

Point of care In vitro Diagnostic devices

Premarket Regulatory Considerations

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Reference Health Laboratory

Definition of POCT:

- ❖ Testing that is performed near or at the site of the patient with the result leading to possible change in the care of the patient

ISO 22870 :2006

Definition of POCT:

- ❖ Analytical patient testing activities provided within the institution but performed outside the physical facilities of the clinical labs.

It does not require permanent dedicated space.

College of American Pathologists



Brain to Brain time

❖ ABG Analyzer in the Central laboratory of a hospital

❖ ABG Analyzer in the

What is the difference?

Same device, Different setting



POC Versus RDT

ASSURED criteria for RDT

- A=Affordable
 - S=Sensitive
 - S=Specific
 - U=User-friendly (simple to perform in a few steps with minimal training)
 - R=Robust and rapid (results available in less than 30 min)
 - E=Equipment-free
 - D=Deliverable to those who need them
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POC testing

- Convenience
- Timeliness
- Potential to improve patient outcome

Increased POCT popularity

Transformation of Healthcare Landscape

Shift from Curative medicine to Predictive, Personalized
and Preemptive medicine

Future of POCT

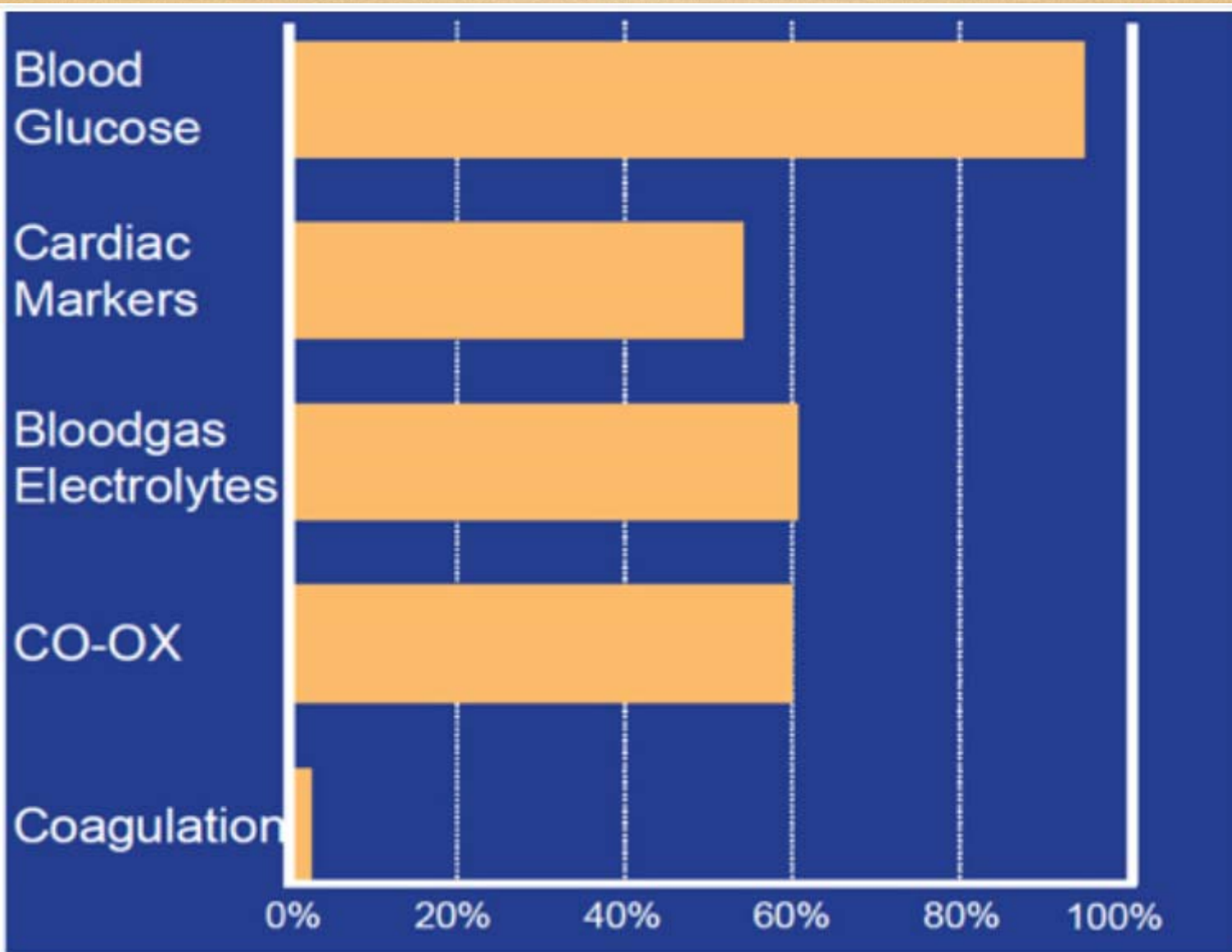
- Automation
- Miniaturization
- Diversification

move from qualitative tests to
automated information intelligence
ones (POCT generations)

Segmentation of global POC diagnostics market

- Based on the type of **end users**:
 - 1- patient professional monitoring kits
 - 2- patient self monitoring kits
- Based on **prescription mode**:
 - 1- OTC
 - 2- Prescription-based POCs

- Blood
- **Card**
- Cho
- Coag
- Dru
- Feca
- Foo



Source: 2004 Enterprise Analysis Corporation Survey of 493 Acute care Hospitals

Knowledge

Training and experience

Reagents and materials preparation

Characteristics of operational steps

Calibration , QC and PT materials

Test system troubleshooting and equipment maintenance

Interpretation and judgement

- Simple
- The t
- Likel

Complexity of diagnostic tests: CLIA

- Waived tests
- Tests of low complexity
- Tests of moderate complexity

CLIA waive tests are:

- So easy to perform
 - Probability of erroneous results is minimal
- No significant harm to patient if performed incorrectly,

Con

Determine
Level of Risk

Device
Description

Analytical
Performance

Clinical
Performance

- Test Measure
- Intended Target Population
- Test results to be used

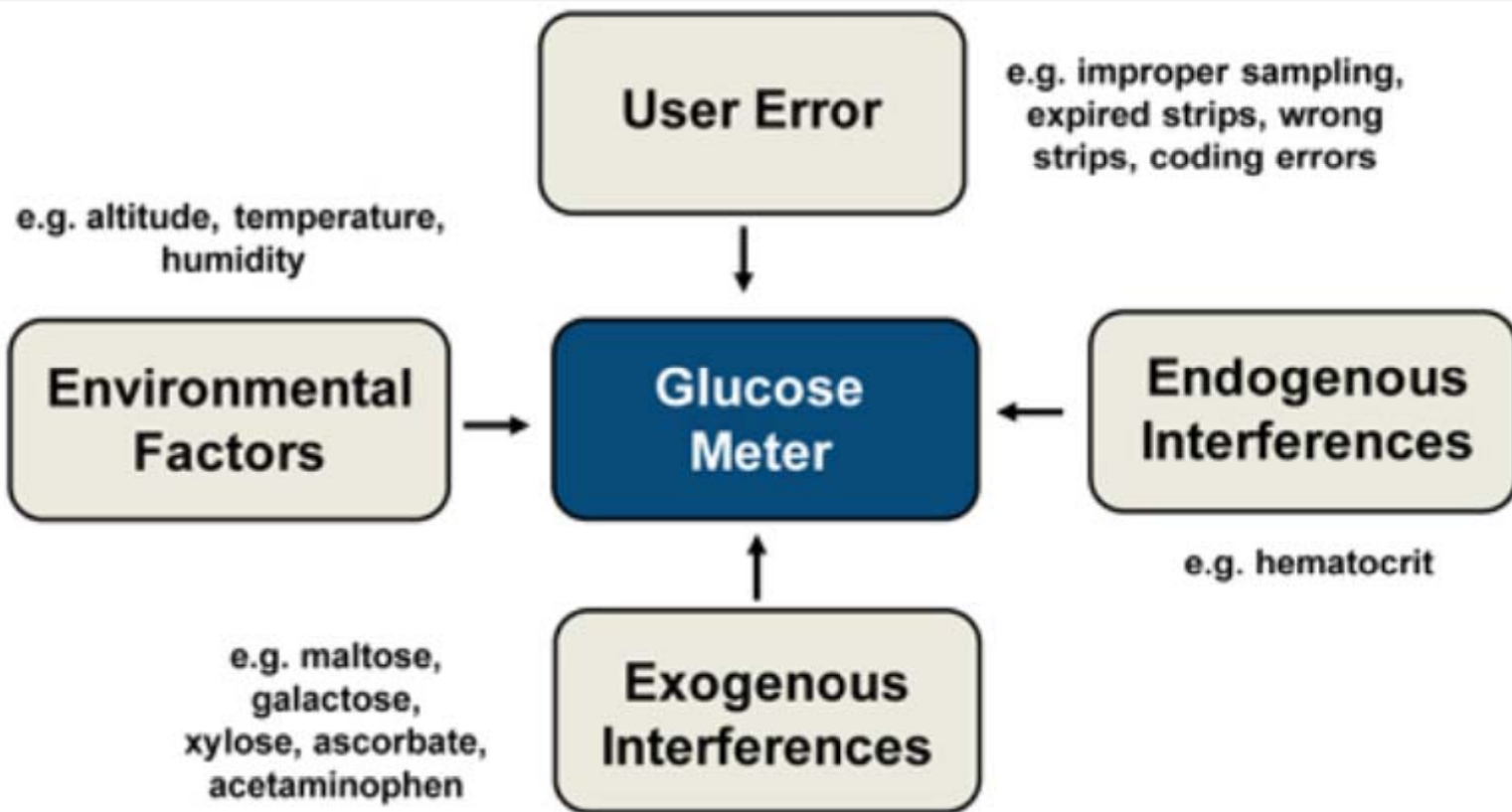
- Define all components of test system

- Precision and accuracy
- Linearity/reportable range
- Traceability
- Stability
- LOD & LOQ
- Interference, cross reactivity
- Matrix and sample type comparisons

- Clinical cut off
- Sensitivity/specificity
- Positive/negative predictive value
- Expected value/reference interval

General points

- Intended use
- Intended user
- Intended use setting
- Intended use matrix
- AMR



Source: Boston Biomedical Consultants – personal communication April 2010

Performance characteristics

- Including : Precision, accuracy , sensitivity , specificity
- End-points should be Linked to
 - Clinical claims
 - Statistical hypothesis provided with supporting sample size calculations

Performance characteristics

- Acceptable criteria are specifically determined according to the test and **clinically acceptable performance**
- By using biological specimens (spanning claimed AMR) and control materials
- In **multiple sites**(similar to intended setting of use) with **multiple operators**
- In comparison to a laboratory reference and registered POC device

POC tests

- Wide spectrum of sites
- Wide spectrum of operators
- Wide spectrum of regulatory claims

Challenges of POC testing

- Increased testing variability
 - Less- controlled testing environment
 - Pre-analytical variables
- Less operator laboratory knowledge and training
- Sample matrices & interferences
- Degradation of kits and reagents

Increased testing variability

- Precision studies with multi level controls and patient specimens

Operator knowledge and training

- Labeling requirements (IFU)
- Training material
- Control sample

Sample matrices & interferences

- Performance evaluation on all the claimed matrices separately
- Assessing the effect of interfering factors by the manufacturer considering patient condition

Degradation of kits and reagents

- Stability testing for all the components of kit or system separately

Additional requirements for OTC IVDs

- Aspects related to lay users with no expertise in laboratory testing



Lab-in-a-Backpack



Lab-in-a-Backpack in Ecuador





Thank you