



UNIVERSITÄTS**medizin.**
MAINZ

**In vitro Diagnostics in the Health
Care System of Germany**

Karl J. Lackner

Laboratory Medicine in Germany

- Major goal is to analyze body fluids (e.g. blood, urine, CSF) to support clinical diagnostics and treatment.
- Analysis includes clinical chemistry, immunology, hematology, hemostaseology, molecular biology, drug monitoring, microbiology and virology.
- Solid tissues are usually not in the domain of laboratory medicine.
- **It is estimated that laboratory diagnostics affects ~70% of all clinical diagnoses.**

Laboratory Medicine in Germany

- The differences to other countries concern mainly organizational aspects rather than medical-scientific issues
 - Separation of hospitals and out-patient medicine
 - Professions involved in laboratory medicine
 - Increasing concentration and industrialization of diagnostic laboratories

Separation of Hospitals and Out-Patient Care

- All costs for hospitalized patients are reimbursed according to the German DRG system, which is based on “flat-rates“. This includes laboratory diagnostics.
- Out-patient care is reimbursed depending on the individual amount of medical services performed (with some restrictions).
- Until recently hospitals had only very limited access to out-patient care including laboratory tests for out-patients.

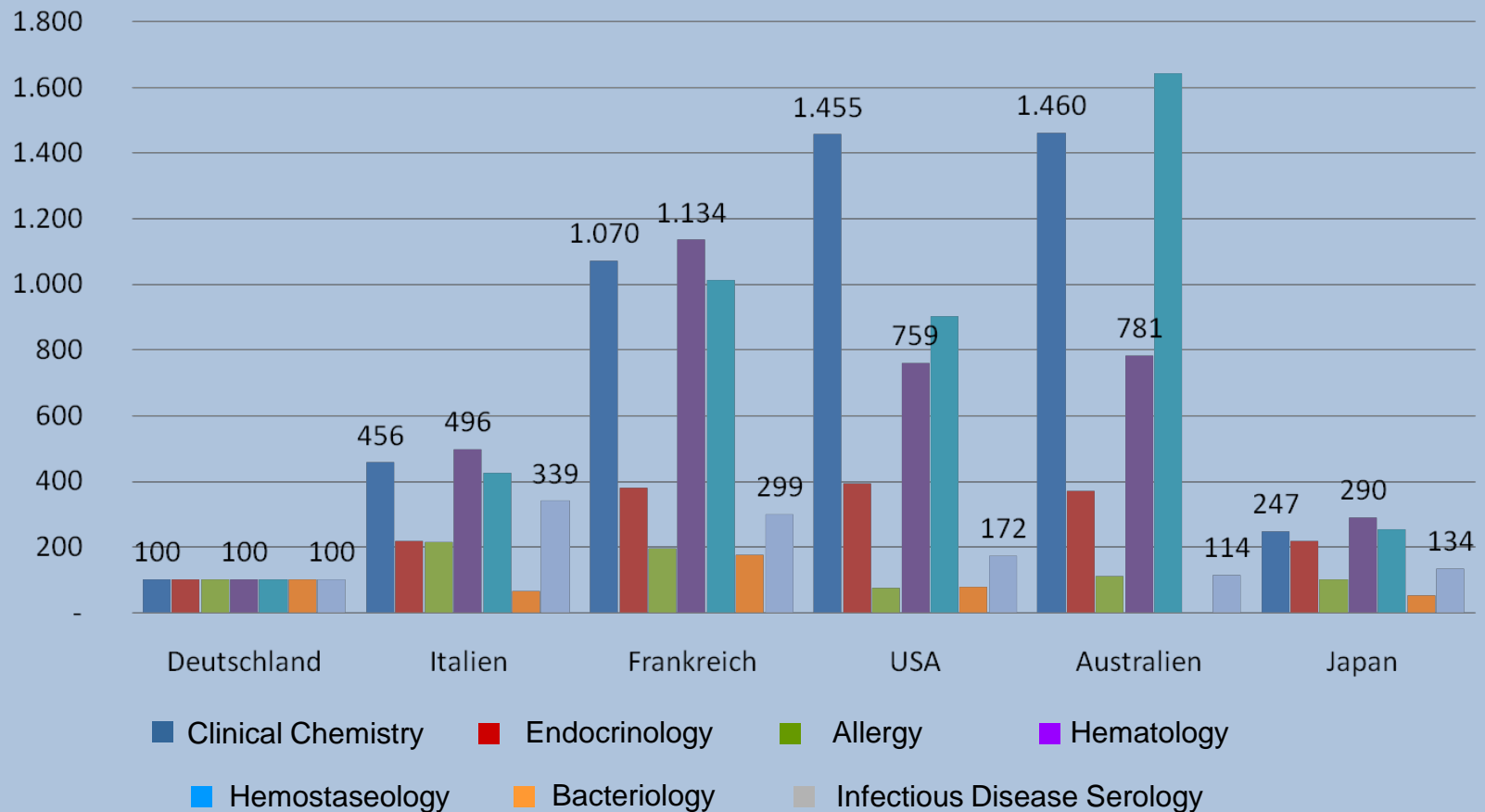
Professions Involved in Laboratory Medicine

- Physicians
 - Board certification in „Laboratory Medicine“, „Microbiology“, or „Transfusion Medicine“ - Others

- Natural Scientists (Chemists, Biochemists, Biologists)
 - Certification as Clinical Chemist (Germany, DGKL)

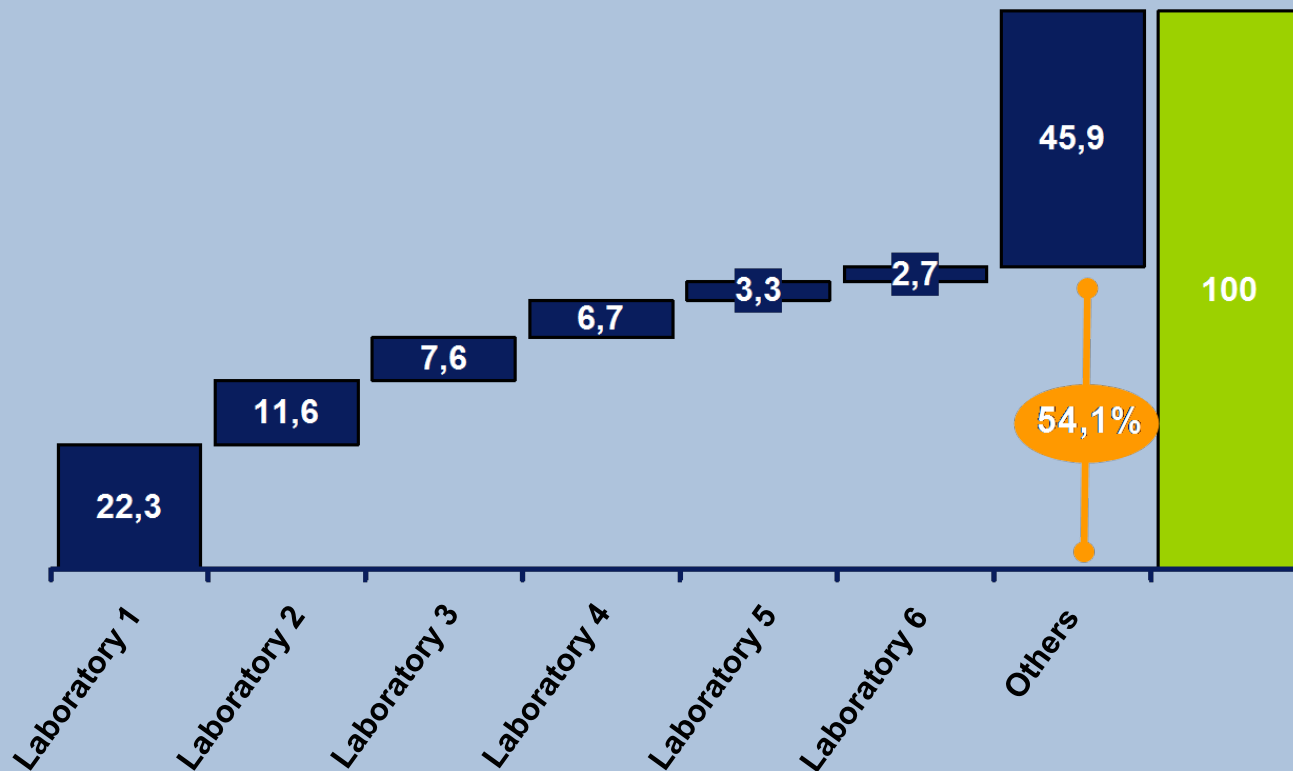
- Laboratory Technicians
 - State examination after 3 year curriculum

Comparison of Reimbursement



Source: BDL/Deloitte

Concentration of Diagnostic Laboratories

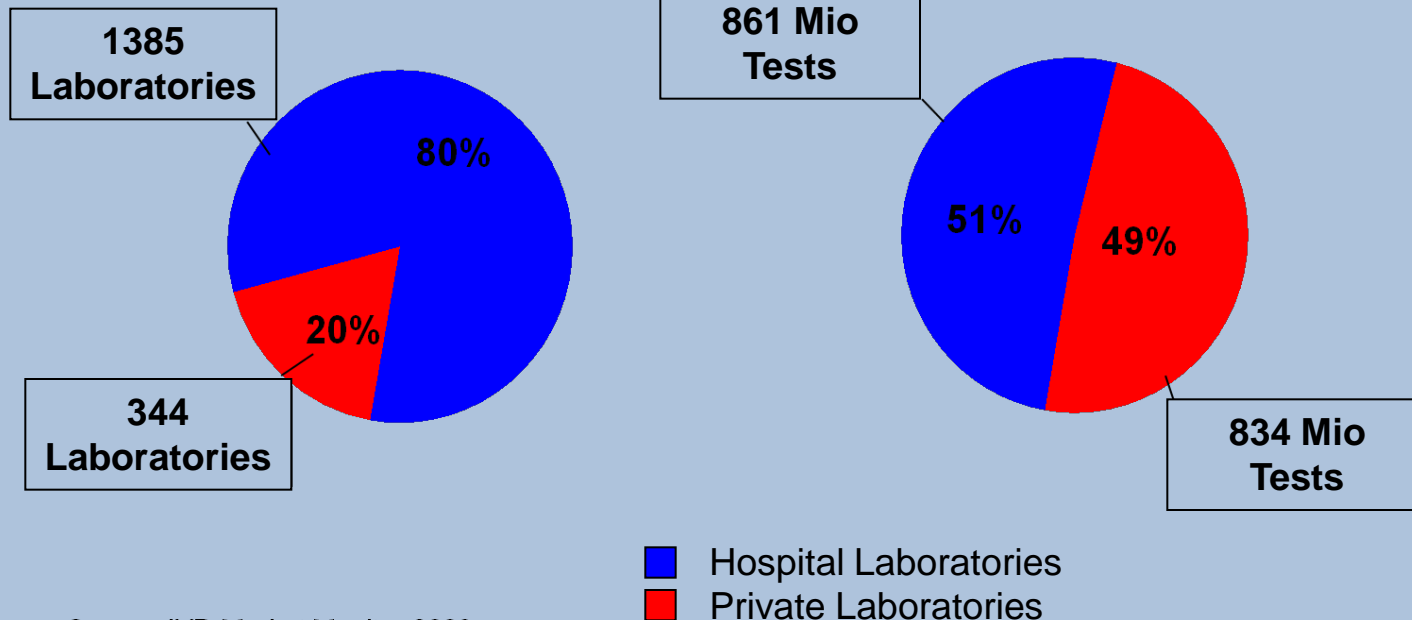


Source: BDL/Deloitte

Concentration of Diagnostic Laboratories

Total number of labs:
1729

Total number of tests:
1.7 Billion



Source: IVD Market Monitor 2009

Where is German Laboratory Medicine Headed to?



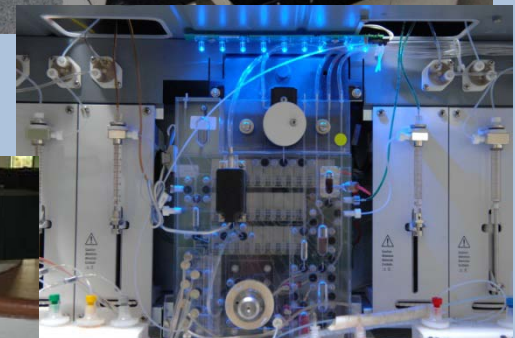
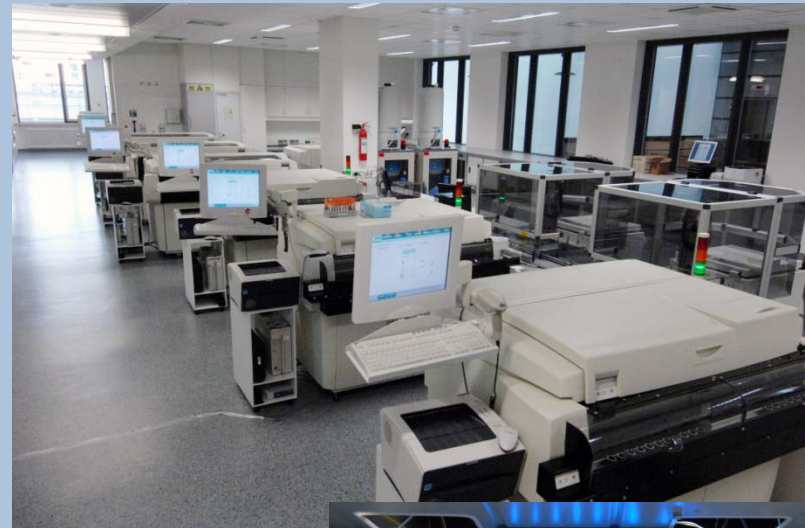
Experts and Prognoses

- Fooling around with alternating current is just a waste of time. Nobody will use it, ever. Thomas A. Edison - 1889
- There is not the slightest indication that nuclear energy will ever be obtainable. It would mean that the atom would have to be shattered at will. Albert Einstein - 1932
- 640K should be enough for anybody. Bill Gates - 1981

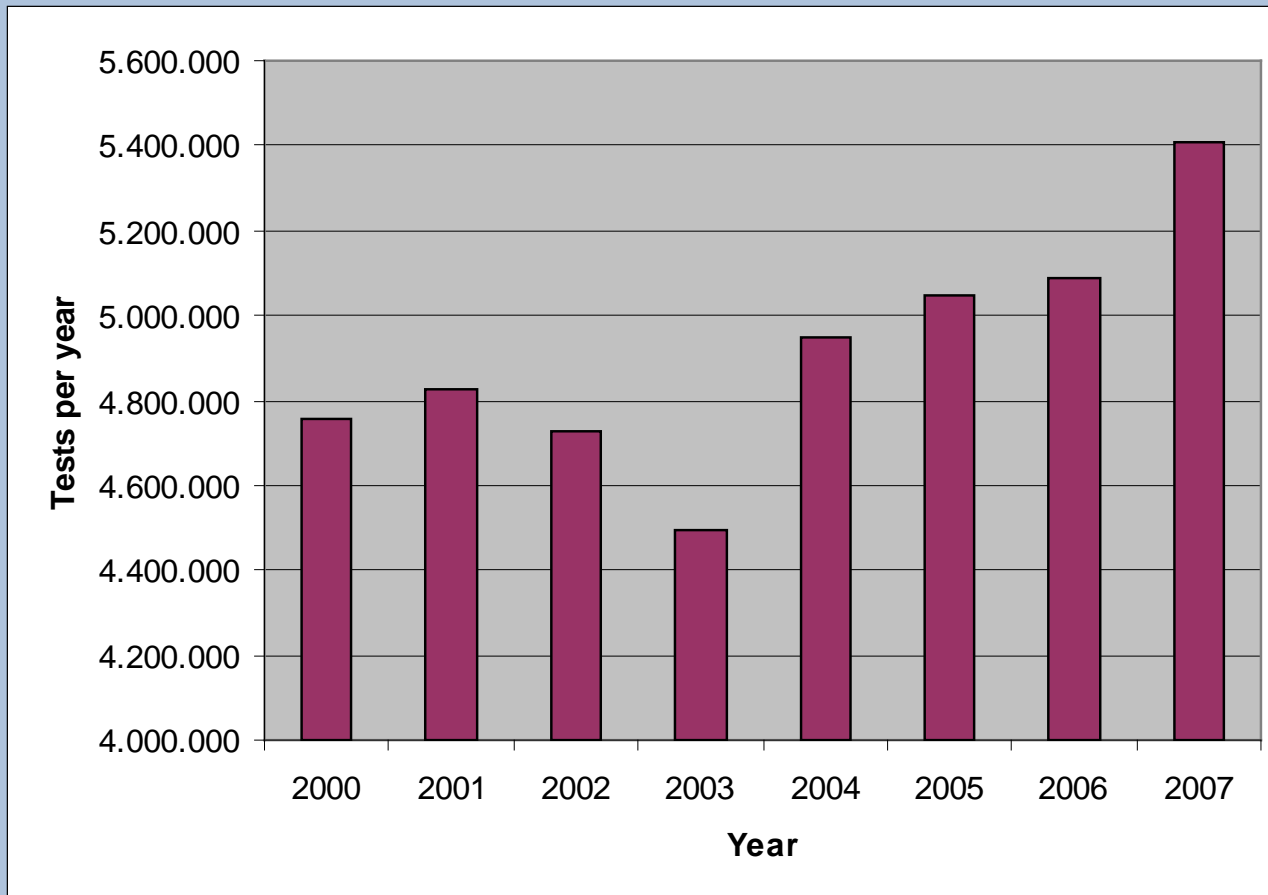
Drivers of Future Trends

- Scientific and technical progress
- Availability of expertise in laboratory diagnostics
- Positioning of laboratory diagnostics as a medical specialty
- Cooperation/competition between medical disciplines
- Demand and expectations towards the health care system
- Economic conditions

Consolidation and Automation

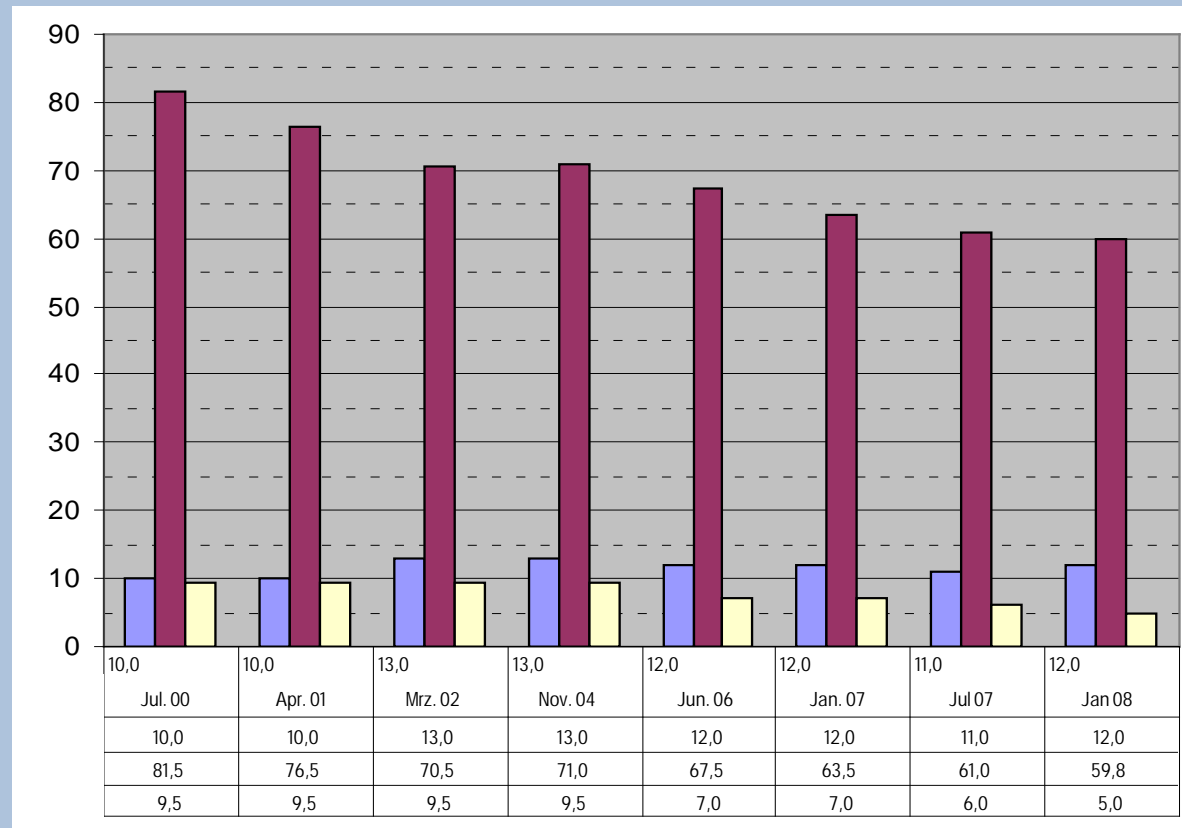


Consolidation and Automation



Consolidation and Automation

Full-time Equivalents



Consolidation and Automation

**Increase in productivity of approx. 90 %
from 2000 to 2009**

approx.

1/3 from 2000-2004

2/3 from 2005-2009

Structural Changes in Laboratory Diagnostics

- Consolidation and automation
- **Concentration of laboratories into larger units**
- Outsourcing of hospital laboratory diagnostics
- Concentration of independent disciplines into diagnostic centres

Reaction to economic pressure and competition

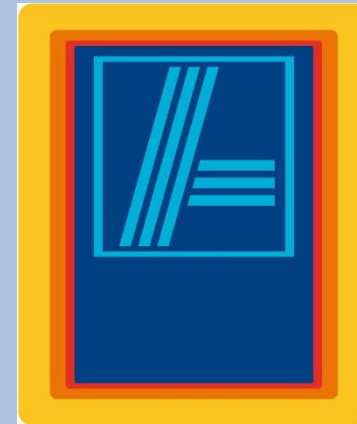
Concentration in Laboratory Diagnostics

From Shop to Supermarket



Strengths

- Individual service and counseling
- Customer orientation
- Flexible
- Locally present



Strengths

- Lower costs
- All common products
- Quality standards according to regulations

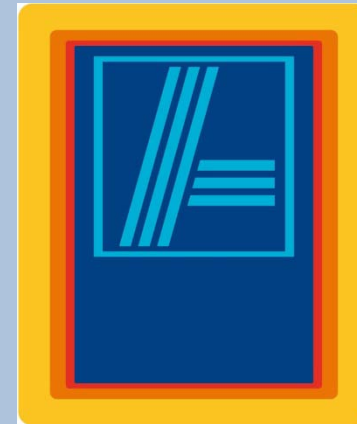
Concentration in Laboratory Diagnostics

From Shop to Supermarket



Weaknesses

- Higher costs
- Incomplete assortment
- Limited capacity for innovations
- Limited flexibility



Weaknesses

- Standardized assortment
- "One size fits all"-strategy
- No local presence
- Moment of inertia
- Market power

Concentration in Laboratory Diagnostics

- **Is there an added value of the smaller laboratory headed by specialists?**
- **Does the own laboratory provide an added value for a hospital?**
- **There are two core competencies of medicine:
Diagnostics and Treatment**

Outsourcing of Laboratory Diagnostics

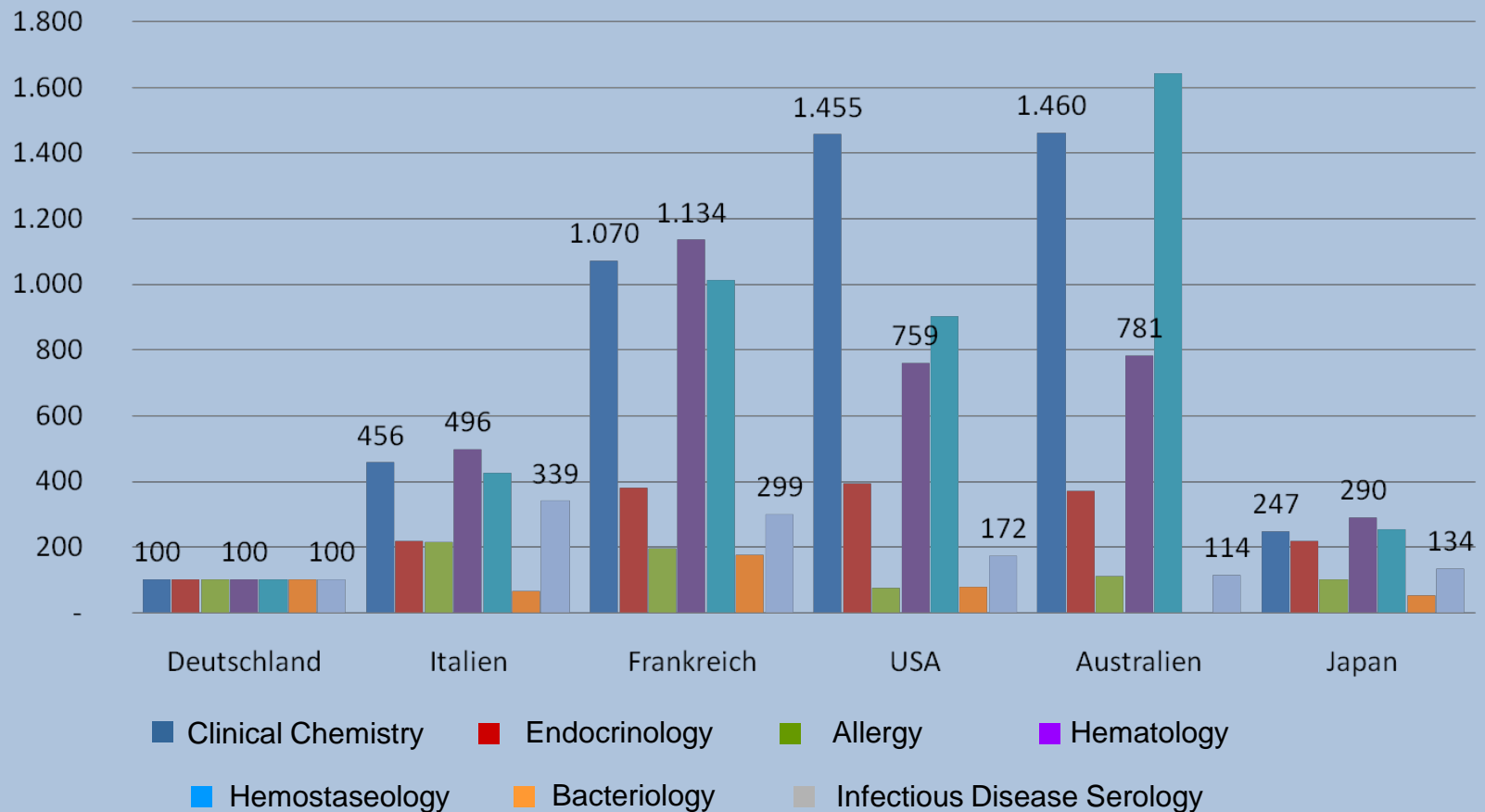


Outsourcing of Laboratory Diagnostics

- The disaster can be traced back to two causes: Boeing has carried outsourcing too far If a company loses control over the subprojects of its contractors, the whole project suffers. Perhaps aircraft manufacturers will take over a larger share of the production process themselves .

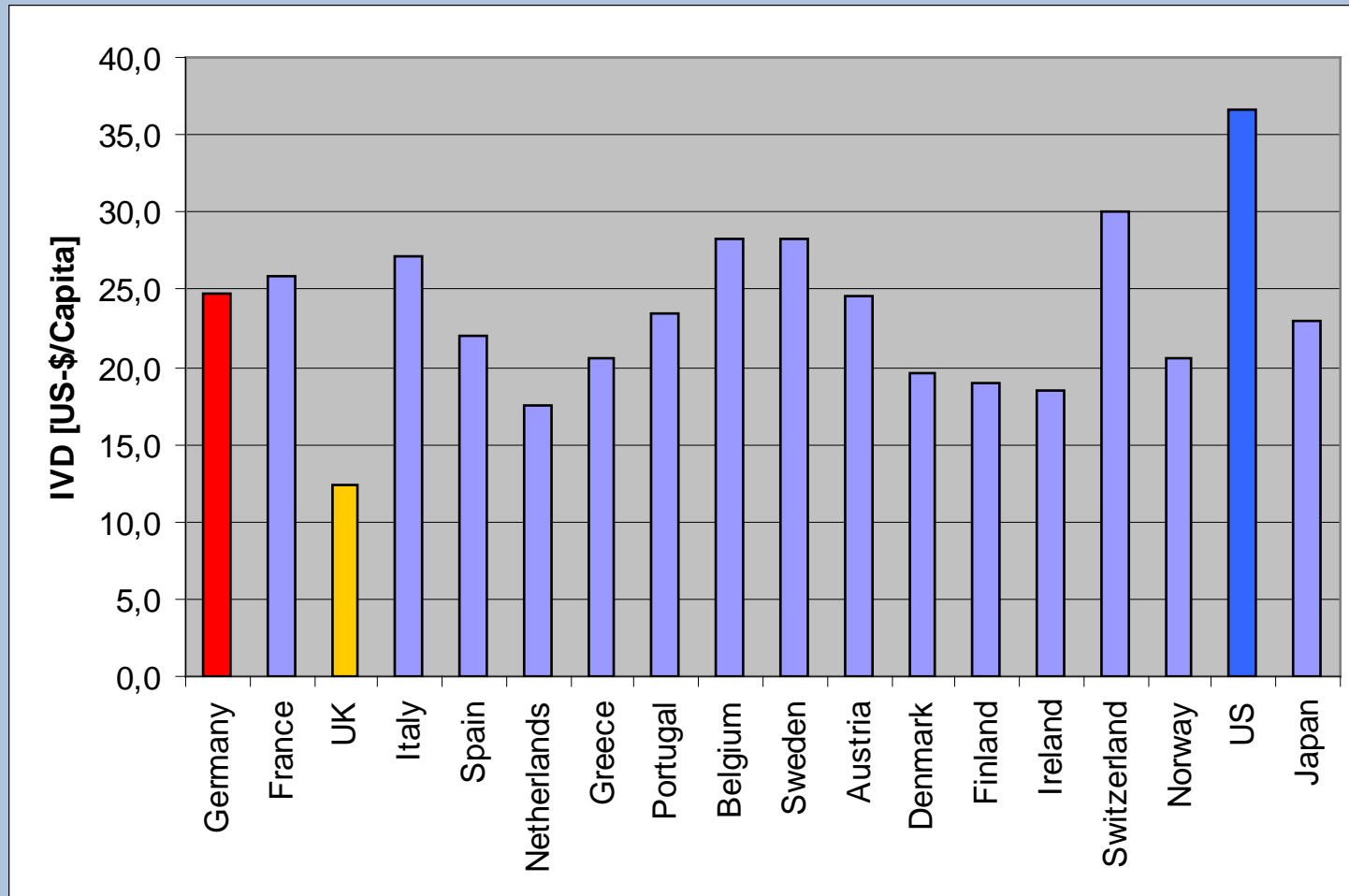
FAZ 15.8.2009

Comparison of Reimbursement

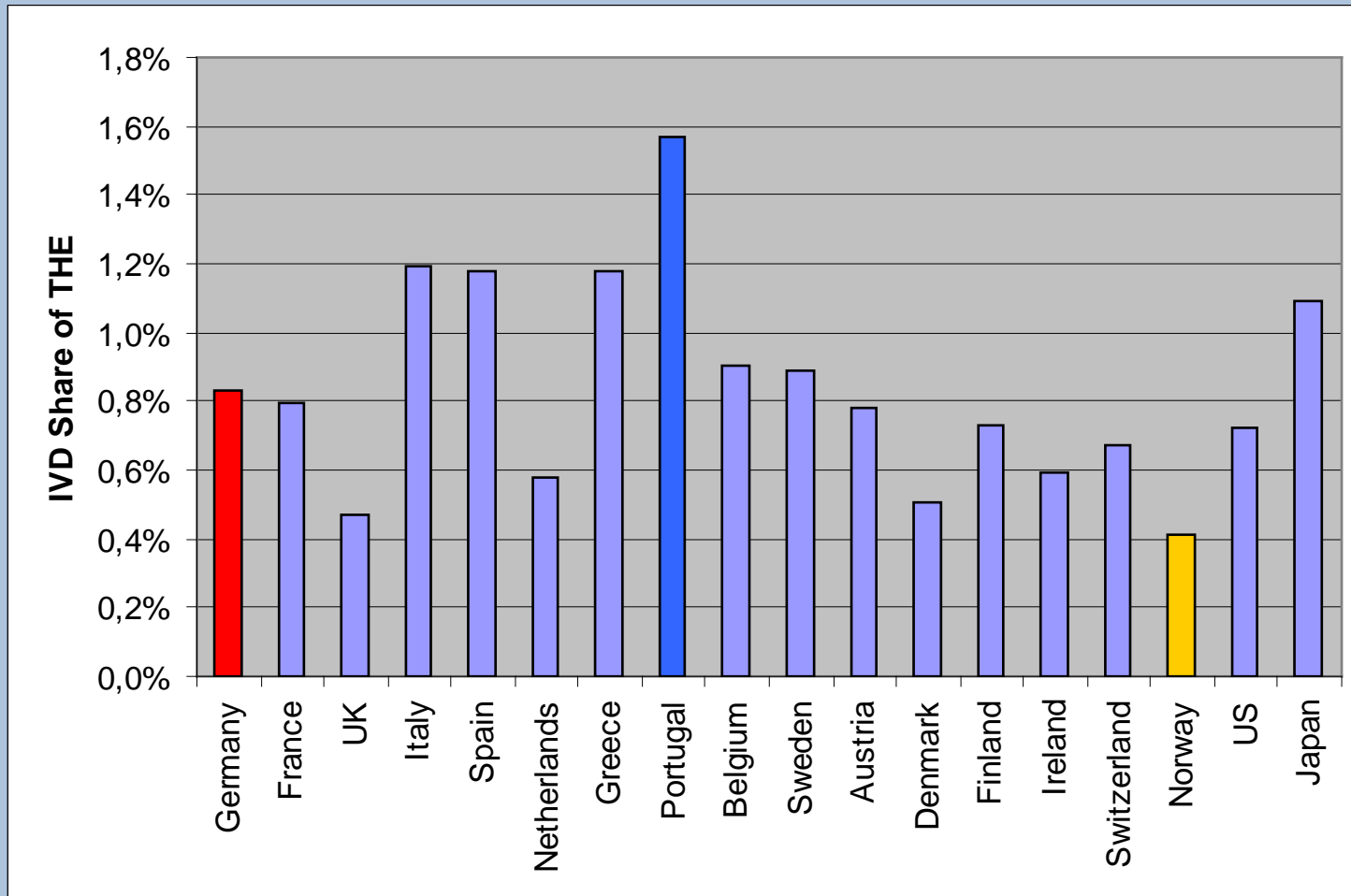


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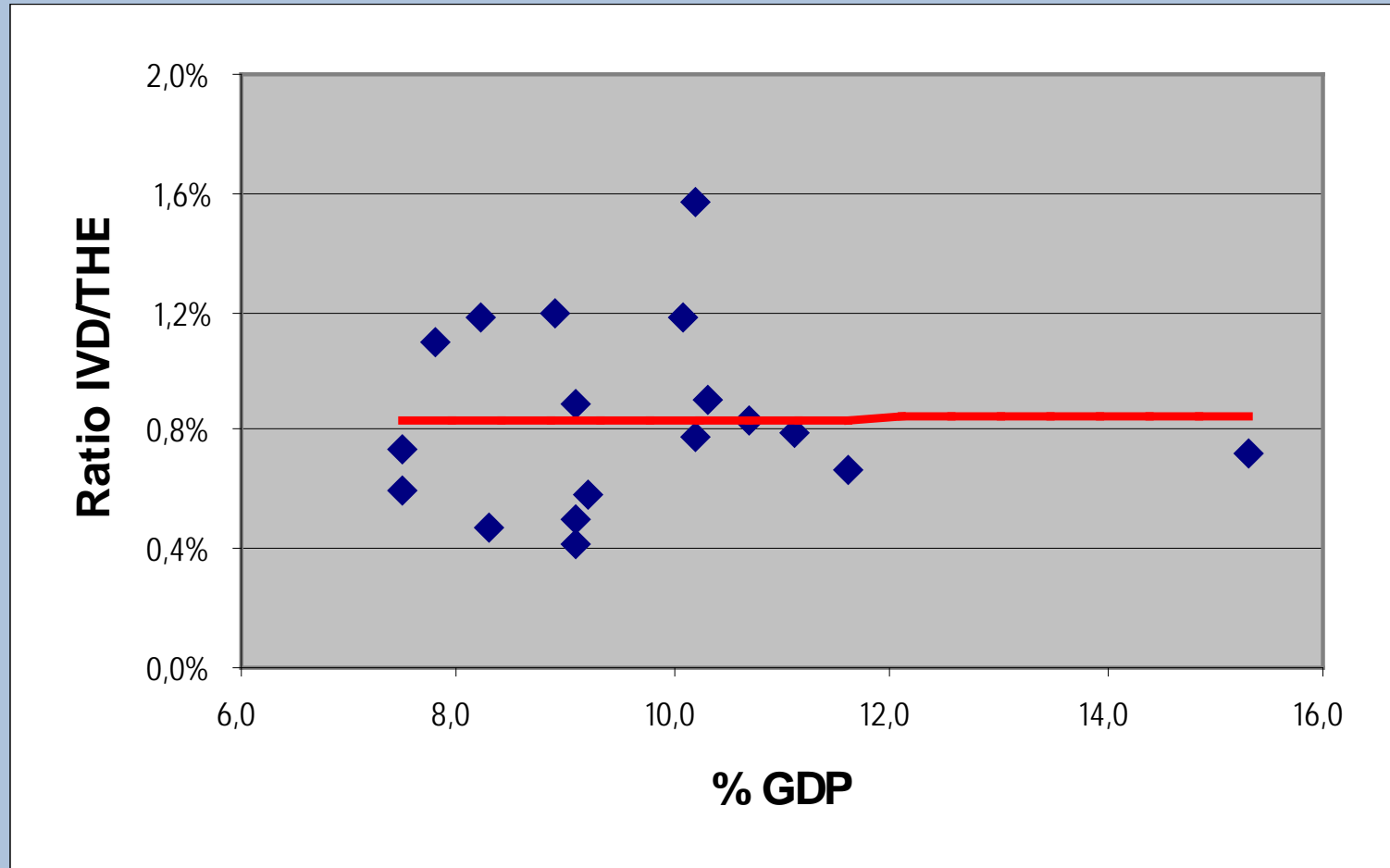
IVD Expenditures 2006



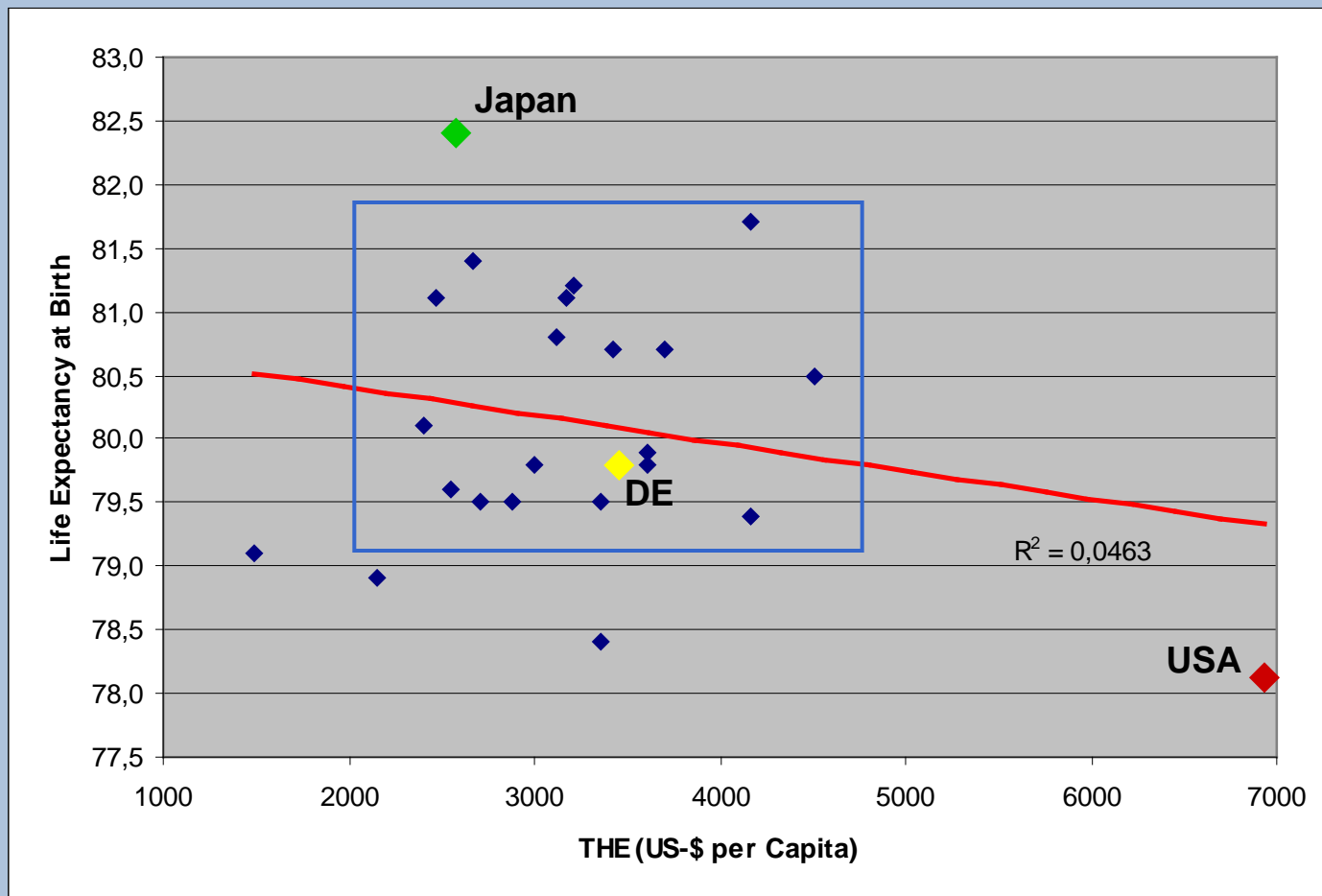
Ratio IVD to THE 2006



Ratio IVD to THE 2006



Ratio THE to Life Expectancy within the OECD



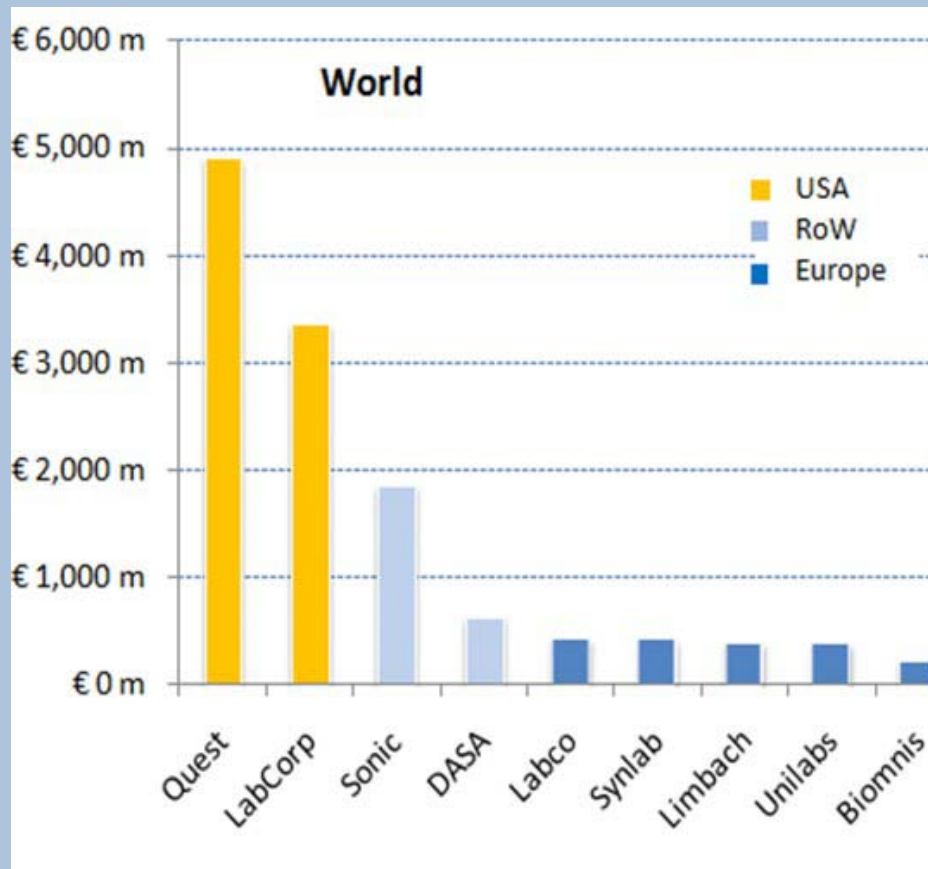
Added Value of the Specialist-headed Diagnostic Laboratory

- Guidance with indication for tests and interpretation of results
- Guarantee of a high level of quality
- Active role in development of new diagnostics
- Training of qualified young people
- Partner in clinical trials and scientific studies

Trends in Medical Laboratories

	2006	2008
Specialists for Laboratory Medicine	942	951
Private Laboratory	516	562
Independent	456	378
Employed	60	184
Hospital	313	306
Other	113	83

Research and Development



LabCorp[ad]

16 hits since 1999

Research and Development

Sensitive Troponin I Assay in Early Diagnosis of Acute Myocardial Infarction

Till Keller, M.D., Tanja Zeller, Ph.D., Dirk Peetz, M.D., Stergios Tzikas, M.D.,
Alexander Roth, Ph.D., Ewa Czyz, M.D., Christoph Bickel, M.D.,
Stephan Baldus, M.D., Ascan Warnholtz, M.D., Meike Fröhlich, M.D.,
Christoph R. Sinning, M.D., Medea S. Eleftheriadis, Philipp S. Wild, M.D.,
Renate B. Schnabel, M.D., Edith Lubos, M.D., Nicole Jachmann, Ph.D.,
Sabine Genth-Zotz, M.D., Felix Post, M.D., Viviane Nicaud, M.A.,
Laurence Tiret, Ph.D., Karl J. Lackner, M.D., Thomas F. Münzel, M.D.,
and Stefan Blankenberg, M.D.

NEJM 2009; 361: 868-77

Research and Development

Sensitive Troponin I Assay in Early Diagnosis of Acute Myocardial Infarction

Till Keller, M

Alexa

Stephan

Christoph

Renate B

Sabine

Laurence

Time of Testing

On admission

0 to <6 hr after chest-pain onset

6 to 12 hr after chest-pain onset

>12 hr after chest-pain onset

After admission

At 3 hr

At 6 hr

Detection of Myocardial Infarction

% of patients

87.7

94.5

100

100

100

Summary and Outlook

- The current changes in German IVD with a trend to larger laboratory units and outsourcing of hospital laboratories are strongly driven by economic considerations.
- While the price per test may decrease, it is not clear whether these developments will affect overall IVD costs and total health care expenditures.
- The loss of trained laboratory specialists will affect research and training in laboratory medicine.
- The ensuing lack of specialists will change laboratory diagnostics to a purely technical profession.

Hypothesis

- The structure of practice of laboratory medicine and the available expertise are more relevant for the overall cost-effectiveness of laboratory diagnostics than a reduction of price per test.

Consequences

- Laboratory Medicine must be part of every medical faculty in order to
 - secure the medical scientific basis of the specialty
 - ensure proper training of young people in laboratory diagnostics
 - broaden the evidence base of laboratory diagnostics
- Laboratory tests should be performed by specialists rather than become a low-price high-volume commodity.

Zukunft der Labordiagnostik

Verstand dient der Wahrnehmung der eigenen Interessen,
Vernunft ist Wahrnehmung des Gesamtinteresses.

Carl Friedrich von Weizsäcker



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Thank you for your attention