egypt, France, Germany, India, Indonesia, Italy, Japan, Mexico, Netherlands, Poland, Romania, Russia, Saudi Arabia, South Africa, South Korea, Spain, Sweden, Switzerland, Turkey, UAE, U.K., U.S., Vietnam]	13
 CHAPTER 2: U.S. IVD MARKET.....	14
UNITED STATES IVD MARKET OVERVIEW	14
Table 2-1: U.S. IVD Market by Segment, Estimated 2024-2029 (\$ million)	
[Blood Bank Screening - Immunos, Critical Care (core lab), General Chemistries, Hematology and Routine Coagulation, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other ¹ , Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility].....	15
Figure 2-1: U.S. IVD Market by Segment, Estimated 2024 (\$ million)	
[Blood Bank Screening - Immunos, Critical Care (core lab), General Chemistries, Hematology and Routine Coagulation, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other ¹ , Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility].....	16

Figure 2-2: U.S. IVD Market by Segment, Estimated 2029 (\$ million)

[Blood Bank Screening - Immunos, Critical Care (core lab), General Chemistries, Hematology and Routine Coagulation, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other ¹ , Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility].....	17
IVD NEWS IN THE UNITED STATES	18

CHAPTER 3: GERMANY IVD MARKET.....29

GERMANY IVD MARKET OVERVIEW	29
-----------------------------------	----

Table 3-1: Germany IVD Market by Segment, Estimated 2024-2029 (\$ million)

[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular - Other, Molecular Respiratory, Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility].....	30
---	----

Figure 3-1: Germany IVD Market by Segment, Estimated 2024 (\$ million)

[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular - Other, Molecular Respiratory, Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility].....	31
---	----

Figure 3-2: Germany IVD Market by Segment, Estimated 2029 (\$ million)

[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular - Other, Molecular Respiratory, Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility].....	32
IVD NEWS IN GERMANY	33

CHAPTER 4: CHINA34

CHINA IVD MARKET OVERVIEW	34
---------------------------------	----

Table 4-1: China IVD Market by Segment, Estimated 2024-2029 (\$ million)

[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular - Other, Molecular Respiratory, Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility].....	35
---	----

Figure 4-1: China IVD Market by Segment, Estimated 2024 (\$ million)	
[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular - Other, Molecular Respiratory, Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]	36
Figure 4-2: China IVD Market by Segment, Estimated 2029 (\$ million)	
[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular - Other, Molecular Respiratory, Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]	37
IVD NEWS IN CHINA	38

CHAPTER 5: JAPAN IVD MARKET.....39

JAPAN IVD MARKET OVERVIEW	39
Table 5-1: Japan IVD Market by Segment, Estimated 2024-2029 (\$ million)	
[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular - Other, Molecular Respiratory, Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]	40
Figure 5-1: Japan IVD Market by Segment, Estimated 2024 (\$ million)	
[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular - Other, Molecular Respiratory, Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]	41
Figure 5-2: Japan IVD Market by Segment, Estimated 2029 (\$ million)	
[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular - Other, Molecular Respiratory, Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]	42
IVD NEWS IN JAPAN	43

CHAPTER 6: FRANCE 44

FRANCE IVD MARKET OVERVIEW 44

Table 6-1: France IVD Market by Segment, Estimated 2024-2029 (\$ million)

[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular - Other¹, Molecular Respiratory, Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]..... 45

Figure 6-1: France IVD Market by Segment, Estimated 2024 (\$ million)

[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular - Other¹, Molecular Respiratory, Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]..... 46

Figure 6-2: France IVD Market by Segment, Estimated 2029 (\$ million)

[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular - Other¹, Molecular Respiratory, Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]..... 47

IVD NEWS IN FRANCE 48

CHAPTER 7: UNITED KINGDOM..... 49

UNITED KINGDOM IVD MARKET OVERVIEW 49

Table 7-1: United Kingdom IVD Market by Segment, Estimated 2024-2029 (\$ million)

[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular - Other¹, Molecular Respiratory, Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]..... 50

Figure 7-1: United Kingdom IVD Market by Segment, Estimated 2024 (\$ million)

[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular - Other¹, Molecular Respiratory, Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]..... 51

Figure 7-2: United Kingdom IVD Market by Segment, Estimated 2029 (\$ million)

[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular - Other¹, Molecular Respiratory,

Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]	52
IVD NEWS IN THE UNITED KINGDOM	53
CHAPTER 8: ITALY.....	54
ITALY IVD MARKET OVERVIEW	54
Table 8-1: Italy IVD Market by Segment, Estimated 2024-2029 (\$ million)	
[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular - Other ¹ , Molecular Respiratory, Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]	55
Figure 8-1: Italy IVD Market by Segment, Estimated 2024 (\$ million)	
[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular - Other ¹ , Molecular Respiratory, Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]	56
Figure 8-2: Italy IVD Market by Segment, Estimated 2029 (\$ million)	
[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular - Other ¹ , Molecular Respiratory, Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]	57
IVD NEWS IN ITALY	58
CHAPTER 9: CANADA.....	59
CANADA IVD MARKET OVERVIEW	59
Table 9-1: Canada IVD Market by Segment, Estimated 2024-2029 (\$ million)	
[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular - Other ¹ , Molecular Respiratory, Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]	60
Figure 9-1: Canada IVD Market by Segment, Estimated 2024 (\$ million)	
[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular - Other ¹ , Molecular Respiratory,	

Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]	61
Figure 9-2: Canada IVD Market by Segment, Estimated 2029 (\$ million)	
[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular - Other ¹ , Molecular Respiratory, Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]	62
IVD NEWS IN CANADA	63

CHAPTER 10: SPAIN 64

SPAIN IVD MARKET OVERVIEW	64
Table 10-1: Spain IVD Market by Segment, Estimated 2024-2029 (\$ million)	
[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other ¹ , Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]	65
Figure 10-1: Spain IVD Market by Segment, Estimated 2024 (\$ million)	
[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other ¹ , Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]	66
Figure 10-2: Spain IVD Market by Segment, Estimated 2029 (\$ million)	
[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other ¹ , Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]	67
IVD NEWS IN SPAIN	68

CHAPTER 11: AUSTRALIA 69

AUSTRALIA IVD MARKET OVERVIEW	69
Table 11-1: Australia IVD Market by Segment, Estimated 2024-2029 (\$ million)	
[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other ¹ ,	

Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]	70
Figure 11-1: Australia IVD Market by Segment, Estimated 2024 (\$ million)	
[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other ¹ , Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]	71
Figure 11-2: Australia IVD Market by Segment, Estimated 2029 (\$ million)	
[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other ¹ , Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]	72
IVD NEWS IN AUSTRALIA	73

CHAPTER 12: BRAZIL..... 74

BRAZIL IVD MARKET OVERVIEW	74
Table 12-1: Brazil IVD Market by Segment, Estimated 2024-2029 (\$ million)	
[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other ¹ , Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]	75
Figure 12-1: Brazil IVD Market by Segment, Estimated 2024 (\$ million)	
[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other ¹ , Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]	76
Figure 12-2: Brazil IVD Market by Segment, Estimated 2029 (\$ million)	
[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other ¹ , Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]	77

CHAPTER 13: INDIA 78

INDIA IVD MARKET OVERVIEW 78

Table 13-1: India IVD Market by Segment, Estimated 2024-2029 (\$ million)

[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other¹, Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]..... 79

Figure 13-1: India IVD Market by Segment, Estimated 2024 (\$ million)

[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other¹, Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]..... 80

Figure 13-2: India IVD Market by Segment, Estimated 2029 (\$ million)

[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other¹, Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]..... 81

IVD NEWS IN INDIA 82

CHAPTER 14: RUSSIA 83

RUSSIA IVD MARKET OVERVIEW 83

Table 14-1: Russia IVD Market by Segment, Estimated 2024-2029 (\$ million)

[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other¹, Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]..... 84

Figure 14-1: Russia IVD Market by Segment, Estimated 2024 (\$ million)

[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other¹, Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]..... 85

Figure 14-2: Russia IVD Market by Segment, Estimated 2029 (\$ million)

[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other¹,

Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]	86
--	----

CHAPTER 15: THE NETHERLANDS87

THE NETHERLANDS IVD MARKET OVERVIEW	87
---	----

Table 15-1: The Netherlands IVD Market by Segment, Estimated 2024-2029 (\$ million)

[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other ¹ , Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]	88
--	----

Figure 15-1: The Netherlands IVD Market by Segment, Estimated 2024 (\$ million)

[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other ¹ , Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]	89
--	----

Figure 15-2: The Netherlands IVD Market by Segment, Estimated 2029 (\$ million)

[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other ¹ , Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]	90
--	----

IVD NEWS IN THE NETHERLANDS	91
-----------------------------------	----

CHAPTER 16: SWITZERLAND92

SWITZERLAND IVD MARKET OVERVIEW	92
---------------------------------------	----

Table 16-1: Switzerland IVD Market by Segment, Estimated 2024-2029 (\$ million)

[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other ¹ , Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]	93
--	----

Figure 16-1: Switzerland IVD Market by Segment, Estimated 2024 (\$ million)

[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other ¹ , Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]	94
--	----

Figure 16-2: Switzerland IVD Market by Segment, Estimated 2029 (\$ million)

[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other ¹ , Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility].....	95
IVD NEWS IN SWITZERLAND	96

CHAPTER 17: POLAND 97

POLAND IVD MARKET OVERVIEW	97
----------------------------------	----

Table 17-1: Poland IVD Market by Segment, Estimated 2024-2029 (\$ million)

[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other ¹ , Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility].....	98
---	----

Figure 17-1: Poland IVD Market by Segment, Estimated 2024 (\$ million)

[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other ¹ , Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility].....	99
---	----

Figure 17-2: Poland IVD Market by Segment, Estimated 2029 (\$ million)

[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other ¹ , Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility].....	100
---	-----

CHAPTER 18: TURKEY 101

TURKEY IVD MARKET OVERVIEW	101
----------------------------------	-----

Table 18-1: Turkey IVD Market by Segment, Estimated 2024-2029 (\$ million)

[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other ¹ , Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility].....	102
---	-----

Figure 18-1: Turkey IVD Market by Segment, Estimated 2024 (\$ million)

[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries,	
---	--

Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other ¹ , Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility].....	103
Figure 18-2: Turkey IVD Market by Segment, Estimated 2029 (\$ million)	
[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other ¹ , Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility].....	104
CHAPTER 19: MEXICO	105
MEXICO IVD MARKET OVERVIEW.....	105
Table 19-1: Mexico IVD Market by Segment, Estimated 2024-2029 (\$ million)	
[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other ¹ , Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility].....	106
Figure 19-1: Mexico IVD Market by Segment, Estimated 2024 (\$ million)	
[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other ¹ , Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility].....	107
Figure 19-2: Mexico IVD Market by Segment, Estimated 2029 (\$ million)	
[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other ¹ , Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility].....	108
CHAPTER 20: SWEDEN	109
SWEDEN IVD MARKET OVERVIEW	109
Table 20-1: Sweden IVD Market by Segment, Estimated 2024-2029 (\$ million)	
[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other ¹ ,	

Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]	110
Figure 20-1: Sweden IVD Market by Segment, Estimated 2024 (\$ million)	
[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other ¹ , Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]	111
Figure 20-2: Sweden IVD Market by Segment, Estimated 2029 (\$ million)	
[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other ¹ , Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]	112
CHAPTER 21: BELGIUM	113
BELGIUM IVD MARKET OVERVIEW	113
Table 21-1: Belgium IVD Market by Segment, Estimated 2024-2029 (\$ million)	
[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other ¹ , Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]	114
Figure 21-1: Belgium IVD Market by Segment, Estimated 2024 (\$ million)	
[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other ¹ , Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]	115
Figure 21-2: Belgium IVD Market by Segment, Estimated 2029 (\$ million)	
[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other ¹ , Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]	116

CHAPTER 22: AUSTRIA..... 117**AUSTRIA IVD MARKET OVERVIEW 117****Table 22-1: Austria IVD Market by Segment, Estimated 2024-2029 (\$ million)**

[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other¹, Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]..... 118

Figure 22-1: Austria IVD Market by Segment, Estimated 2024 (\$ million)

[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other¹, Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]..... 119

Figure 22-2: Austria IVD Market by Segment, Estimated 2029 (\$ million)

[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other¹, Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]..... 120

CHAPTER 23: SAUDI ARABIA..... 121**SAUDI ARABIA IVD MARKET OVERVIEW 121****Table 23-1: Saudi Arabia IVD Market by Segment, Estimated 2024-2029 (\$ million)**

[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other¹, Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]..... 122

Figure 23-1: Saudi Arabia IVD Market by Segment, Estimated 2024 (\$ million)

[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other¹, Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]..... 123

Figure 23-2: Saudi Arabia IVD Market by Segment, Estimated 2029 (\$ million)

[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other¹, Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]..... 124

CHAPTER 24: SOUTH KOREA 125

SOUTH KOREA IVD MARKET OVERVIEW 125

Table 24-1: South Korea IVD Market by Segment, Estimated 2024-2029 (\$ million)	
[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other ¹ , Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility].....	126

Figure 24-1: South Korea IVD Market by Segment, Estimated 2024 (\$ million)	
[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other ¹ , Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility].....	127

Figure 24-2: South Korea IVD Market by Segment, Estimated 2029 (\$ million)	
[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other ¹ , Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility].....	128

IVD NEWS IN SOUTH KOREA 129

CHAPTER 25: EGYPT 130

EGYPT IVD MARKET OVERVIEW 130

Table 25-1: Egypt IVD Market by Segment, Estimated 2024-2029 (\$ million)	
[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other ¹ , Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility].....	131

Figure 25-1: Egypt IVD Market by Segment, Estimated 2024 (\$ million)	
[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other ¹ , Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility].....	132

Figure 25-2: Egypt IVD Market by Segment, Estimated 2029 (\$ million)	
[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other ¹ ,	

Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility].....	133
---	-----

CHAPTER 26: ROMANIA..... 134

ROMANIA IVD MARKET OVERVIEW	134
-----------------------------------	-----

Table 26-1: Romania IVD Market by Segment, Estimated 2024-2029 (\$ million)

[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other ¹ , Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility].....	135
---	-----

Figure 26-1: Romania IVD Market by Segment, Estimated 2024 (\$ million)

[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other ¹ , Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility].....	136
---	-----

Figure 26-2: Romania IVD Market by Segment, Estimated 2029 (\$ million)

[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other ¹ , Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility].....	137
---	-----

CHAPTER 27: SOUTH AFRICA 138

SOUTH AFRICA IVD MARKET OVERVIEW	138
--	-----

Table 27-1: South Africa IVD Market by Segment, Estimated 2024-2029 (\$ million)

[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other ¹ , Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility].....	139
---	-----

Figure 27-1: South Africa IVD Market by Segment, Estimated 2024 (\$ million)

[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other ¹ , Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility].....	140
---	-----

Figure 27-2: South Africa IVD Market by Segment, Estimated 2029 (\$ million)

[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other¹, Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]..... 141

CHAPTER 28: INDONESIA..... 142

INDONESIA IVD MARKET OVERVIEW 142

Table 28-1: Indonesia IVD Market by Segment, Estimated 2024-2029 (\$ million)

[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other¹, Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]..... 143

Figure 28-1: Indonesia IVD Market by Segment, Estimated 2024 (\$ million)

[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other¹, Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]..... 144

Figure 28-2: Indonesia IVD Market by Segment, Estimated 2029 (\$ million)

[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other¹, Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]..... 145

CHAPTER 29: CHILE..... 146

CHILE IVD MARKET OVERVIEW 146

Table 29-1: Chile IVD Market by Segment, Estimated 2024-2029 (\$ million)

[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other¹, Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]..... 147

Figure 29-1: Chile IVD Market by Segment, Estimated 2024 (\$ million)

[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST,

Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other ¹ , Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility].....	148
Figure 29-2: Chile IVD Market by Segment, Estimated 2029 (\$ million)	
[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other ¹ , Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility].....	149
CHAPTER 30: UNITED ARAB EMIRATES	150
UNITED ARAB EMIRATES IVD OVERVIEW	150
Table 30-1: United Arab Emirates IVD Market by Segment, Estimated 2024-2029 (\$ million)	
[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other ¹ , Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility].....	151
Figure 30-1: United Arab Emirates IVD Market by Segment, Estimated 2024 (\$ million)	
[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other ¹ , Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility].....	152
Figure 30-2: United Arab Emirates IVD Market by Segment, Estimated 2029 (\$ million)	
[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other ¹ , Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility].....	153
IVD NEWS IN THE UNITED ARAB EMIRATES	154
CHAPTER 31: VIETNAM.....	155
VIETNAM IVD MARKET OVERVIEW	155
Table 31-1: Vietnam IVD Market by Segment, Estimated 2024-2029 (\$ million)	
[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other ¹ ,	

Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]	156
Figure 31-1: Vietnam IVD Market by Segment, Estimated 2024 (\$ million)	
[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other ¹ , Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]	157
Figure 31-2: Vietnam IVD Market by Segment, Estimated 2029 (\$ million)	
[Blood Bank Screening - Immunos, Coagulation PT/INR, Critical Care (core lab), General Chemistries, Hematology, Histology, Immunoassays – Micro, Immunoassays - Non-Micro, Microbiology – ID/AST, Molecular Bloodstream/HAI, Molecular HIV & Hepatitis, Molecular Respiratory, Molecular - Other ¹ , Other IVD, Other POC, POC Critical Care, POC Fecal Occult, POC Glucose (all), POC Infectious Disease (all), POC Pregnancy & Fertility]	158

APPENDIX: 30-COUNTRY IVD SEGMENT TOTALS 159

Table A-1: Blood Bank Screening (Immunos), Global IVD Segment by Leading Countries, Estimated 2024-2029 (\$ million) [Australia, Austria, Belgium, Brazil, Canada, Chile, China, Egypt, France, Germany, India, Indonesia, Italy, Japan, Mexico, Netherlands, Poland, Romania, Russia, Saudi Arabia, South Africa, South Korea, Spain, Sweden, Switzerland, Turkey, UAE, U.K., U.S., Vietnam]	159
Table A-2: Coagulation PT/INR, Global IVD Segment by Leading Countries, Estimated 2024-2029 (\$ million) [Australia, Austria, Belgium, Brazil, Canada, Chile, China, Egypt, France, Germany, India, Indonesia, Italy, Japan, Mexico, Netherlands, Poland, Romania, Russia, Saudi Arabia, South Africa, South Korea, Spain, Sweden, Switzerland, Turkey, UAE, U.K., U.S., Vietnam]	161
Table A-3: Critical Care (core lab), Global IVD Segment by Leading Countries, Estimated 2024-2029 (\$ million) [Australia, Austria, Belgium, Brazil, Canada, Chile, China, Egypt, France, Germany, India, Indonesia, Italy, Japan, Mexico, Netherlands, Poland, Romania, Russia, Saudi Arabia, South Africa, South Korea, Spain, Sweden, Switzerland, Turkey, UAE, U.K., U.S., Vietnam]	163
Table A-4: General Chemistries, Global IVD Segment by Leading Countries, Estimated 2024-2029 (\$ million) [Australia, Austria, Belgium, Brazil, Canada, Chile, China, Egypt, France, Germany, India, Indonesia, Italy, Japan, Mexico, Netherlands, Poland, Romania, Russia, Saudi Arabia, South Africa, South Korea, Spain, Sweden, Switzerland, Turkey, UAE, U.K., U.S., Vietnam]	165
Table A-5: Hematology, Global IVD Segment by Leading Countries, Estimated 2024-2029 (\$ million) [Australia, Austria, Belgium, Brazil, Canada, Chile, China, Egypt, France, Germany, India, Indonesia, Italy, Japan, Mexico, Netherlands, Poland, Romania, Russia, Saudi Arabia, South Africa, South Korea, Spain, Sweden, Switzerland, Turkey, UAE, U.K., U.S., Vietnam]	167
Table A-6: Histology, Global IVD Segment by Leading Countries, Estimated 2024-2029 (\$ million) [Australia, Austria, Belgium, Brazil, Canada, Chile, China, Egypt, France, Germany, India, Indonesia, Italy, Japan, Mexico, Netherlands, Poland, Romania, Russia, Saudi Arabia, South Africa, South Korea, Spain, Sweden, Switzerland, Turkey, UAE, U.K., U.S., Vietnam]	169

Table A-7: Immunoassays (Micro), Global IVD Segment by Leading Countries, Estimated 2024-2029 (\$ million) [Australia, Austria, Belgium, Brazil, Canada, Chile, China, Egypt, France, Germany, India, Indonesia, Italy, Japan, Mexico, Netherlands, Poland, Romania, Russia, Saudi Arabia, South Africa, South Korea, Spain, Sweden, Switzerland, Turkey, UAE, U.K., U.S., Vietnam]	171
Table A-8: Immunoassays (Non-Micro), Global IVD Segment by Leading Countries, Estimated 2024-2029 (\$ million) [Australia, Austria, Belgium, Brazil, Canada, Chile, China, Egypt, France, Germany, India, Indonesia, Italy, Japan, Mexico, Netherlands, Poland, Romania, Russia, Saudi Arabia, South Africa, South Korea, Spain, Sweden, Switzerland, Turkey, UAE, U.K., U.S., Vietnam]	173
Table A-9: Microbiology (ID/AST), Global IVD Segment by Leading Countries, Estimated 2024-2029 (\$ million) [Australia, Austria, Belgium, Brazil, Canada, Chile, China, Egypt, France, Germany, India, Indonesia, Italy, Japan, Mexico, Netherlands, Poland, Romania, Russia, Saudi Arabia, South Africa, South Korea, Spain, Sweden, Switzerland, Turkey, UAE, U.K., U.S., Vietnam]	175
Table A-10: Molecular Bloodstream/HAI, Global IVD Segment by Leading Countries, Estimated 2024-2029 (\$ million) [Australia, Austria, Belgium, Brazil, Canada, Chile, China, Egypt, France, Germany, India, Indonesia, Italy, Japan, Mexico, Netherlands, Poland, Romania, Russia, Saudi Arabia, South Africa, South Korea, Spain, Sweden, Switzerland, Turkey, UAE, U.K., U.S., Vietnam]	177
Table A-11: Molecular HIV & Hepatitis, Global IVD Segment by Leading Countries, Estimated 2024-2029 (\$ million) [Australia, Austria, Belgium, Brazil, Canada, Chile, China, Egypt, France, Germany, India, Indonesia, Italy, Japan, Mexico, Netherlands, Poland, Romania, Russia, Saudi Arabia, South Africa, South Korea, Spain, Sweden, Switzerland, Turkey, UAE, U.K., U.S., Vietnam]	179
Table A-12: Molecular Respiratory, Global IVD Segment by Leading Countries, Estimated 2024-2029 (\$ million) [Australia, Austria, Belgium, Brazil, Canada, Chile, China, Egypt, France, Germany, India, Indonesia, Italy, Japan, Mexico, Netherlands, Poland, Romania, Russia, Saudi Arabia, South Africa, South Korea, Spain, Sweden, Switzerland, Turkey, UAE, U.K., U.S., Vietnam]	181
Table A-13: Molecular (Other*), Global IVD Segment by Leading Countries, Estimated 2024-2029 (\$ million) [Australia, Austria, Belgium, Brazil, Canada, Chile, China, Egypt, France, Germany, India, Indonesia, Italy, Japan, Mexico, Netherlands, Poland, Romania, Russia, Saudi Arabia, South Africa, South Korea, Spain, Sweden, Switzerland, Turkey, UAE, U.K., U.S., Vietnam]	183
Table A-14: POC Critical Care , Global IVD Segment by Leading Countries, Estimated 2024-2029 (\$ million) [Australia, Austria, Belgium, Brazil, Canada, Chile, China, Egypt, France, Germany, India, Indonesia, Italy, Japan, Mexico, Netherlands, Poland, Romania, Russia, Saudi Arabia, South Africa, South Korea, Spain, Sweden, Switzerland, Turkey, UAE, U.K., U.S., Vietnam]	185
Table A-15: POC Fecal Occult, Global IVD Segment by Leading Countries, Estimated 2024-2029 (\$ million) [Australia, Austria, Belgium, Brazil, Canada, Chile, China, Egypt, France, Germany, India, Indonesia, Italy, Japan, Mexico, Netherlands, Poland, Romania, Russia, Saudi Arabia, South Africa, South Korea, Spain, Sweden, Switzerland, Turkey, UAE, U.K., U.S., Vietnam]	187
Table A-16: POC Glucose (all), Global IVD Segment by Leading Countries, Estimated 2024-2029 (\$ million) [Australia, Austria, Belgium, Brazil, Canada, Chile, China, Egypt, France, Germany, India, Indonesia, Italy, Japan, Mexico, Netherlands, Poland, Romania, Russia, Saudi Arabia, South Africa, South Korea, Spain, Sweden, Switzerland, Turkey, UAE, U.K., U.S., Vietnam]	189
Table A-17: POC Infectious Disease (all), Global IVD Segment by Leading Countries, Estimated 2024-2029 (\$ million) [Australia, Austria, Belgium, Brazil, Canada, Chile, China, Egypt, France, Germany, India, Indonesia, Italy, Japan, Mexico, Netherlands, Poland, Romania, Russia, Saudi Arabia, South Africa, South Korea, Spain, Sweden, Switzerland, Turkey, UAE, U.K., U.S., Vietnam]	191

Table A-18: POC Pregnancy & Fertility, Global IVD Segment by Leading Countries,

Estimated 2024-2029 (\$ million) [Australia, Austria, Belgium, Brazil, Canada, Chile, China, Egypt, France, Germany, India, Indonesia, Italy, Japan, Mexico, Netherlands, Poland, Romania, Russia, Saudi Arabia, South Africa, South Korea, Spain, Sweden, Switzerland, Turkey, UAE, U.K., U.S., Vietnam] 193

Table A-19: Other IVD, Global IVD Segment by Leading Countries,

Estimated 2024-2029 (\$ million) [Australia, Austria, Belgium, Brazil, Canada, Chile, China, Egypt, France, Germany, India, Indonesia, Italy, Japan, Mexico, Netherlands, Poland, Romania, Russia, Saudi Arabia, South Africa, South Korea, Spain, Sweden, Switzerland, Turkey, UAE, U.K., U.S., Vietnam] 195

Table A-20: Other POC, Global IVD Segment by Leading Countries,

Estimated 2024-2029 (\$ million) [Australia, Austria, Belgium, Brazil, Canada, Chile, China, Egypt, France, Germany, India, Indonesia, Italy, Japan, Mexico, Netherlands, Poland, Romania, Russia, Saudi Arabia, South Africa, South Korea, Spain, Sweden, Switzerland, Turkey, UAE, U.K., U.S., Vietnam] 197

SAMPLE Chapter

IVD Market Demand and Growth

The IVD market is continuing to advance and remains dynamic, demonstrating constant innovations. Major changes in the market include a focus on point-of-care products and advancements in the home testing market. The pandemic ushered in some interesting changes, including self-administered test kits, telehealth, and an overall consumer interest in personal healthcare. AI is also making inroads into several areas of the IVD market, helping healthcare personnel be more efficient.

Major advancements in technology have increased the availability and complexity of tests that can be administered. Cancer remains a major concern as its prevalence is expected to grow. Personalized medicine is critical for targeting treatments that are beneficial.

Innovative product launches worldwide contribute to the market, and clinical decision-making is reaching new heights. Due to the growing burden of chronic disease, IVD manufacturers have continued to invest in research and development at higher levels than in the past.

Several countries made gains in the IVD diagnostic market in 2024 compared to 2023, including:

- China
- Egypt
- Mexico
- Netherlands
- South Africa

Russia's IVD revenues dropped due to the retraction of foreign businesses, mainly due to the ongoing Ukrainian war.

Scope and Methodology

The **30-Country IVD Market Atlas, 2025** is presented in U.S. dollars for the years 2024—2029. Future quarterly editions in the second half of the year will feature data estimates covering 2025-2030. Market sizes represent manufacturer-level revenue. Market values are provided as estimates and may reflect adjustments from previously published editions of this report. They may also deviate from other Kalorama Information IVD reports, reflecting differences in market segmentation, interpretation of segmentation, currency fluctuations, and sources of information.

The information presented in this report is derived from publicly available sources such as company, government, and medical organization reports. The analysis is based on the author's industry knowledge combined with literature searches and interviews with industry professionals and experts in the IVD industry.

Major information sources include, but are not limited to, the following:

- American Association for Clinical Chemistry, www.aacc.org
- American Association of Blood Banks, www.aabb.org
- Association for Molecular Pathology, www.ampweb.org
- Centers for Medicare & Medicaid Services
- CAP Today Online, <http://captodayonline.com/>
- China Cancer Registry
- Clinical Lab News
- Croatian Institute of Public Health, Department of Epidemiology
- EDMA (the European Diagnostic Manufacturers Association), www.edma-ivd.be
- FDA, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD), www.fda.gov/cdrh/oivd/index.html
- The Freedonia Group Economic Data
- FX Investors, historical currency exchange rates (www.oanda.com)
- GenomeWeb

- Interviews and surveys conducted by Kalorama Information
- Institute of Health Information and Statistics of the Czech Republic
- India Public Sector News
- IVD company websites, annual reports, financial statements, investor conferences, press conferences
- Japan Analytical Instruments Manufacturers Association, IVD Committee
- Joint Commission International, Mexico
- Kalorama Information's Knowledge Center and previous reports
- Laboratory Equipment, www.laboratoryequipment.com
- LabPulse.com
- Medec Canada
- MDDI Magazine
- National Bureau of Statistics of China
- Surveys, Science and Medicine Group/Bioinformatics
- Strategic Directions International (SDi)
- The New England Journal of Medicine
- Oncology KnowledgeBASE, <http://oncologyknowledgebase.com>
- World Health Organization databases and fact sheets
- World Bank

Market Segmentation

The scope of the report includes the following market segmentations for 30 key countries of interest in the IVD Market.

- General Chemistries
- Critical Care (core lab)
- Hematology
- Coagulation PT/INR
- Immunoassays – Micro
- Immunoassays - Non-Micro
- Blood Bank Screening - Immunos
- Microbiology – ID/AST
- Molecular Respiratory
- Molecular Bloodstream/HAI
- Molecular HIV & Hepatitis
- Molecular NAT and Other
- POC Glucose (all)
- POC Critical Care
- POC Infectious Disease (all)
- POC Pregnancy & Fertility
- POC Fecal Occult
- Other POC
- Histology
- Other IVD

General Chemistries - Clinical chemistry testing is performed in the core lab at workstations alongside immunoanalyzers and as part of immunochemistry combined platforms. Routine clinical chemistry panels comprise 30 to 40 tests, including substrates, metabolites, enzymes,

and lipids. Renal clearance, liver function, and metabolic status also factor into clinical chemistry testing.

Critical Care (core lab) - Chemistry stations also perform tests for blood gas and electrolyte levels, which are routine in cases of admitted and hospitalized patients. The market segment in this section does not include point-of-care (POC) chemistry tests completed using portable or handheld analyzers.

Hematology - Hematology uses various counts and measures from whole blood samples to aid in the diagnosis and monitoring of leukemia, anemia, and autoimmune diseases. Complete blood cell (CBC) tests performed on hematology analyzers include various test parameters relating to hemoglobin (Hg/HGB), red blood cells (RBC), platelets (PLT), white blood cells (WBC), nucleated red blood cells (NRBCs), and reticulocytes (immature RBCs; RETIC). Differentials provide cell counts and other parameters relating to blood-borne cell populations such as WBC subtypes, reticulocytes, or platelets. Ancillary hematology instrumentation includes slidemakers/slidestainers and specialized digital cell imaging systems that perform automated visual differentials or counts and analysis of blood cells.

The hematology diagnostics segment includes instrumentation and consumables used for the following tests and lab procedures:

- Automated full or complete blood counts (CBC)
- Manual or automated blood cell differentials
- Slidemaking/staining for hematology testing samples
- Digital blood cell imaging

Coagulation PT/INR - patients using warfarin require coagulation monitoring or a regular blood clotting test known as the International Normalized Ratio (INR, formerly known as the Prothrombin Time test).

Immunoassays – Micro - immunoassays are widely used for the detection of infections, patient immune status, and quantitation of viral loads in cases of hepatitis and HIV. Immunoassay testing for infectious disease has advantages over culture microbiology in terms of time to test results and ability to assay viral pathogens and over molecular diagnostics in terms of cost.

Immunoassays - Non-Micro – immunoassays in non-infectious disease disciplines include cardiac markers, tumor markers, HbA1c, autoimmune and drug monitoring among others. Most immunoassays have been centralized and commoditized on analyte panels run on core lab-integrated chemistry analyzers or immunoanalyzers including assays for thyroid function, drugs of abuse, therapeutic drugs, anemia, fertility and protein biomarkers related to diabetes, cancer and cardiovascular health. Additional laboratory immunoassays – enzyme immunosorbent assays (EIA/ELISA) and other single-test formats – represent the remainder of the market.

Blood Bank Screening – Immunos - includes all blood bank screening of immunoassays.

Microbiology – ID/AST - culture-based identification and antimicrobial susceptibility testing (ID/AST) remains a gold standard for infectious disease confirmatory testing. Microbiology testing using ID/AST reagents and systems is accomplished using a variety of samples including blood, urine, and body fluid and swabs from wounds, post-surgical dressing and sutures, urogenital and respiratory sites. The most-time sensitive ID/AST workups are done on urine, wound, aspirate and blood samples from hospitalized patients with suspected hospital-acquired infections or sepsis. Outpatient samples, which make up some 85% of the workload, include respiratory samples tested for throat and lung infections, urogenital samples for STDs, and urines for urinary tract infections.

Molecular Respiratory – molecular respiratory tests detect genetic material of viruses consisting of COVID-19, Influenza A, Influenza B, and RSV infections. These tests are done using reverse transcription polymerase chain reaction (RT-PCR).

Molecular Bloodstream/HAI – molecular bloodstream/HAI test identifies the most common pathogens and associated genetic determinants of antibiotic resistance. Because

bloodstream infections are associated with considerable morbidity, rapid molecular testing has taken center stage in the diagnosis and treatment of bloodstream infections.

Molecular HIV & Hepatitis – molecular HIV and hepatitis tests are done through the PCR method that detects genetic material (RNA) in the blood.

Molecular NAT and Other – molecular nucleic acid testing searches for the actual virus in the blood and is capable of detecting viruses sooner than other types of tests. The test is used to detect a particular nucleic acid sequence to identify the virus or bacterium.

POC Glucose (all) – includes manual and continuous glucose monitoring.

POC Critical Care - includes tests performed for blood gas and electrolyte levels using handheld instruments.

POC Infectious Disease (all) – includes immunoassay and molecular tests.

POC Pregnancy & Fertility – includes all pregnancy and fertility testing by professionals and patients.

POC Fecal Occult – includes all types of self-collected and self-testing for fecal occult blood.

Histology - histology and cytology are the study of tissue (and cells, respectively). Histological or tissue analysis involves a two-step procedure: preanalytical sample preparation and advanced staining. Sputum, cervical and synovial fluids, and bits of tissue that have been biopsied or surgically removed are processed, placed on glass slides, and stained to characterize targeted cellular constructions, tissue morphology and cell components. Trained technologists perform a first-pass screen of the stained slides. Pathologists further investigate tumor section slides and others that are found to have suspicious or aberrant cells. The tests are used primarily to detect cancer and infectious agents in tissue and cervical fluid, but the reader is reminded that every organ or piece of tissue removed from a patient during surgery is also processed and analyzed in this two-step procedure.

Coagulation PT/INR - Patients using warfarin require coagulation monitoring or a regular blood clotting test known as the International Normalized Ratio (INR, formerly known as the Prothrombin Time test).

Immunoassays – Micro - Immunoassays are widely used for the detection of infections, patient immune status, and quantitation of viral loads in cases of hepatitis and HIV. Immunoassay testing for infectious diseases has advantages over culture microbiology in terms of time to test results and the ability to assay viral pathogens, and over molecular diagnostics in terms of cost.

Immunoassays - Non-Micro - Immunoassays in non-infectious disease disciplines include cardiac markers, tumor markers, HbA1c, autoimmune and drug monitoring, among others. Most immunoassays have been centralized and commoditized on analyte panels run on core lab-integrated chemistry analyzers or immunoanalyzers, including assays for thyroid function, drugs of abuse, therapeutic drugs, anemia, fertility, and protein biomarkers related to diabetes, cancer, and cardiovascular health. Additional laboratory immunoassays – enzyme immunosorbent assays (EIA/ELISA) and other single-test formats – represent the remainder of the market.

Blood Bank Screening – Immunos - Includes all blood bank screening of immunoassays.

Microbiology – ID/AST - Culture-based identification and antimicrobial susceptibility testing (ID/AST) remains the gold standard for infectious disease confirmatory testing. Microbiology testing using ID/AST reagents and systems is accomplished using a variety of samples, including blood, urine, body fluid, and swabs from wounds, post-surgical dressings and sutures, urogenital and respiratory sites. The most time-sensitive ID/AST workups are done on urine, wound, aspirate, and blood samples from hospitalized patients with suspected hospital-acquired infections or sepsis. Outpatient samples, which make up some 85% of the workload, include respiratory samples tested for throat and lung infections, urogenital samples for STDs, and urine samples for urinary tract infections.

Molecular Respiratory - Molecular respiratory tests detect genetic material of viruses, including COVID-19, Influenza A, Influenza B, and RSV infections. These tests are done using reverse transcription polymerase chain reaction (RT-PCR).

Molecular Bloodstream/HAI - Molecular bloodstream/HAI tests identify the most common pathogens and associated genetic determinants of antibiotic resistance. Because bloodstream infections are associated with considerable morbidity, rapid molecular testing has taken center stage in the diagnosis and treatment of bloodstream infections.

Molecular HIV & Hepatitis - Molecular HIV and hepatitis tests are done through the PCR method that detects genetic material (RNA) in the blood.

Molecular NAT and Other - Molecular nucleic acid testing searches for the actual virus in the blood and is capable of detecting viruses sooner than other types of tests. The test is used to detect a particular nucleic acid sequence to identify the virus or bacterium.

POC Glucose (all) - Includes manual and continuous glucose monitoring.

POC Critical Care - Includes tests performed for blood gas and electrolyte levels using handheld instruments.

POC Infectious Disease (all) - Includes immunoassay and molecular tests.

POC Pregnancy & Fertility - Includes all pregnancy and fertility testing by professionals and patients.

POC Fecal Occult - Includes all types of self-collected and self-testing for fecal occult blood.

Histology - Histology and cytology are the study of tissue (and cells, respectively). Histological or tissue analysis involves a two-step procedure: preanalytical sample preparation and advanced staining. Sputum, cervical and synovial fluids, and bits of tissue that have been biopsied or surgically removed are processed, placed on glass slides, and stained to characterize targeted cellular constructions, tissue morphology, and cell components. Trained technologists perform a first-pass screen of the stained slides. Pathologists further investigate tumor section slides and others that are found to have suspicious or aberrant cells. The tests are used primarily to detect cancer and infectious agents in tissue and cervical fluid, but every organ or piece of tissue removed from a patient during surgery is also processed and analyzed in this two-step procedure.

Country Atlas Scope

The scope of the atlas encompasses 30 of the most active countries in the IVD sector. Countries were selected based on total revenues and evidence of a healthy IVD market.

SAMPLE Table: Global IVD Market by Leading Countries, Estimated 2024-2029 (\$ million)

Segment	2024	2029	CAGR
U.S.	\$XX million	\$XX million	XX%
Germany	\$XX million	\$XX million	XX%
China	\$XX million	\$XX million	XX%
Japan	\$XX million	\$XX million	XX%
France	\$XX million	\$XX million	XX%
U.K.	\$XX million	\$XX million	XX%
Italy	\$XX million	\$XX million	XX%
Canada	\$XX million	\$XX million	XX%
Spain	\$XX million	\$XX million	XX%
Australia	\$XX million	\$XX million	XX%
Brazil	\$XX million	\$XX million	XX%
India	\$XX million	\$XX million	XX%
Russia	\$XX million	\$XX million	XX%
Netherlands	\$XX million	\$XX million	XX%
Switzerland	\$XX million	\$XX million	XX%
Poland	\$XX million	\$XX million	XX%
Turkey	\$XX million	\$XX million	XX%
Mexico	\$XX million	\$XX million	XX%
Sweden	\$XX million	\$XX million	XX%
Belgium	\$XX million	\$XX million	XX%
Austria	\$XX million	\$XX million	XX%
Saudi Arabia	\$XX million	\$XX million	XX%
South Korea	\$XX million	\$XX million	XX%

Segment	2024	2029	CAGR
Egypt	\$XX million	\$XX million	XX%
Romania	\$XX million	\$XX million	XX%
South Africa	\$XX million	\$XX million	XX%
Indonesia	\$XX million	\$XX million	XX%
Chile	\$XX million	\$XX million	XX%
UAE	\$XX million	\$XX million	XX%
Vietnam	\$XX million	\$XX million	XX%
Total Top 30 IVD Countries	\$XX million	\$XX million	XX%

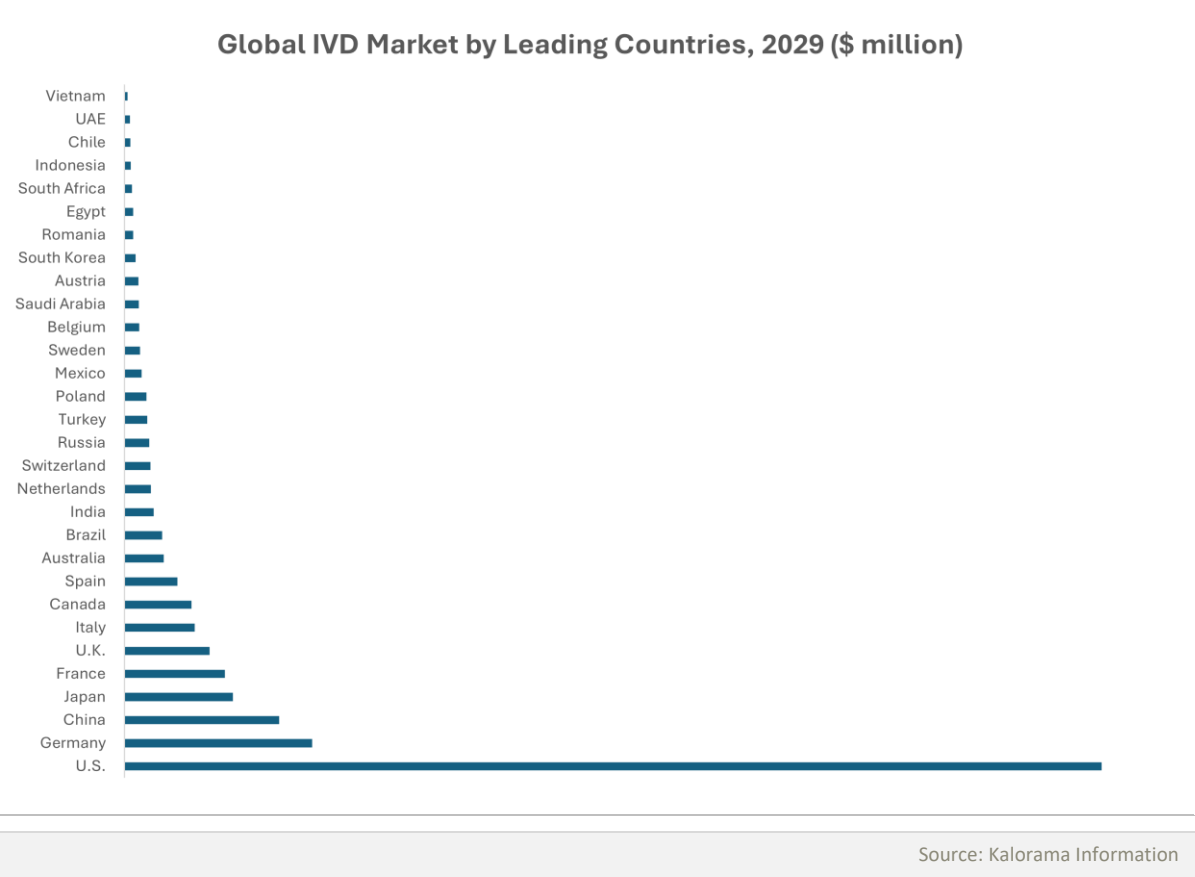
Source: Kalorama Information

SAMPLE Figure: Global IVD Market by Leading Countries, Estimated 2024 (\$ million)



Source: Kalorama Information

SAMPLE Figure: Global IVD Market by Leading Countries, Estimated 2029 (\$ million)



Canada

Canada IVD Market Overview

Demographics and healthcare spending fuel Canada's relatively large IVD market. The population of Canada will retain a slightly younger age distribution than its U.S. neighbor but will increase in line with U.S. trends. A moderately high birth rate and a comparatively low death rate will account for overall demographic changes. Due to the low death rate and increasing longevity, Canada's 65 years and older segment will expand much faster than the total population, increasing by 3.2 percent annually to 7.0 million. Growth in elderly age groups will intensify the country's healthcare cost burden. This trend will prompt the provincial health plans to impose tighter controls on the coverage and cost of medical services, including IVD procedures.

Growth opportunities for IVD procedures and products in the country benefit from a prosperous economy, an expanding and aging population, and high healthcare spending intensity.

The publicly funded Medicare universal health insurance program covers all Canadian residents for hospital care, physician consultations, mental health counseling, laboratory testing, and nursing home care. In addition, elderly and low-income residents are eligible for varying prescription drug benefits. Medicare is funded through federal and provincial income taxes. The administration and payment of benefits are delegated to the 10 provincial governments, each operating a separate plan that complies with general guidelines set by federal law. Most government funding (94%) comes from the provincial level.

Total IVD market revenues reached **\$XX billion** in 2024.

SAMPLE Table: Canada IVD Market by Segment, Estimated 2024-2029 (\$ million)

Segment	2024	2029	CAGR
Immunoassays – Micro	\$XX million	\$XX million	XX%
Immunoassays - Non-Micro	\$XX million	\$XX million	XX%
POC Glucose (all)	\$XX million	\$XX million	XX%
Other IVD	\$XX million	\$XX million	XX%
General Chemistries	\$XX million	\$XX million	XX%
Histology	\$XX million	\$XX million	XX%
Other POC	\$XX million	\$XX million	XX%
Hematology	\$XX million	\$XX million	XX%
Molecular - Other ¹	\$XX million	\$XX million	XX%
Microbiology – ID/AST	\$XX million	\$XX million	XX%
POC Infectious Disease (all)	\$XX million	\$XX million	XX%
POC Fecal Occult	\$XX million	\$XX million	XX%
Molecular Respiratory	\$XX million	\$XX million	XX%
Critical Care (core lab)	\$XX million	\$XX million	XX%
Coagulation PT/INR	\$XX million	\$XX million	XX%
Molecular HIV & Hepatitis	\$XX million	\$XX million	XX%
Molecular Bloodstream/HAI	\$XX million	\$XX million	XX%
POC Critical Care	\$XX million	\$XX million	XX%
Blood Bank Screening - Immunos	\$XX million	\$XX million	XX%
POC Pregnancy & Fertility	\$XX million	\$XX million	XX%
Total Canada IVD Market	\$XX million	\$XX million	XX%

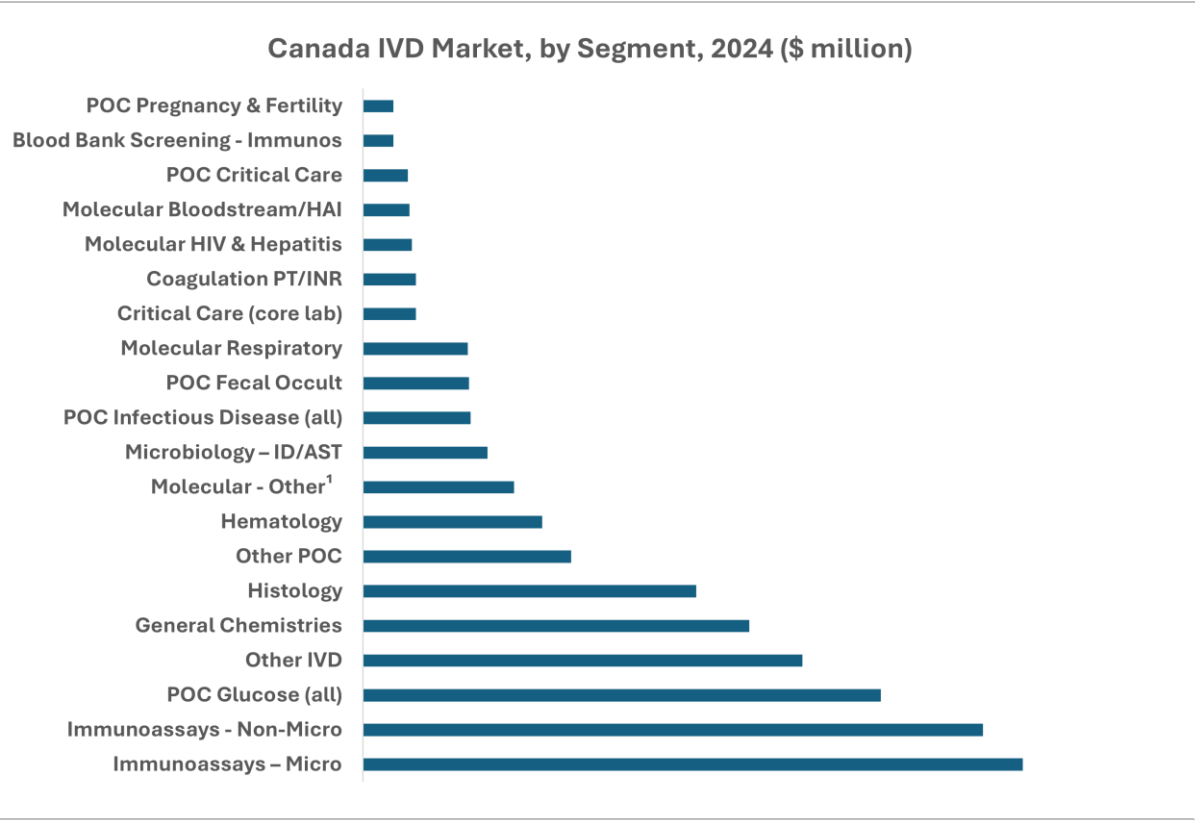
Note: Updated March 2025

¹blood screening, STDs, and other microbiology

Source: Kalorama Information

Canada

SAMPLE Figure: Canada IVD Market by Segment, Estimated 2024 (\$ million)

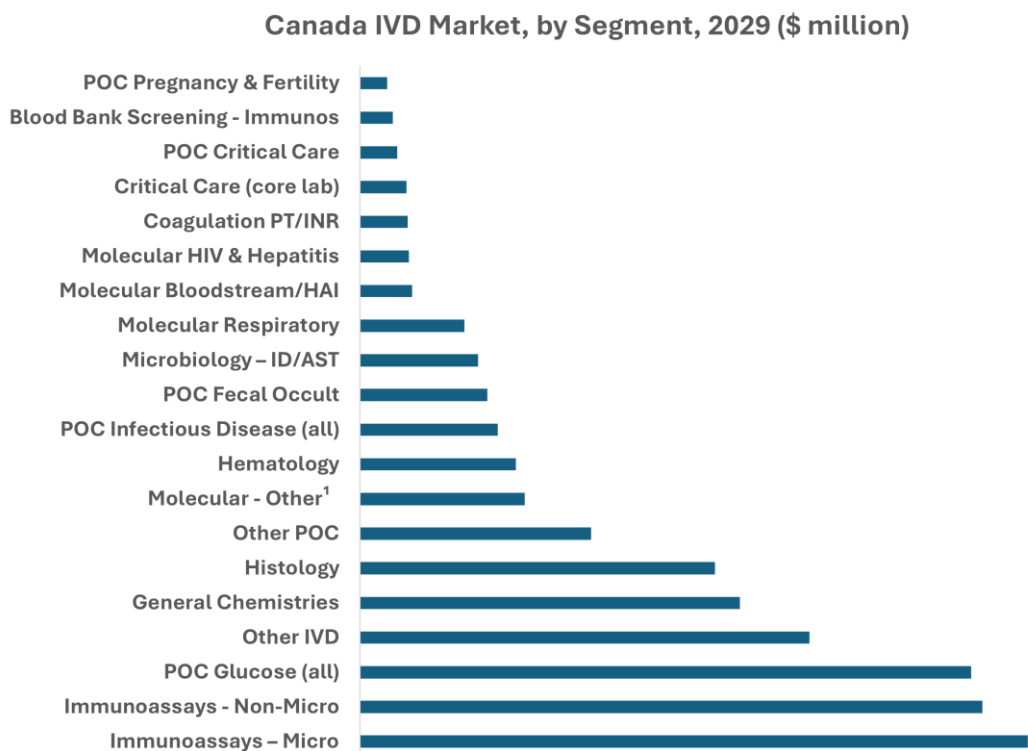


Note: Canada IVD Market (\$ million) - \$XX million

Note: ¹blood screening, STDs, and other microbiology

Source: Kalorama Information

SAMPLE Figure: Canada IVD Market by Segment, Estimated 2029 (\$ million)



Note: Canada IVD Market (\$ million) - \$XX million

Note: ¹blood screening, STDs, and other microbiology

Source: Kalorama Information

IVD News in Canada

Avitia, an AI company involved in developing solutions to identify cancer mutations, has launched its platform for advanced molecular testing directly on-site. This technology will provide physicians with insights into the cancer type, enabling them to begin treating patients more quickly.

"Avitia believes that all patients deserve access to advanced, cost-effective testing, regardless of geographic or economic constraints," said Avitia CEO and Partner of PacBridge James Lumsdaine. "Avitia will build on technology originally developed by Imagia Canexia Health, including an AI platform developed in Quebec in collaboration with Mila, the Quebec Artificial Intelligence Institute, to continue to deliver access to advanced cancer care to patients globally."

MedMira received a Canadian patent for its new quantitative test system, the Rapid Vertical Flows Technology (RVF), which is based on diagnostic tests.

"All our rapid tests are based on MedMira's patented RVF Technology® and provide an immediate quality Yes or No answer(s). Our speed in addition to our unique control line, allow for the fastest and high quality answer(s) at a real Point-of-Care setting. While the use of rapid tests have significantly increased over the last years, rapid tests are the first step by providing qualitative result(s). MedMira's vision is to expand this further by adding a unique value with its MIROQ™ system. The Company's RVF Technology® together with the MIROQ™ technology allows health care providers to receive an immediate diagnosis with both qualitative AND quantitative results." said Hermes Chan, CEO of MedMira Inc. "The synergies of both systems provide the highest quality answers within in minutes and at the most economical costs for health care providers. This combination allows for a truly Point-of-Care situation and enables for immediate treatment of patients. Our future vision has already become reality with MIROQ™."

Augurex announced that it has obtained UK Conformity Assessed (UKCA) Authorization for its JointStat assay, which detects the protein biomarker 14-3-3eta in blood. This biomarker is used to diagnose rheumatoid arthritis in blood samples.

"This UKCA marking is an important step in expanding global access to JointStat, providing a path for patients and clinicians in the UK to access a valuable tool to support the diagnosis and management of rheumatoid arthritis," Neil Klompas, CEO of Augurex, said in a statement."
