

# The IVD Industry

Innovation in a challenging environment

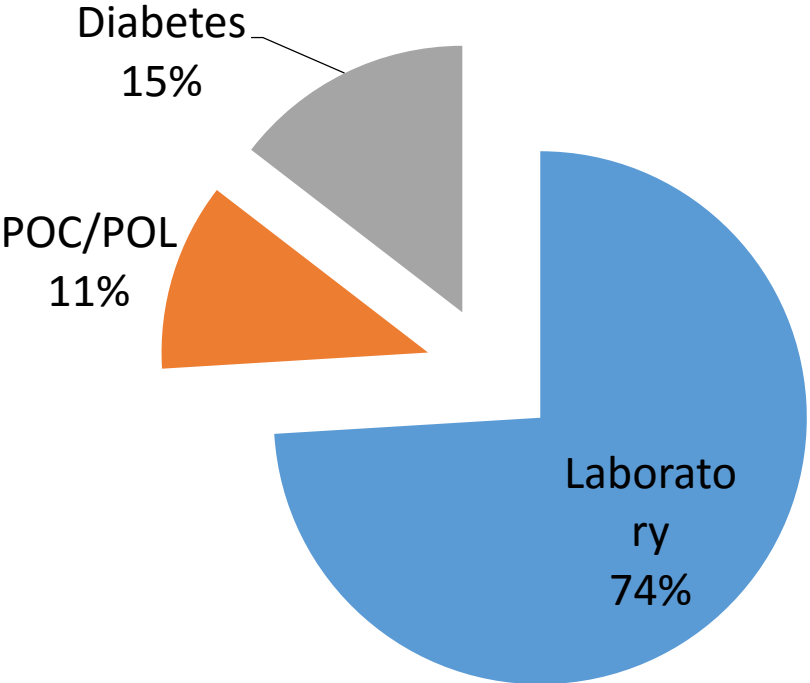
Serving Patients, Physicians and Payers

# Key Figures

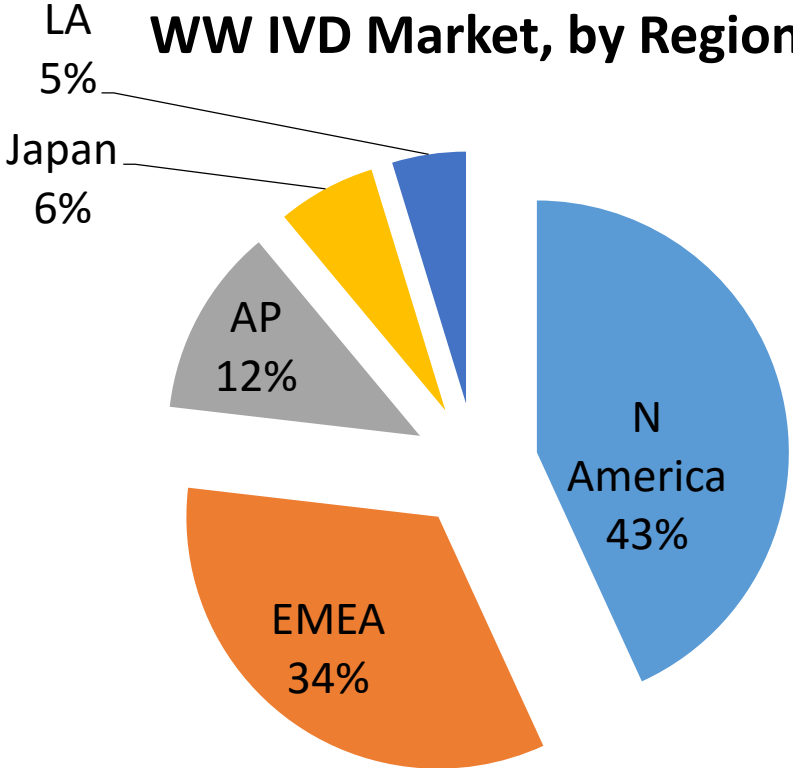
- **The total IVD market is worth 57Bn\$ in 2015; stable in value due to important currency variations (€/\$/Y)**
- **Glucose self-monitoring accounts for >8bn; POC for 6bn**
- **Emerging markets continue to grow faster than the rest of the World**
- **High revenue countries are rather trying to keep healthcare budgets under control, (price pressure)**

# The IVD WW Market

**WW IVD Market, by segment**



**WW IVD Market, by Region**

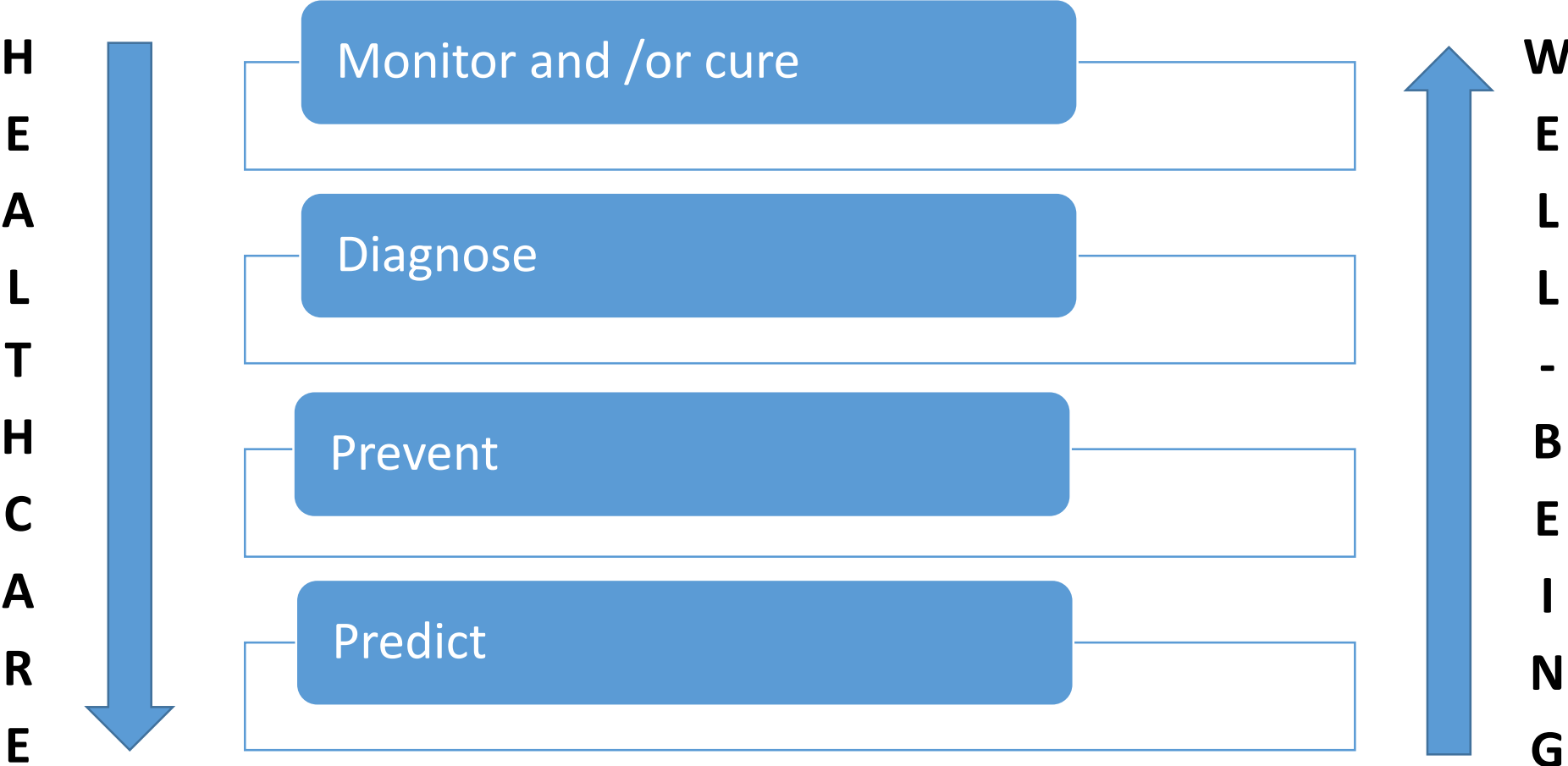


Source: Enterprise Analysis Corporation (EAC) April 2015

# Opportunities for IVD

- **Ageing population: monitoring chronic diseases**
- **Personalised medicine: cancer, cardiac**
- **Infectious diseases**
  - HAI
  - Control of antibiotic resistencies
  - Addressing emerging diseases alerts: SARS, Dengue, Chick, Ebola, Zika.....
- **And also ...**
  - Prevention: need for more predictive assays
- **Healthcare becomes part of a more global concept: well-being**

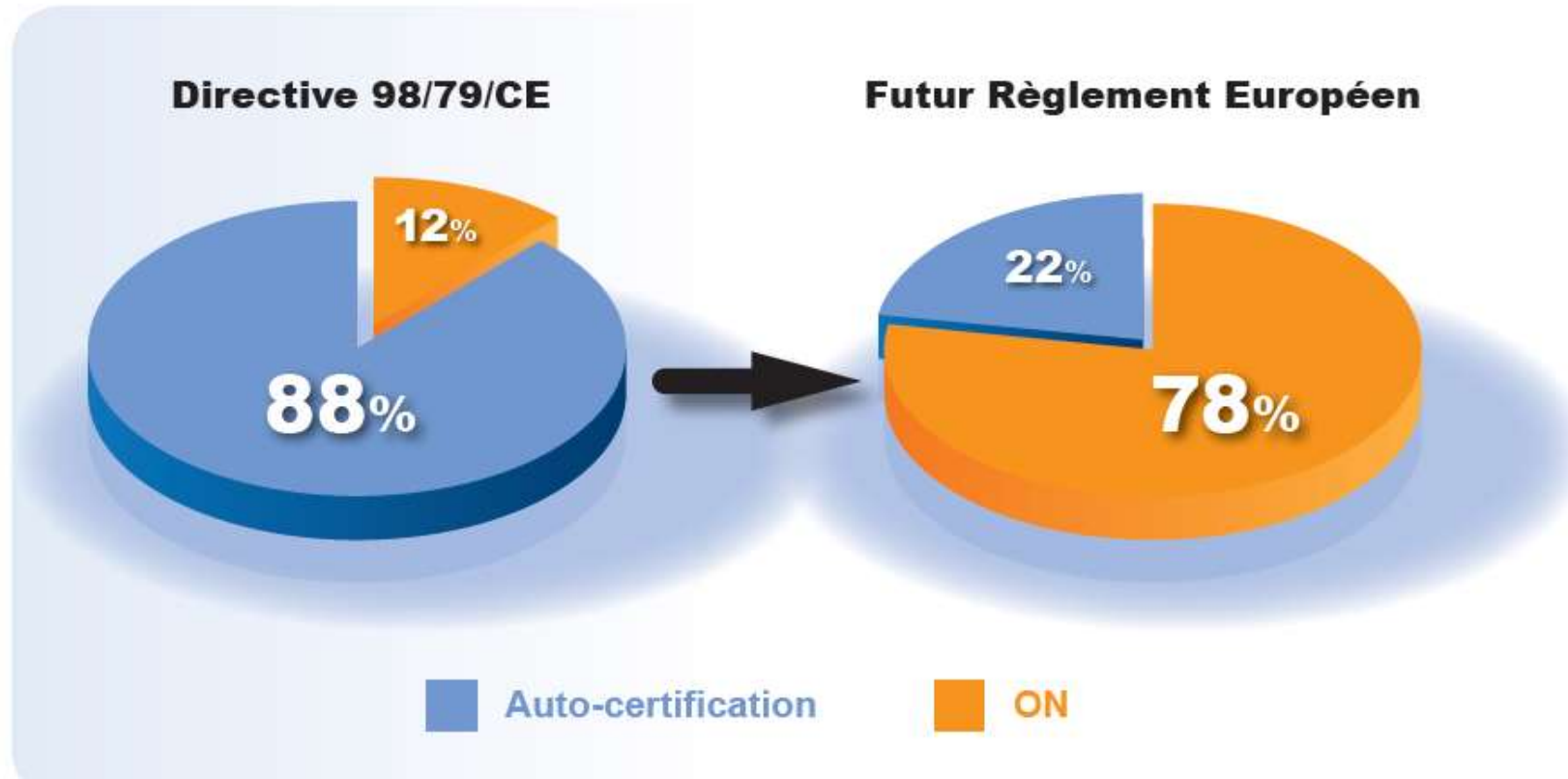
# A new vision for health



# A more regulated environment

- **Many national regulatory systems in place, with no mutual recognition**
  - Increased costs for access to market
  - Slowing down innovation
- **In Europe**
  - A new directive is under preparation for CE-IVD products
  - New constraints under discussion: HTA
- **Reinforced rules for Ethics and compliance (FCPA, Loi Bertrand, ...)**
  - Relationships with third parties (customers, consultants, distributors) are more formalised and restricted to comply with the rules

# EU: the future regulation



**78% of the IVD products will have to be reviewed by Notified Bodies**  
**The costs to comply with the new regulation are estimated at 2Bn€ by the Industry**

# Impact on the IVD Industry

- **Market access is going to be more difficult:**
  - Development time
  - Cost
  - Post market surveillance costs
  - Regulatory harmonization and/or mutual recognition could help
- **Innovation is not paid at the right price**
  - In most cases, no fast track for reimbursement
  - Adjacent cost savings are barely considered by Health authorities to provide the right level of price and reimbursement



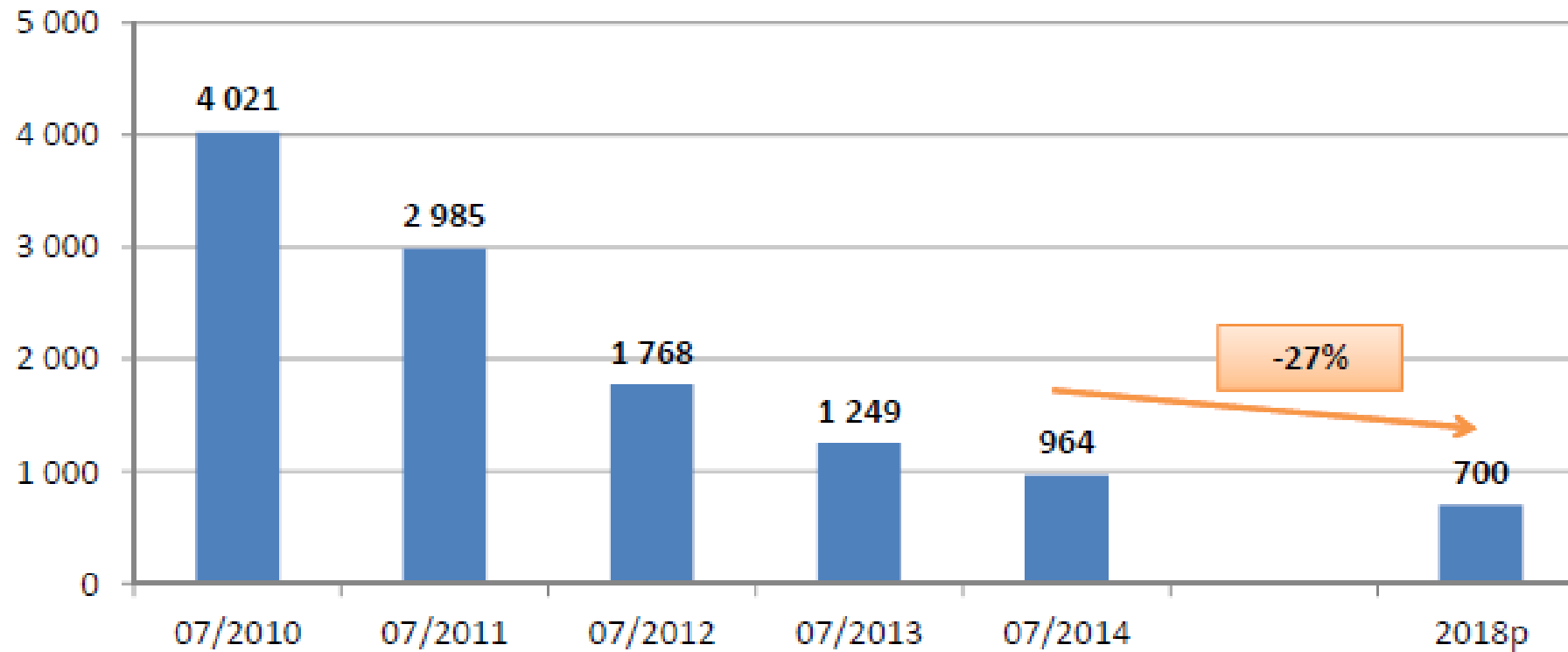
# Our Customers evolve

- **Pressure on reimbursement**
- **Improved quality requirements: Accreditation**
- **Rationalization of hospital structure**
- **Private labs Concentration → Full automation**
- **Data management and data transfer → traceability, cybersecurity**
- **Boarding new technologies and new markers**

**The IVD industry is affected by each point**

# Labs concentration in France

Nombre de laboratoires privés inscrits au CNQ



Source : ANSM

# The economic environment

- **Growing needs in a context of budget restrictions**
- **The IVD industry productivity is balanced by higher services provided at lower costs:**
  - **Reagent rentals**
  - **Hardware and software interface**
  - **Hot line support , remote maintenance**
  - **Service, metrology**

# Trends

- **Customers are looking for less complexity**
  - Total automation and IT interface
  - Improve cash flow management (inventory management)
- **From local to « global » agreements**
  - *Global suppliers*
  - Global supply agreements for international groups
- **From a « product supply » pattern to « providing a service »**
  - Cost per reportable result / cost per patient

# Consequences for the IVD industry

- **The market growth rate does not favour major investments for costs improvements and innovation (R&D investments >10% in average)**
- **The need to reach a more critical mass requires more concentration (M&A) → less competition**

# The Industry in 2015

- **The top 5 groups(\*):** **60% M.S.**
- **The top 10 :** **75%**
- **The top 20:** **84%**

(\* ) Taking into account the recent M&A announcement

# New growth areas in IVD

- **Labs concentration and chronic diseases monitoring create new needs for low volume remote testing and /or unitary tests:**
  - **Emergencies**
  - **POC /POL /NPT**
  - **Self testing**
- **Companion diagnostics required for expensive treatments**
- **Self testing can open a path to cost savings for Governments (not reimbursed)**

# New Trends in the landscape

- **Decentralization is boosted by the emergence of « e-health » and « connected health » concepts**
- **For lab testing as for remote testing, data safety and transmission are key. New operators are coming (GAFA)**
- **The IOT is coming with this revolution. This new segment raises interest, as it is not financed by the Healthcare systems**
- **This fits with the new decisions models shared with patients**
- **Connectivity providers may come with different economic models**



# What we shall do

- **Continue to support our customers in all market segments and adapt our offer to their new environment**
- **Sustain our investments in science and new technologies to bring cost effective solutions addressing the new needs in healthcare**
- **Pursue our lobbying to facilitate market access**
  - **Fast track procedure for innovation / Accurate reimbursement level**
  - **More harmonization in regulatory requirements and mutual recognition?**
- **Collaborate with the new players**

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THANK YOU