149 Grosvenor Road, London, SW1V 3JY, UK

Tel: +44 (0) 630 0300
Fax: +44 (0) 630 8202
e-Mail: elzbieta.franklyn@hbs-consulting.com

Business Insights:

An Evaluation of Product Usage for Molecular Testing within Infectious Diseases

Author: Dr. Martin Pfister – Senior Consultant

The new report by HBS Consulting examines the **reality** of **221 laboratories and hospitals** in **11 European countries** and provides you with following information:

Molecular Tests

- Description of laboratory landscape per country

Market Quantification

- the number of performed molecular tests for 42 pathogens per country
- products/manufacturers per test and country
- market growth per disease and country

Market Qualification:

- What criteria influence purchase decisions
- Who is responsible for purchase decisions
- Purchase patterns
- Budget resources
- Financing methods
- The regulatory issues per country (legislation, reimbursement)
- The consequences of the implementation of the IVD Code

Interview Split

Country	Private Laboratories	Public Laboratories	Total
G	13	19	**32**
UK	7	26	**33**
F	1	30	**31**
I	4	24	**28**
Es	15	16	**31**
No	1	6	**7**
DK		12	**12**
Se		8	**8**
Fi	2	9	**11**
Be		13	**13**
Ch	6	9	**15**
Total	**49**	**172**	**221**

Product Value Proposition

The study will allow the owner of the information to:

- **Assess current market realities** in terms of currently performed tests / Used technologies at an unparalleled level of segmentation
- **Get detailed knowledge on suppliers** of molecular test kits / equipment, (by segmentation criteria)
- Reflect the current situation not only at a specific point in time, but **monitor trends** over a period of time (both in terms of market participants as well as system types)
- **Model market and own sales forecasts** on system types **based on investment plans of customers**
- **Reflect the expected behaviour of buyers**, not just the expectations of sellers; but by the motivations of buyers.
- **Model market forecasts on associated product lines** (e.g. PCR Cycler, NAT related devices) based on procedure data
- Make decisions regarding the market entry/marketing strategy

Respondents have been chosen randomly in order to guarantee that the respondents reflect the real market situation. However the definition of the project required the focus on such institutions that perform molecular testing particularly.

Segmentation by Indication

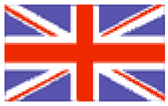
- STD
  - Chlamydia trachomatis
  - Neisseria gonorrhoeae
  - HIV
  - HCV
- Mycobacteria
  - Mycobacterium tuberculosis
  - Mycobacterium avium
- Atypical Pneumoniae
  - Bordetella sp.
  - Legionella pneumophilia
  - Chlamydia sp.
  - Mycoplasma pneumoniae
- CMV
  - quantitative
  - qualitative
- Virale Meningitis/Encephalitis
  - HSV 1,2
  - Enterovirus
  - West Nile Virus
- Respiratory Virus
  - SARS
  - Adenovirus
  - Influenza A
  - Influenza A and B
  - RSV
  - Parainfluenza
- HPV
- Chronic Meningitis
  - Blastomyces
  - Histoplasma
  - Cryptococcus
  - Coccidioides
  - TB
- Bacterial Meningitis
  - Neisseria meningitidis
  - Haemophilus
  - Pneumokokken
  - Listeria
  - Enterobacteriacea/Nonfermentors
- Tick Born Encephalitis
  - RMSF
  - Babesia
  - Ehrlichia
  - Anaplasma
  - Borrelia
- MRSA
- Fungi

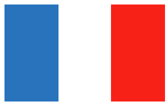
Segmentation by Technology

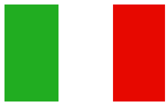
- commercial available tests with amplification (methods: PCR, LCR, SDA)
- Commercial tests without amplification (method: DNA probes)
- Others**:** EIA (enzyme linked tests), Antibody/Antigen-complex tests, serology, microscopy, strip tests

Segmentation by Country

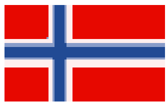
Germany

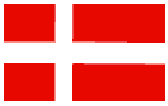

UK


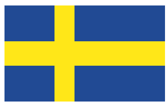
France


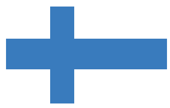
Italy


Spain


Norway


Denmark


Sweden


Finland


Belgium

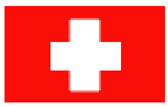

Switzerland


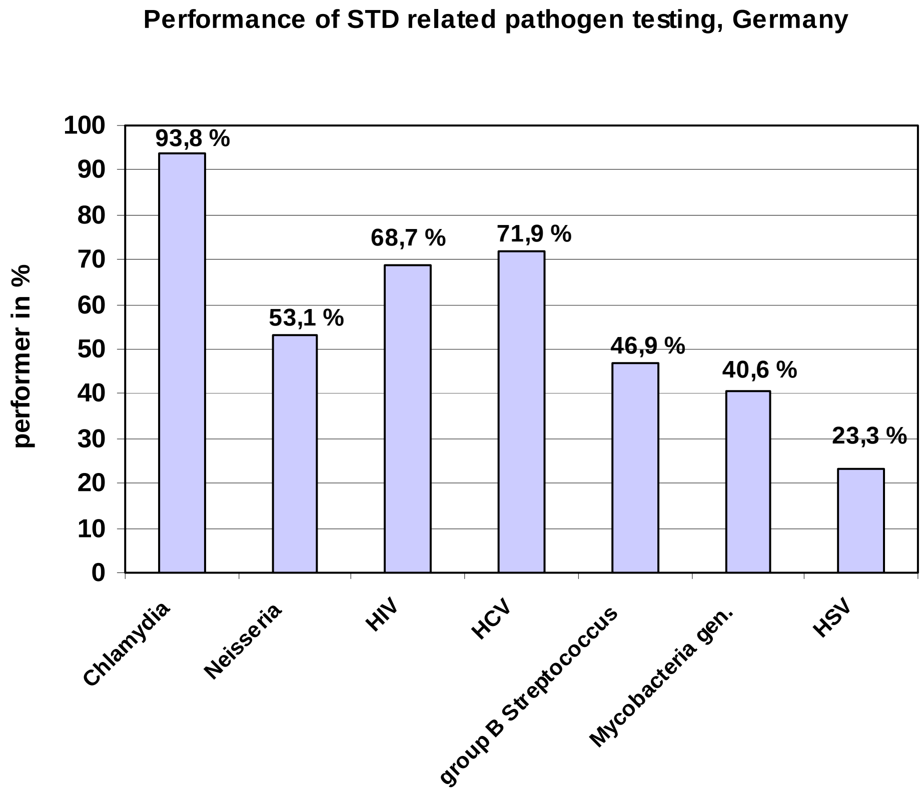
Table of Content (Germany)

Sample Information

2.1 Sexual Transmitted Diseases (STD)

HBS Consulting has asked respondents to provide numbers of performed tests per month and pathogen. We have subsumed groups with test ranges that are narrow enough for market estimations rather than detailed numbers.

The following table shows how many % of the laboratories test for the given STD-related pathogens.



Source: HBS Consulting

The following table provides an overview about the number of samples per month, performed in the interviewed laboratories within STD. The grey column indicates the percentage of laboratories (total n=32) that run tests for the respective pathogens.

Pathogen	% performer total	Samples per month (% of laboratories, n =32)				
		0 tests	<100	<300	<500	<1000
Chlamydia	93,7	6,3	50,0	37,5	3,1	3,1
Neisseria	53,1	46,9	40,6	9,4	3,1	0,0
HIV	68,7	31,3	34,4	15,6	6,3	12,5
HCV	71,9	28,1	34,4	21,9	6,3	9,4
group B Streptococcus	46,9	53,1	21,9	12,5	6,3	6,3
Mycobacteria gen.	40,6	59,4	31,3	6,3	0,0	3,1
HSV	23,3	78,1	18,8	3,1	0,0	0,0

Source: HBS Consulting

Chlamydia Trachomatis

Performer: 93,8% (30/32)

For Germany, projections estimate about 100.000 new infections per year countrywide. Up to 90% of the infections are without symptom and therefore not diagnosed (source: health authorities Cologne).

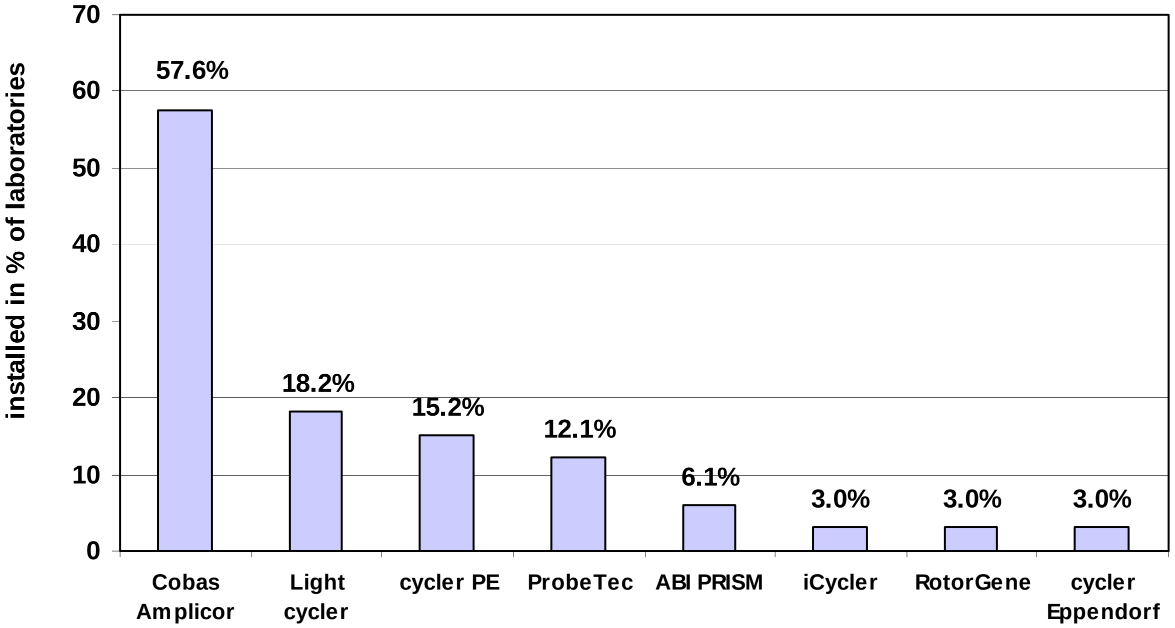
The following table shows the used technique (in % of laboratories) among the laboratories that have been interviewed.

performer in %	Used technique*
53,3	PCR
13,3	culture
10,0	HCA
6,7	SDA
6,7	EIA/ELISA
10,0	other

**multiple answers (more than one technique used) possible*

(...)

Installation of devices for amplification, Germany



Source HBS Consulting

An overview of the manufacturers whose devices and/or tests are used to analyze for Chlamydia is given in the next table:

performer in %	manufacturer
54,5	
9,1	
13,6	
22,8	

Other manufacturers comprise of:

• bioMérieux	Hybridowell™
• Corbett Research	RotorGene
• Biometra	cycler
• Applied Biosystems	ABI PRISM 7700
• Biolab	ELISA

(...)

Market Sizes

For the calculation HBS Consulting used the sample sizes per month that laboratories provided on the question "how many tests do you run per month" and the total number of laboratories that potentially perform molecular tests for the pathogens. We calculated with a total of 334 laboratories that are involved in microbiology testing.

Private laboratories are included. From a total of 464, we estimated on the basis of the contacts made for this survey a share of 58,8% (273 laboratories) that use molecular diagnostic techniques.

We provide a calculation that rests upon maximum test numbers possible (for instance "*up to 100 tests per month*" was included in the calculations as "100 tests per month". Thus, the market volumes provided here are the absolute maximum estimation that could be generated by the laboratories involved in testing for infectious diseases. The numbers provided in the tables below are calculated as follows:

The final number of laboratories that potentially perform the given number of tests per month or year has been calculated as follows:

Total number of laboratories (*607*)

⇓

share of laboratories that perform tests of the given pathogen, no matter which technique applied (*variable*)

⇓

share of laboratories that perform molecular testing (MT) in Germany, split based upon the contacts made during the survey (52,2*%)*

⇓

share of laboratories that perform tests for the given pathogen with MT respectively (*variable*)

The resulting number of laboratories that use molecular techniques for the selected pathogens has been multiplied with the following data, gathered during primary research:

- the average number of MT based tests (samples per month),
- the median number of MT based tests (samples per month).

In cases where mean and median sample sizes per month differed widely, we have weighted the calculation the way that it mirrors the split between laboratories that perform small sample numbers (usually up to ten tests per month), medium sample numbers (usually up to 200 tests per month) and numbers that are 500 tests/month and up.

All numbers have been cross checked with available secondary information (by Health Institutions, disease centres, disease control systems etc) and our experience in these markets.

We have refrained from calculating market volumes based on the number of tests and costs given per tests. The cost for selected test provided by the interviewed end users are too heterogeneous and we think that it would be more valid for the reader to develop own calculations based on internal (price) data and our calculations rather than having the average averaging of all prices. As for Germany, end-users provided information on price per test, meaning that the numbers include the price for the kit and the price for labour, but we have no indication about the split.

All figures are calculated in "test numbers" and represent an estimation of the market volume for tests performed within the laboratory population interviewed and with the use of molecular techniques (MT) only.

STD

The following table shows key facts for the number of tests per month within the interviewed laboratory population using molecular techniques for selected STD related pathogens.

Our Sample	# of test/month **Average**	# of test/month **Median**	# of test/month **Min**	# of test/month **Max**
Chlamydia trachomatis	185,0	100	4	1.000
Neisseria gonorrhoeae*	81,7	65	4	200
HSV	50,5	46,5	5	100

**cave: data based on one MT performing laboratory*

Based on this test numbers per month and the total number of laboratories that we expect to use molecular techniques for these pathogens (as outlined above), we have calculated the following market volume (MT based test number per year):

Total Market	**# of laboratories using MT**	# of tests/month **Mean**	# of tests/month **Median**	# of tests/year **Mean**	# of tests/year **Median**
Chlamydia trachomatis	208				
Neisseria gonorrhoeae*	129				
HSV	59				

**cave: data based on one MT performing laboratory*

Prices and Order Information

Report Modules	Content	Price	Order
Full report	Evaluation of Product Usage for Molecular Tests within Infectious Diseases, Europe (G, UK, F, I, Es, No, Se, DK, Ch, Be, Fi)	9.945 €	
only big 5	Evaluation of Product Usage for Molecular Tests within Infectious Diseases, G & UK & F & I & Es	6.975 €	
Only Rest of Europe	Evaluation of Product Usage for Molecular Tests within Infectious Diseases (No, Se, DK, Fi, Be, Ch)	3.500 €	
per country big 5	Evaluation of Product Usage for Molecular Tests within Infectious Diseases, G or UK or F or I or Es	2.000 €	
per country	Evaluation of Product Usage for Molecular Tests within Infectious Diseases, No or Se or DK or Fi or Be or Ch	1.000 €	
Per disease / Topic		On request	

If you would like to order a module of the Market Study "Evaluation of Product Usage for Molecular tests within Infectious Diseases"

Please complete your details

Company ______________________ Your Name ______________________

Company Address ______________________ Job Title ______________________

Country ______________________ Department ______________________

Telephone ______________________ Fax ______________________

Signature: ______________________

Contact HBS Consulting

Elzbieta Franklyn
HBS Consulting
149 Grosvenor Road, London, SW1V 3JY, UK

☎: +44 (0) 207 630 0300
🖷: +44 (0) 207 630 0300
✉: elzbieta.franklyn@hbs-consulting.com

HBS Consulting

HBS Consulting - is a leading consulting firm that works in partnership with in-house Business Development and Marketing Teams exclusively within the medical device, biotechnology, diagnostic and pharmaceutical industries. Further information about HBS Consulting can be found on our website www.hbs-consulting.com.

Other available titles are:

- **Trends and Developments in the European Urinary Incontinence Treatments Market** – Published January 2003
- **Telehealth - A Keystone for Future Healthcare Delivery** - Published March 2003
- **Rigid Endoscopes – are you though enough to compete -** Published April 2003
- **Molecular Diagnostics - Revolution or Hype** (Europe) - Published May 2003
- **European Hospital Financing Reform** – Developments and Business Implications – Published May 2003
- **European Hospital Purchasing and Tender Practices** – Realisation and Reform – Published September 2003
- **Point of Care Testing** – A Market Opportunity Analysis for Point of Care Diagnostic in Selected European Countries, to be published in October 2003
- **European Market for Installed x-Ray units**, the future of European of Computer Radiography (CR) and Direct Radiography (DR), **European Market for RIS and PACS Solutions,** published in Mai 2004

Head Office: 149 Grosvenor Road, London, SW1V 3JY, UK, Tel: +44 (0)207 630 0300, Fax: +44 (0) 20 7630 8202
HBS Consulting GmbH: Thomasiusstr. 2, 04109 Leipzig, Germany, Tel: +49-341-215 45 0, Fax: +49-341 215 4521
HBS Consulting Inc: 100 N. LaSalle Street Suite 1104 Chicago IL 60602-3539, USA, Te: 1-312-377-3816, Fax: 1-312-377-8828
Houghton Bhatti Segurola Limited, Registered in England, No. 3923094 At 35 Sussex Street, London SW1V 4NR

