# Integration of Medical Laboratory Technology Management in National Medical Laboratory Regulatory Authority (RHL); A promising approach to respond appropriately to an essential need.

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# Role of IVD in Laboratory Diagnosis

- Physicians and providers of medical care to diagnosis and provide appropriate care need information produced by doing diagnostic laboratory tests.
- It is estimated that more than 70% of medical diagnoses are based on the results produced in medical laboratories.
- More than 60% of the information gathered in the patient's medical record is result of these experiments.
- Correct and appropriate diagnosis depends on the quality of laboratory services: In Vitro Diagnostics.

# Elements of IVD Regulatory Activities

- Registration
  - Manufacturing or Supplying Firm
    - Legal issues
    - Qualified Person
    - Certificates (e.g. ISO13485)
  - Products
    - Technical Dossier
    - Laboratory Examination
    - GMP inspection
- Post Market Surveillance
    - Complaint management and Recalls
    - Spot Testing
    - Proficiency Testing Results


The global IVD market was valued at $44 billion in the year 2011, growing at a CAGR of 7.8% from 2011 to 2016.

U.S. represented the biggest market for the IVD: 47% of the total IVD market in the year 2011.

The European region: 31% of the global IVD market with Germany accounting for the largest share of 23.24% followed France (16.89%) and Italy (16.41%) of the total IVD market.

The Asian region is expected to be ruled by the emerging economies such as China and India, show the highest CAGR by the year 2016.

# Growth Drivers of the IVD Market

- The major factors driving the growth of the IVD market is
  - Increased patient awareness, patient self testing
  - Increasing baby booming population across the globe.
  - Advancement in the technology bringing more of automated tests is also one of the major drivers for the growth of IVD market.
- Other major drivers for the growth of the IVD industry is
  - rise in the number of diseases like respiratory infections, hospital acquired infections, and sexually transmitted diseases.
  - Similarly rise in the chronic diseases such as diabetes, hypertension, cardiovascular diseases, and cancer are driving the overall IVD market
- Molecular diagnostics is the largest growing segment of the global IVD market with a highest CAGR for year 2011 to 2016.

# Hampering the Growth of IVD Industry

- Major financial crisis and thus having deep cuts on the healthcare budgets with limited reimbursements
- Budget constraints causing and unfavorable reimbursement scenario

# Important Events: Iran

- Economical ups and downs
- Managed Test Utilization
  - Family Physician Program
  - Clinical Guidelines

  *"It is time to focus on reducing inappropriate test ordering!"*
- Laboratory Technology Progress( Medium to high throughput Testing): Out-Sourcing
- Medical Laboratory Tariff

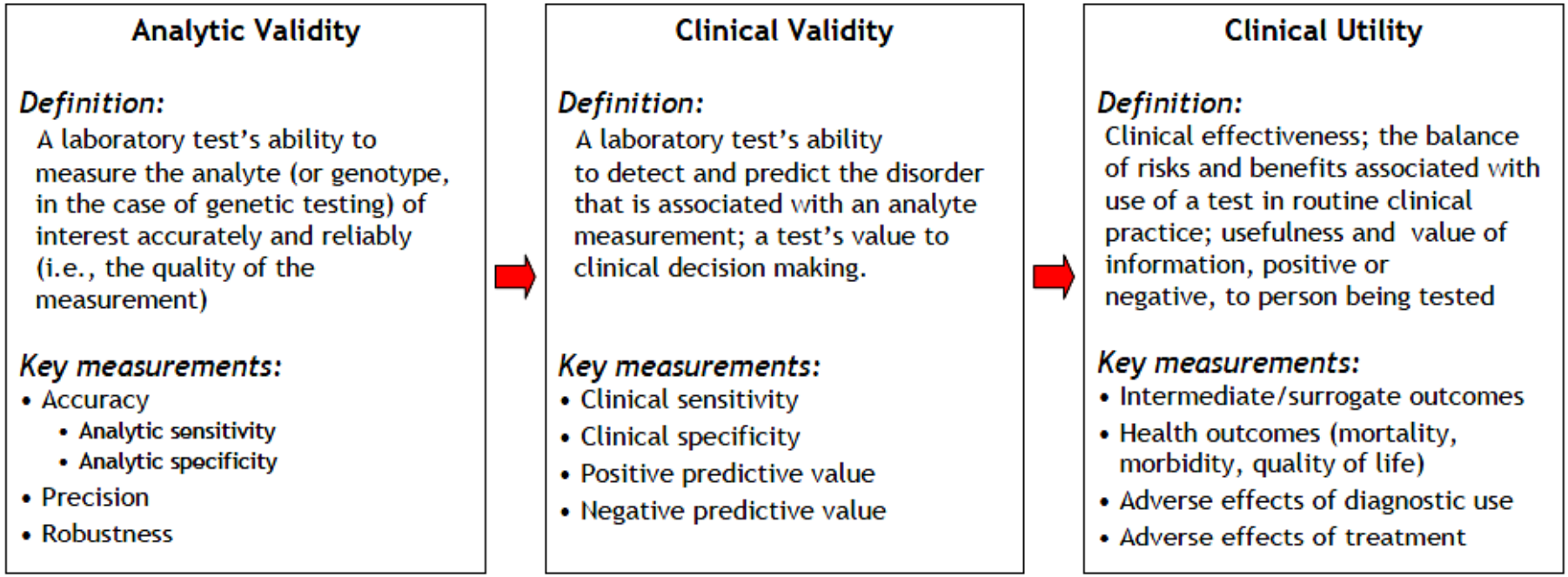
# Medical Laboratory

# IVD growth

- Clinical laboratory/Pathology
- Anatomical Pathology
- Molecular Diagnostic

| | آمار نسخ آزمایشگاهی ۶ ماهه نخست سال۹۱ | آمار نسخ آزمایشگاهی ۶ ماهه نخست سال۹۰ | | |
|---|---|---|---|---|
| Ratio 91/90 | تعداد درخواستی | | عنوان خدمت | کد خدمت |
| | | | | |
| 2.12 | 5,014 | 2,361 | بتا تالاسمی (مرحله اول تعیین نوع موتاسیون ) | 0000000001 |
| 0.50 | 1,102 | 2,186 | بتا تالاسمي ( مرحله دوم تعيين وضعيت نهائي جنين ) | 0000000002 |
| 3.13 | 419 | 134 | اترفي عضلاني اسپينال ((SMAتايپ ۱و۲ (مرحله اول تعيين نوع موتاسيون ) | 0000000003 |
| 2.37 | 426 | 180 | اترفي عضلاني اسپينال ((SMAتايپ ۱و۲ ( مرحله دوم تعيين وضعيت نهائي جنين ) | 0000000004 |
| 103.80 | 519 | 5 | آنمي داسي شكل ( Sickle cell anemiaمرحله اول تعيين نوع موتاسيون ) | 0000000005 |
| 6.24 | 587 | 94 | آنمي داسي شكل ( Sickle cell anemiaمرحله دوم تعيين وضعيت نهائي جنين ) | 0000000006 |
| 11.21 | 1,580 | 141 | بيماريهاي ناشي از تكرارها ( (xشكننده، هانتينگون ميوتونيک ديسترفي (مرحله اول تعيين نوع موتاسيون ) | 0000000007 |
| 3.02 | 501 | 166 | بيماريهاي ناشي از تكرارها ( (xشكننده، هانتينگون ميوتونيک ديسترفي ( مرحله دوم تعيين وضعيت نهائي جنين) | 0000000008 |
| 7.06 | 381 | 54 | نقصهاي انعقادي(هموفيلي (A,Bمرحله اول تعيين نوع موتاسيون | 0000000009 |
| 2.60 | 91 | 35 | نقصهاي انعقادي(هموفيلي (A,Bمرحله دوم تعيين جنسيت | 0000000010 |
| 0.40 | 65 | 161 | نقصهاي انعقادي(هموفيلي (A,Bمرحله سوم تعيين وضعيت نهائي جنين | 0000000011 |
| 2.09 | 1,436 | 687 | بيماريهايي كه با روش حذف ژني قابل بررسي هستند مثل دوشن، بيكر، تالاسمي آلفا مرحله اول تعيين نوع موتاسيون | 0000000012 |
| 2.93 | 41 | 14 | بيماريهايي كه با روش حذف ژني قابل بررسي هستند مثل دوشن، بيكر، تالاسمي آلفا مرحله دوم تعيين جنسيت | 0000000013 |
| 9.00 | 126 | 14 | بيماريهايي كه با روش حذف ژني قابل بررسي هستند مثل دوشن، بيكر، تالاسمي آلفا مرحله سوم تعيين وضعيت نهائي جنين | 0000000014 |

# Chain of inquiry for valuation of laboratory tests




**The Value of Laboratory Screening and Diagnostic Tests for Prevention and Health Care Improvement**
*Prepared for:*
**American Clinical Laboratory Association and**
**Advanced Medical Technology Association (AdvaMed)**
*Prepared by:* **The Lewin Group, Inc., *September 2009***

# Economic outcomes

- Types of economic outcomes measurements:
  - Estimates of the economic value relative to investment and may include analyses such as cost per test, patient, treatment and episode of care
  - Estimates of the budget impact of a test on a provider, provider organization, health system
  - Estimates the tradeoff value between costs and benefits to health care, including cost-effectiveness, cost-utility, and cost-benefit analysis.

# IVD: Recognized Stockholders

- Users
- clinical laboratory associations, medical associations, hospitals and healthcare professionals
- manufacturers and industry associations
- competent authorities
- notified bodies

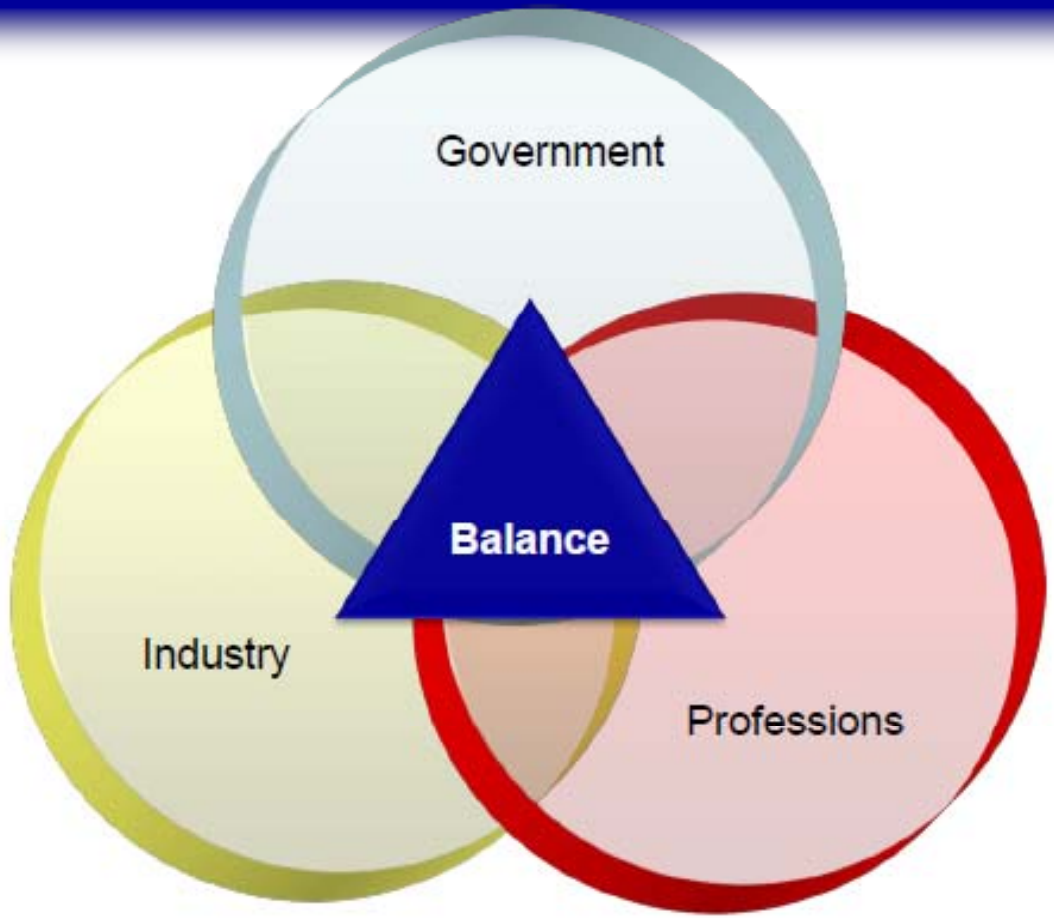
# IVD Working Group: Iran

- Scientific and Professional Associations
  - Iranian Pathology Association
  - Iranian Association Of Clinical Pathologist
  - Iranian Association of Clinical Laboratory Doctors
  - Iranian Genetics Association
- Association for IVD suppliers
- Medical Council Representative
- Food and Drug Organization, MOHME
- Reference Health Laboratory, MOHME
- Office of Medical Devices, MOHME
- Deputy Minister for Research and Technology, MOHME

# IVD Working Group Responsibilities

- Listing the qualified IVD
  - Quality
  - Continuous supply
  - Price
- Laboratory examination
- PMS
- Networking between stockholders.

# CLSI Consensus Process



EUROPEAN COMMISSION

Brussels, 26.9.2012
COM(2012) 541 final

2012/0267 (COD)

Proposal for a

**REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**on *in vitro* diagnostic medical devices**

(Text with EEA relevance)

{SWD(2012) 273}
{SWD(2012) 274}

# Proposed revision of the IVD Directive 97/89/EC

- **Classification and Conformity Assessment**
  - A (lowest risk), conformity assessment will be carried out under the sole responsibility of the manufacturer, except when they are intended for POCT, have a measuring function or are sold sterile.
  - B, C and D (highest risk), the involvement of a Notified Body is compulsory.
- **Qualified person**
  - at least one qualified person who possesses expert knowledge in the field of in vitro diagnostic medical devices.
- **Identification and traceability**
  - Unique Device Identification (UDI)
  - economic operators shall be able to identify who supplied and to whom they have supplied IVDs.
  - obligation for manufacturers of high-risk devices to make publicly available a summary of safety and performance with key elements of the supporting clinical data.

# Proposed revision of the IVD Directive 97/89/EC

- **Clinical evidence**
  - clinical evidence report proportionate to the risk class (summary of the scientific validity data, the analytical performance data, and clinical performance data.)
- **Vigilance and market surveillance**
  - An electronic system to collate and process reports by manufacturers on serious incidents, field safety corrective actions, field safety notices, and periodic summary reports by manufacturers.

- **Notified bodies**
  - right and duty to carry out unannounced factory inspections and to conduct physical or laboratory tests on devices.
  - rotation of the Notified Body's personnel involved in the assessment of IVDs at appropriate intervals to strike a reasonable balance between the knowledge and experience required to carry out thorough assessments.
- **Timetable**
  - The new Regulation will become applicable five years after its entry into force.
  - Proposal allows Notified Bodies to be designated and manufacturers to be assessed under the new regulation prior to the date of application. This may be one year after its entry into force.

# Thank you!

The 6th International and 11th National Congress on Quality Improvement of Clinical Laboratories 20-23 April, 2013