The AACC CPOCT Division Presents

Promoting a Culture of Quality and Consistency in Critical and Point-of-Care Testing

AACC EFCC ČESKÁ SPOLEČNOST KLINICKÉ BIOCHEMIE ifcc International Federation of Clinical Chemistry and Laboratory Medicine

AACC, 1850 K Street, Suite 625, Washington, DC 20006-2213 Email: custserv@aacc.org Web: www.aacc.org

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Promoting a Culture of Quality and Consistency in Critical and Point-of-Care Testing

24th International Symposium October 4-6, 2012
Hilton Prague Hotel Prague, The Czech Republic

Collaborating Societies

AACC Critical and Point-of-Care Testing Division

Czech Society of Clinical Biochemistry (CSKB)

European Federation of Clinical Chemistry and Laboratory Medicine (EFLM)

Under the auspices of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC)

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Alere
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Session 1:

Moderator: Martha Lyon, PhD

Why are there differences in reported benefits and outcomes with tight glycemic protocols in critical care patients? A debate.

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Session 2:

Moderator: Robbert Slingerland, PhD

Sources and Prevention of Errors in Point-of-Care Testing

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Vendor Presentations

Moderator: Anne Skurup

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Session 3:

Moderator: Ian Watson, PhD

Point-of-Care Testing Beyond the Hospital

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Session 4:

Moderator: Linda Sandhaus, MD

Developing Effective Strategies to Achieve Quality POCT Results

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Vendor Presentations

Moderator: Brad Karon, MD, PhD

Siemens Healthcare Diagnostics

Alere

Radiometer

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Session 5:

Moderator: Larry Crolla, PhD

New Technologies in Point-of-Care Testing

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Dr. Jeffrey A. DuBois, Ph.D. FACB
Past Chair AACC POCT Division
Chair of the 24th International Symposium

Our World

*"The **ability** to **convert** **visions** to **things** is the **secret** of **success!**"*

Henry Ward Beecher

Overview

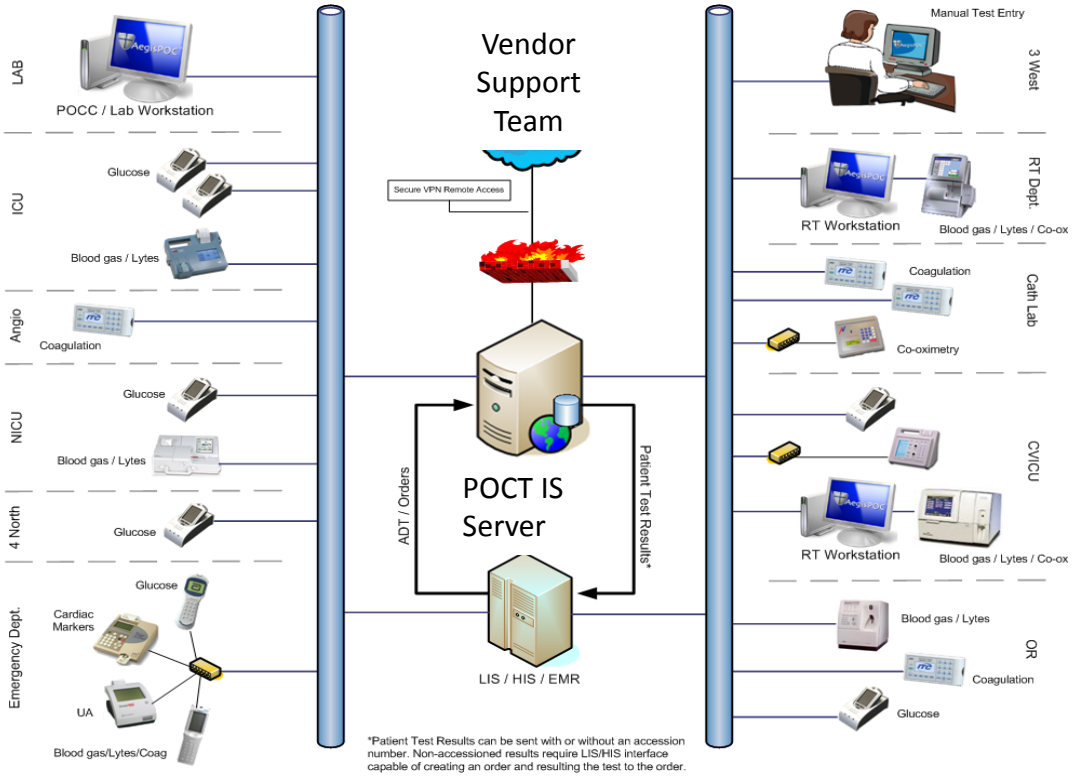
- **Point of Care Industry**
- **Where we are today**
- **Where we are going**
- **Summary and concluding remarks**

CPOCT - Myth or Reality?

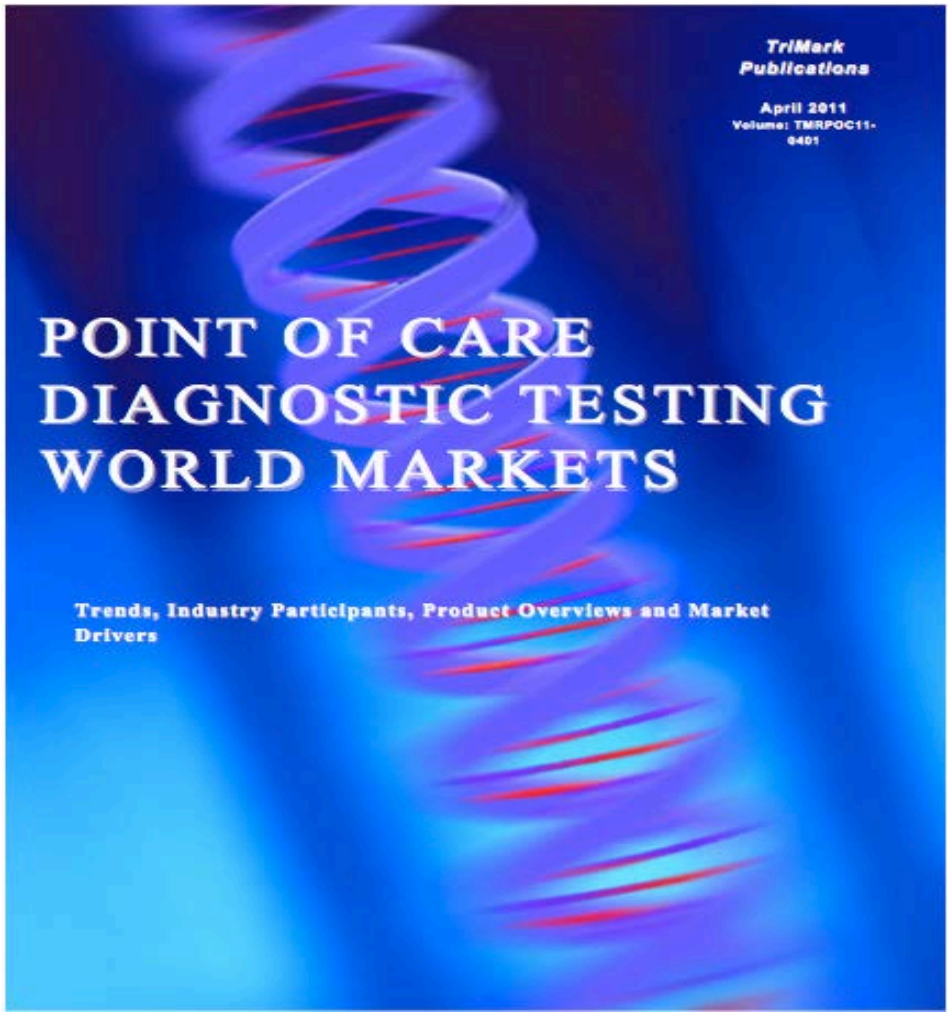
Myth

REALITY

Open Connectivity - Conceptual Diagram



IVD, CPOCT, MDx Markets



IVD Global Market 2011 = 44 BN

- US = 47%
- Europe = 31%
  - Germany #1
  - France #2
- POCT Global Market = ~14 BN
- Molecular Dx Market = ~ 5 BN*

* fastest growing segment %CGR

IVD Market Size Today 44 billion

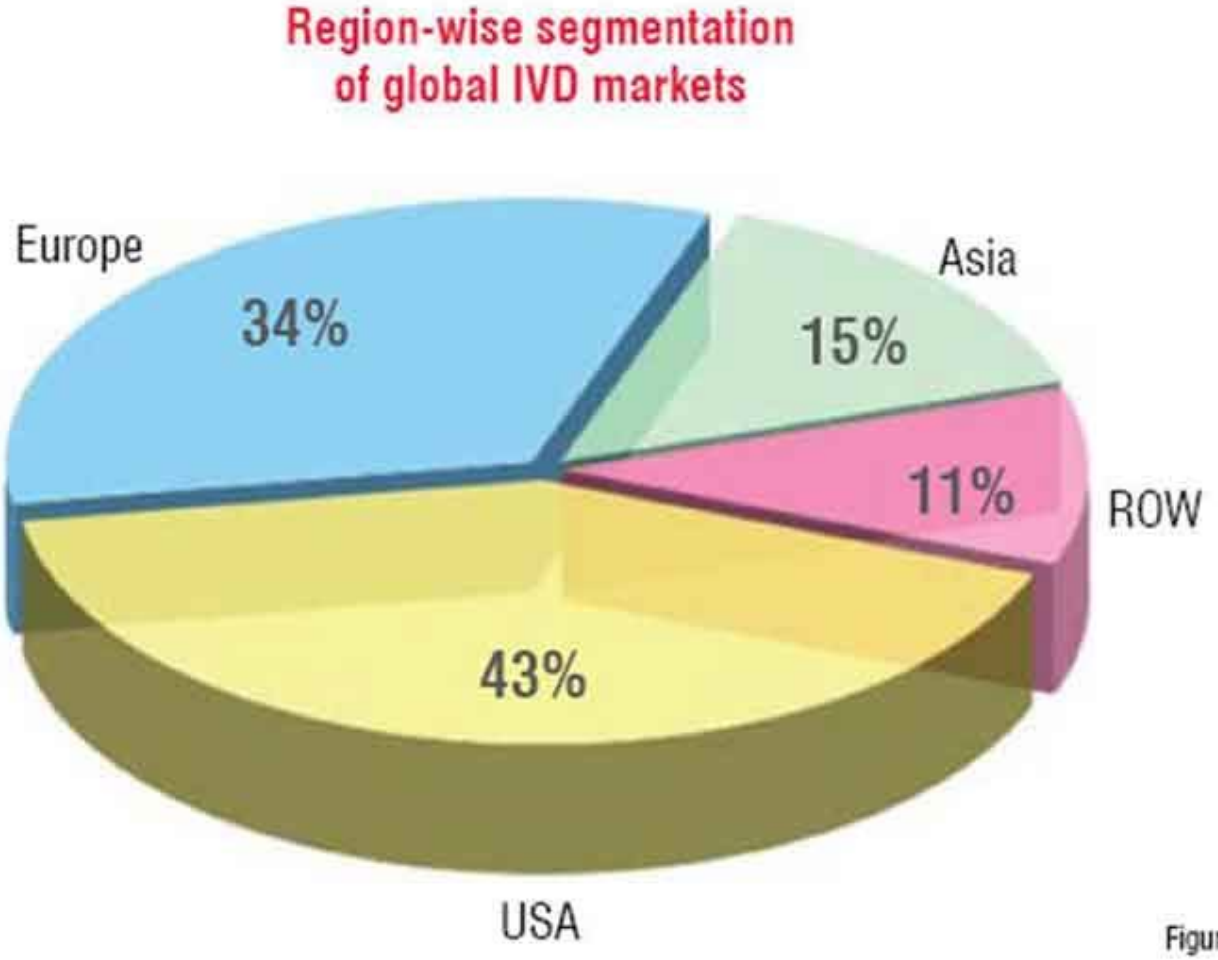
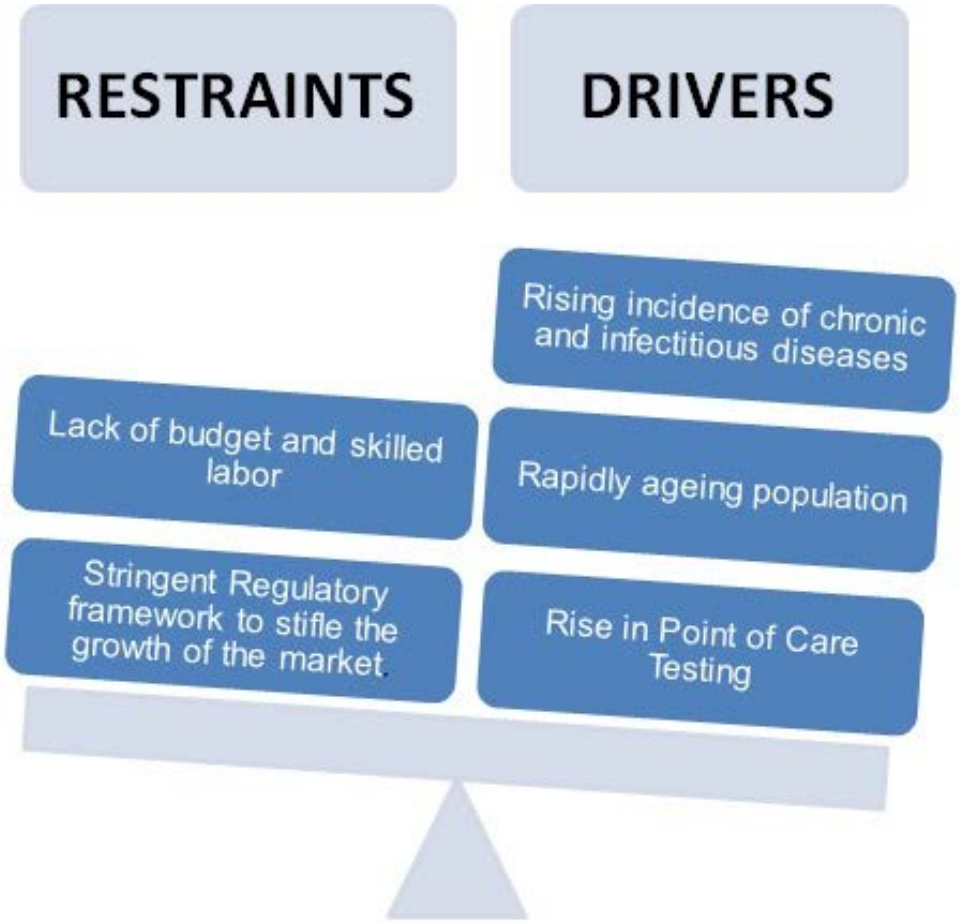


Figure 1

Market Size Drivers



Environmental Differences

	Hospital	Outpatient	Alternative
Test Menu	■Broad range	■Restricted	■Several
Performed By	■Lab staff, RN, MD	■RN, MD, staff	■Tech., Patient
Information Management	■Many CIS/HIS systems	■Uneven access to CIS/HIS/LIS	■Generally, no CIS/HIS access
Regulation	■CLIA	■Hospital Lab	■Primarily unregulated

Novel POCT Issues

- Many axes of scalability
  - Geographic
  - Device complexity
  - Available communication infrastructure
  - Cost
- ‘Razor Blade’ economic model (single use or throw-away device)
- Regulatory & Compliance issues
- Accessibility and Warehousing of Data

Where Are We Today

- POCT provides patients & providers with immediate benefits
- Costs are less controversial:

  Paradox: cost per test (volume vs convenience) or total cost benefit

  Very few studies to show real cost benefit of POCT
- Dramatic clinical benefits

  Portland protocol & Greet van den Berghe

  coagulation

  ABG's for critical care (has become the standard of care)
- New Opportunities:

  Data integration with monitors & pharmacy to improve patient safety

  Expand scope of connectivity beyond lab to patient care services

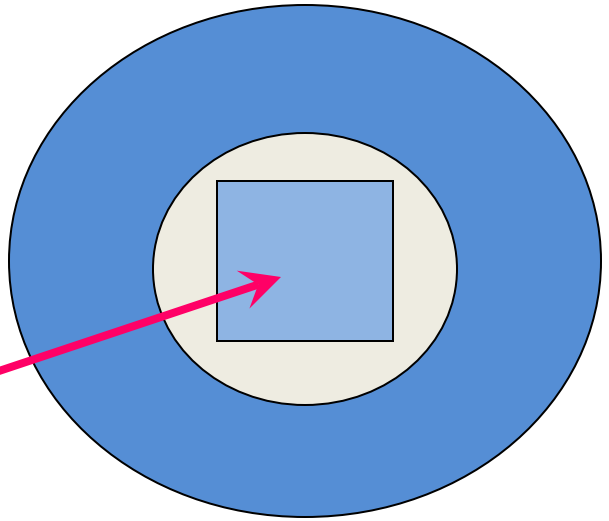
  Data mining

  Better Outcomes for patient, providers, and society

Perspectives

Other Possibilities

- Patient Centered
- Care Provider Centered
- IT Centered



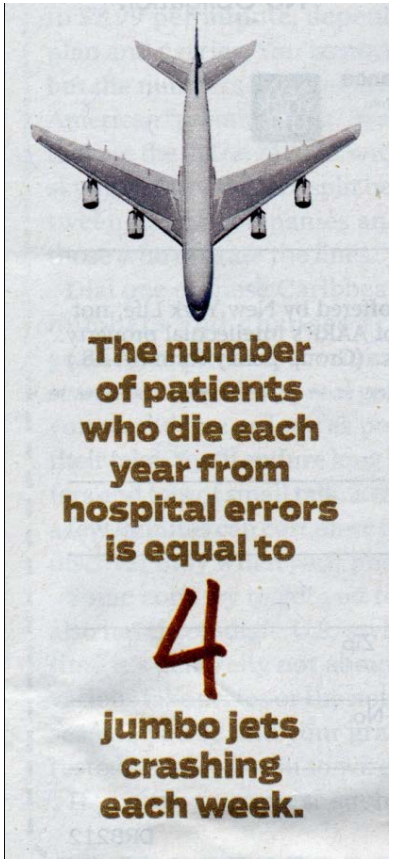
Instrument, Method, or PATIENT ?

Reducing Medical Errors

Under the best of circumstances…

"Things" happen!

The Worst Place to Be If You're Sick



One study of Medicare patients found that

1 in 7

died or were harmed by their hospital care.

"We" need "Quality" Results and Quality Practices!

= Quality

Meeting the requirements or needs of the testing site's customers
-- doctors and patients –
and satisfying their expectations

Criteria for Quality POCT in 2012:

- Correct test ordered
- Correct patient
- Correct time for collection
- Correct specimen and processing
- Correct (accurate) test result
- Correct patient record
- Correct clinical interpretation (leading to the)
- Correct and timely clinical response

"Wrongs" instead of "Corrects"
jeopardize quality and patients' safety

Characteristics of Quality POCT Results

Useful

Accurate

Precise

Reliable

Timely

Quality in POCT Requires:

Planning

Planning

Planning

&

Effective Communication