

# Molecular Diagnostics In Jordan

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## Outline:

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## Classical diagnostics:

- Enzyme activity
- Substrate/metabolite levels
- Cell morphology

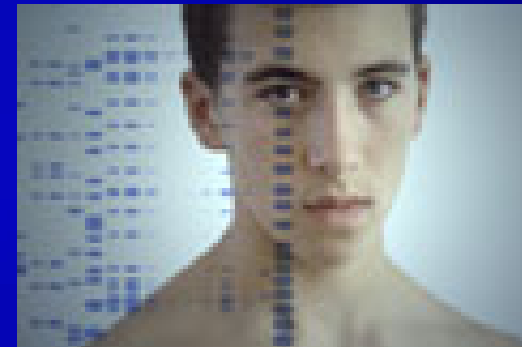
## Molecular diagnostics:

### Genomic/expression data

- DNA
- RNA
- Protein

## Advantages:

- Higher sensitivity
- Higher accuracy
- Shorter turnaround time
- Lower cost





## International market

### For IVD in General

(Hematology, Clinical chemistry, Microbiology, Pathology, Immunoassays, Mol Diagnostics)

- 60% of revenue generated by 7 major companies
- 100 other companies make up the rest

#### Main shares:

Roche  
Siemens  
Abbott  
Bayer  
BD  
Biomerieux

Source: Scientia analysis, 2007

## IVD market:

2005: \$32+ billion

2010: \$46+ billion

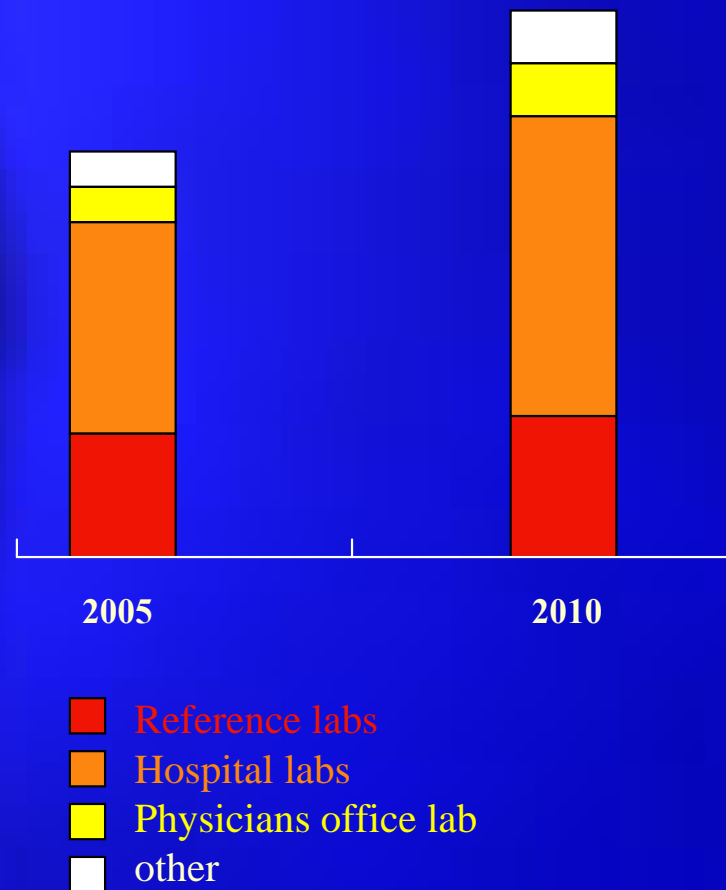
(Molecular Diagnostics: Fastest growing segment)

(more than double)



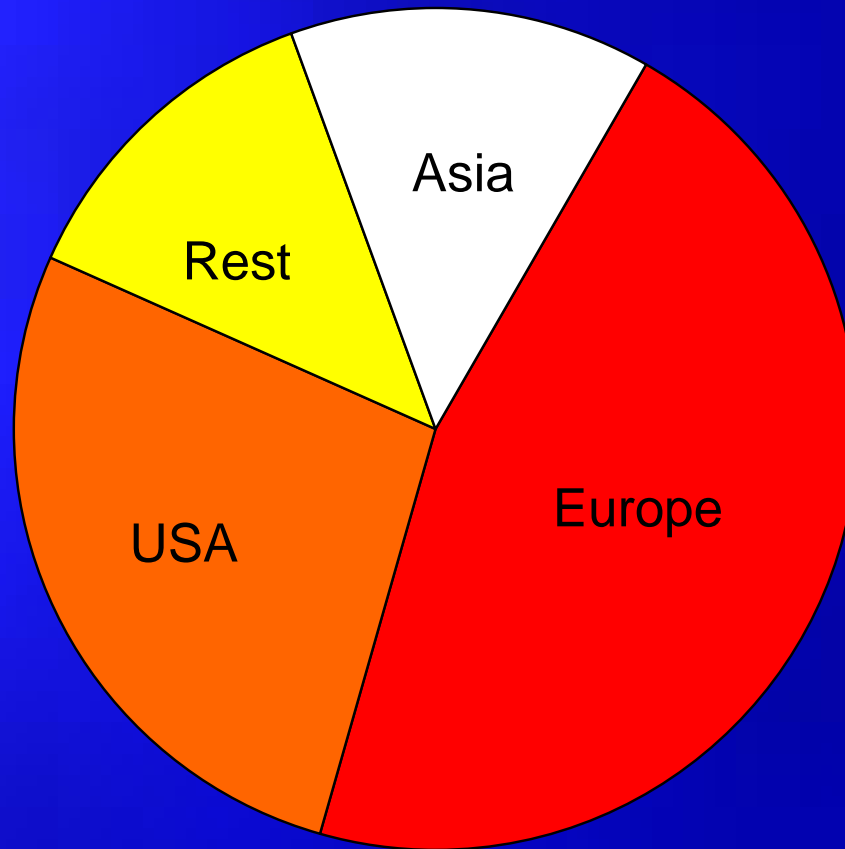
Source: Scientia analysis, 2007

## IVD market by consumer:



Source: Scientia analysis, 2007

## World Market by region

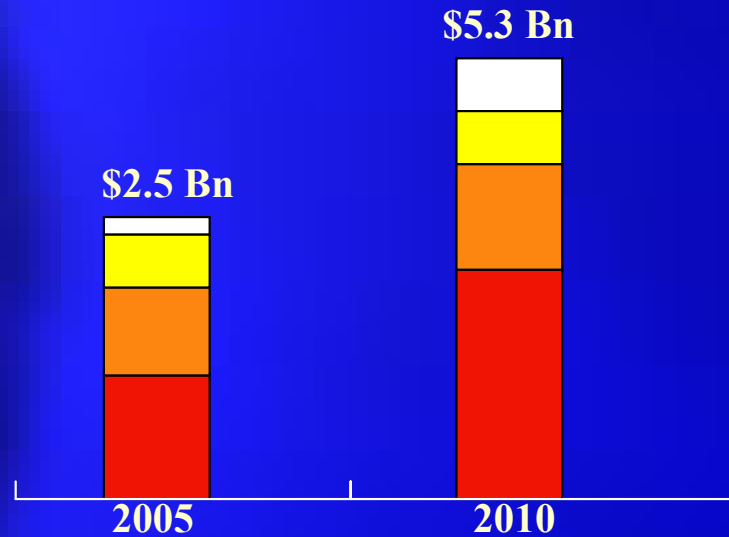


**China, India, Africa: examples of huge markets to be developed**

Source: Scientia analysis, 2007

## Molecular Diagnostics Market:

(Roche controls over 50% of the market)



- Infectious
- Blood screening
- Genetic
- Oncology

- Some segments in infectious will mature in 2012 due to patent expiration
- Significant growth in Oncology due to high value

Source: Scientia analysis, 2007



# Jordanian market

## Service Providers:

- 1- Public sector
- 2- Private hospitals
- 3- Private labs
- 4- University hospitals and research labs





## Public sector:

### **-Ministry of Health central labs:**

- Core lab. serving public hospitals in Amman and districts
- Well established in Molecular diagnosis of infectious disorders

### **-King Hussein Medical Center:**

- well equipped central labs “Princess Iman Center”
- Molecular diagnostics in several lab sections

### **-King Hussein Cancer Center:**

- main focus on molecular oncology



## Private hospitals:

- Many have or are in the process of establishing Molecular labs
- Strong interest in IVF and related molecular techniques
- Major molecular labs at:
  - Islami Hospital
  - Khalidi Hospital
  - Jordan Hospital
  - Specialty Hospital

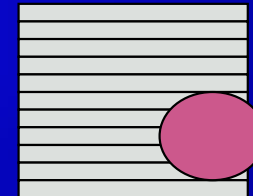
## Private labs:

### 1- Reference labs “chains”:

- MedLabs



- Consulting Medical Labs



2- “Medium” size labs

3- Referral labs



## University Hospitals and Research labs:

- Jordan University of Science and Technology (JUST)
  - King Abdullah II Hospital
  - Princess Haya Biotechnology Center
- University of Jordan (UJ)
  - Jordan Uni. Hospital
  - Molecular Biology Research Laboratory (MBRL)
  - Bleeding and Coagulation Lab
- Diabetes and Genetics Center – (UJ)



## Techniques:

### in use:

1. Probe Hybridization (FISH)
2. Blotting (Southern, Western, ...)
3. PCR (RT, Nested, Multiplex, Real time, ...)
3. RFLP
4. DNA Sequencing

### Not yet:

1. Microarrays
2. Proteomics



## Lists of Common requested tests:

### - Infectious disorders

- *Chlamydia*
- HBV
- HIV
- *Mycobacterium tuberculosis*
- HCV

### - Genetic disorders

- Thalassemia
- Sickle cell anemia
- MTHFR mutations
- Familial Mediterranean fever (FMF)
- Muscular dystrophy
- Factors II & V mutations

### - Cancer markers

- Leukemia & Lymphoma translocations  
(BCR-ABL, PML-RARA, Inversion 16, t(14;18),....other)

### - Identity and Forensic medicine

- HLA typing
- DNA fingerprinting



## Kits and reagents:

### - Commercial

**Licensed for diagnostic applications:**

- Roche
- Abbot/Celera

**For Research use only !!!  
(uncontrolled market)**

### - In-house kits

Scattered efforts !!!



## Our experience:



## The MBRL (molecular Biology Research Lab)

- **Based at Medical School / University of Jordan**
- **Activities:**
  - **Research**
  - **Training**
  - **Special PCR tests for hematological malignancies**
- **In-House developed protocols**
  - **thorough optimization**
  - **Extensive validation**
  - **Quality control (ISO certification)**



## Quality !

- **Internal quality control (QC officers !)**
- **External quality control (QCMD)**
- **Continuous personnel training**
- **Lab accreditation (ISO, CAP, ....)**
- **Local/regional accreditation bodies !**
- **Inter-lab cooperation**

## QCMD (Quality Control for Molecular Diagnostics)

[www.qcmd.org](http://www.qcmd.org)



- **EU organization providing QC programs for assessment of clinical laboratory tests.**
- **For clinical laboratories, blood banks and diagnostic test manufacturers**

# Jordanian Biotech and Mol Diagnostics:

## The ARAGEN Biotech story:

- Daughter company of JPM pharmaceuticals

- Established 1999:

- Collaboration through:

**Jordan Uni. FFF (Faculty For Factory) program**

- Products:

1. RAPID Diagnostics
2. Serological tests
3. In 2005: Molecular Diagnostics Line



## ARAGEN PCR kits:



- **Qualitative and Quantitative**
- **Extensive optimization, validation, and stability check**
- **High sensitivity and specificity (comparable to Int. market leaders)**
- **ISO and CE certification**
- **QCMD panels**
- **WHO Biological standard**
- **Cost advantage**
- **Technical support**

## **Examples of Mol. Diagnostic kits:**

### **Infectious Disorders:**

- 1. Human Immunodeficiency Virus (HIV)**
- 2. Hepatitis B Virus (HBV)**
- 3. Hepatitis C Virus (HCV)**

### **Cancer:**

- 1. BCR-ABL (Leukemia)**

### **Genetic disorders:**

- 1. Factor II**
- 2. Factor V**





## Future Recommendation:

- Encouraging inter-laboratory QC collaboration
- Participation in external QC programs (e.g. QCMD)
- Supporting the emerging local Mol. Diag. Biotechs
- Establishing an official regulatory body to monitor the sector
  - only certified kits (CE, FDA,...)
  - local QC programs
  - pricing
- Raising awareness among physicians
- Offering training workshop to qualify personnel