Selecting a PoCT Device Fitting the Intended Clinical Use

Trevor Allison, Director R&D, Siemens DX POC
I am not selling

Siemens is best
blah blah blah blah...
POCT Device Selection

Address a Clinical Need
Timely Results
Affordable System

Improved Patient Outcomes
The Selection Process Iceberg

- Accurate, Timely Results
- Reliable, Dependable System
- Improved Patient Outcomes
- Easy to Use
- Affordable Total System Cost
The Selection Process Iceberg

- Accurate, Timely Results
- Correlation to Lab Method
- Agreement with National & International Standards
- Interferences & Limitations
- Accreditation & Audit
- Quality Control QC & EQA

Improve Patient Outcomes
The Selection Process Iceberg

- Backup Plan
- Service Contract
- Fast Vendor Service Response
- Reliable, Dependable System
- Simple, Quick User Maintenance
The Selection Process Iceberg

- Improve Patient Outcomes
- Quantifiable Benefits
- Affordable Total System Cost
- Budget
- Consumables Cost

Budget

Improve Patient Outcomes

Quantifiable Benefits

Consumables Cost

System Cost

Affordable Total System Cost
The Selection Process Iceberg

- Improve Patient Outcomes
- Easy to Use
- Operator Workflow SOP
- Staff Training & Competency Assessment
- Pre & Post Analytical Error
- Patient & Operator Safety
- Connectivity & Traceability
The Selection Process Iceberg

Quality Management System QMS
Quality Management System

It is not enough to do your best; you must know what to do, and then do your best.

W. Edwards Deming
1900 - 1993
Quality Management System

Plan
Do
Check
Act

W. Edwards Deming
1900 - 1993
Quality Management System
Quality in the Planning Process

Planning

- Identify the Stakeholders
- Form a small team
- Write a Plan document
  - include all the detail
  - get the stakeholders to review & approve it
good luck is the result of good planning
Further Reading

IFCC TF-POCT - Thinking of Introducing POCT – Things to Consider

ISO 22870 Point-of-care testing (POCT) — Requirements for quality and competence
ISO 15189 Medical laboratories – Particular requirements for quality and competence

CLSI POCT09-A - Selection Criteria for Point-of-Care Testing Devices

Thank you for your attention