



" New Directions in Point of care testing "

2010

2009

2008



Is POCT a new concept ?



NO



Yesterday's Yardstick for tomorrow's instrumentation



Sequence

- Definition
- Introduction
- Historical background
- Available modalities
- Personal observation
- Future
- conclusion

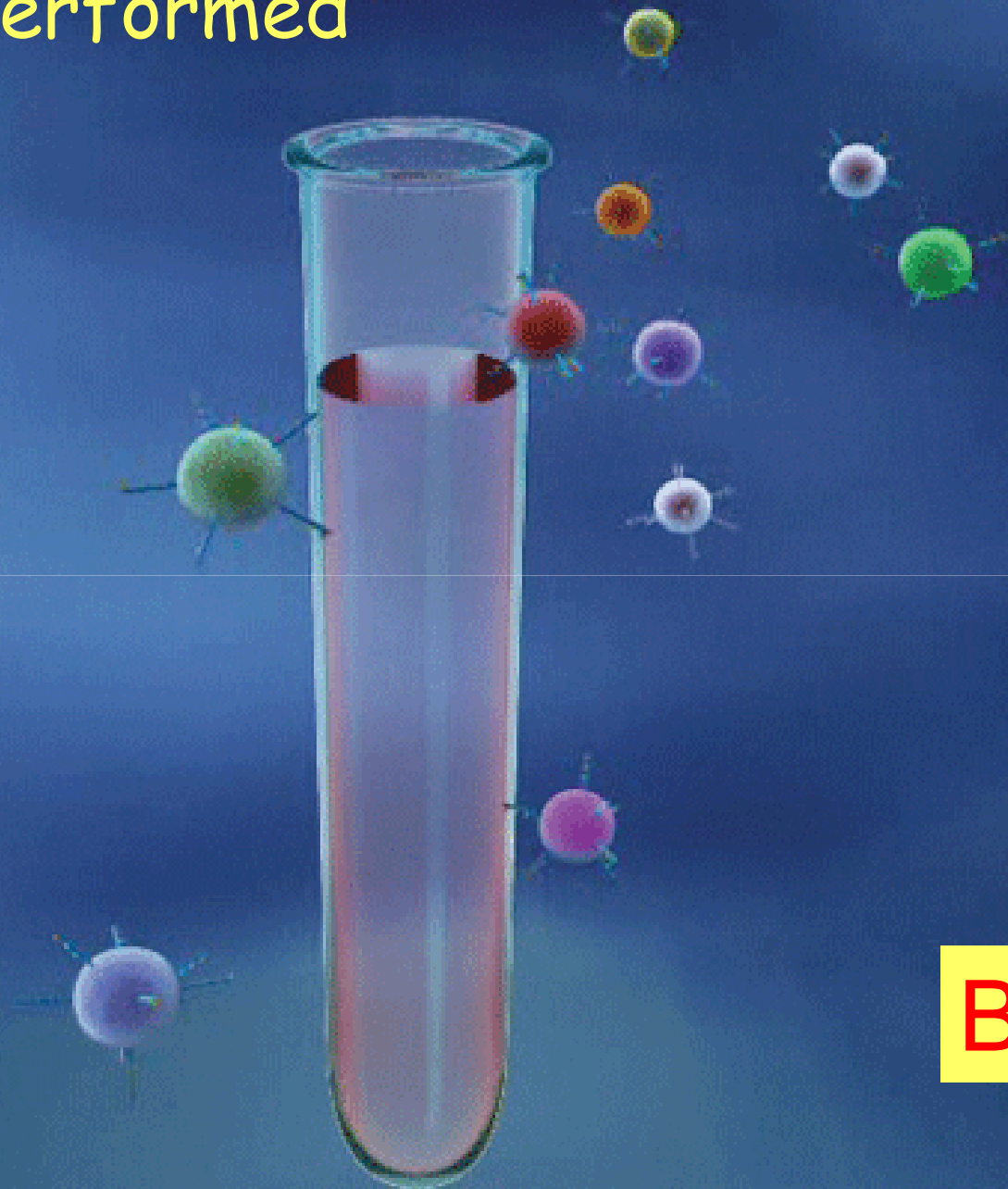


Definition

An analytical test undertaken by a member of the health team or by a non-medical individual in a setting distinct from a hospital lab

**So what have we gathered from
this definition ?**

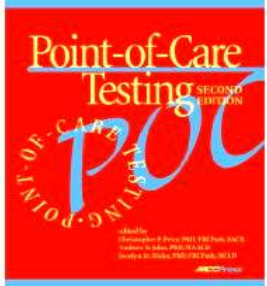
A test is performed



By



Where ?

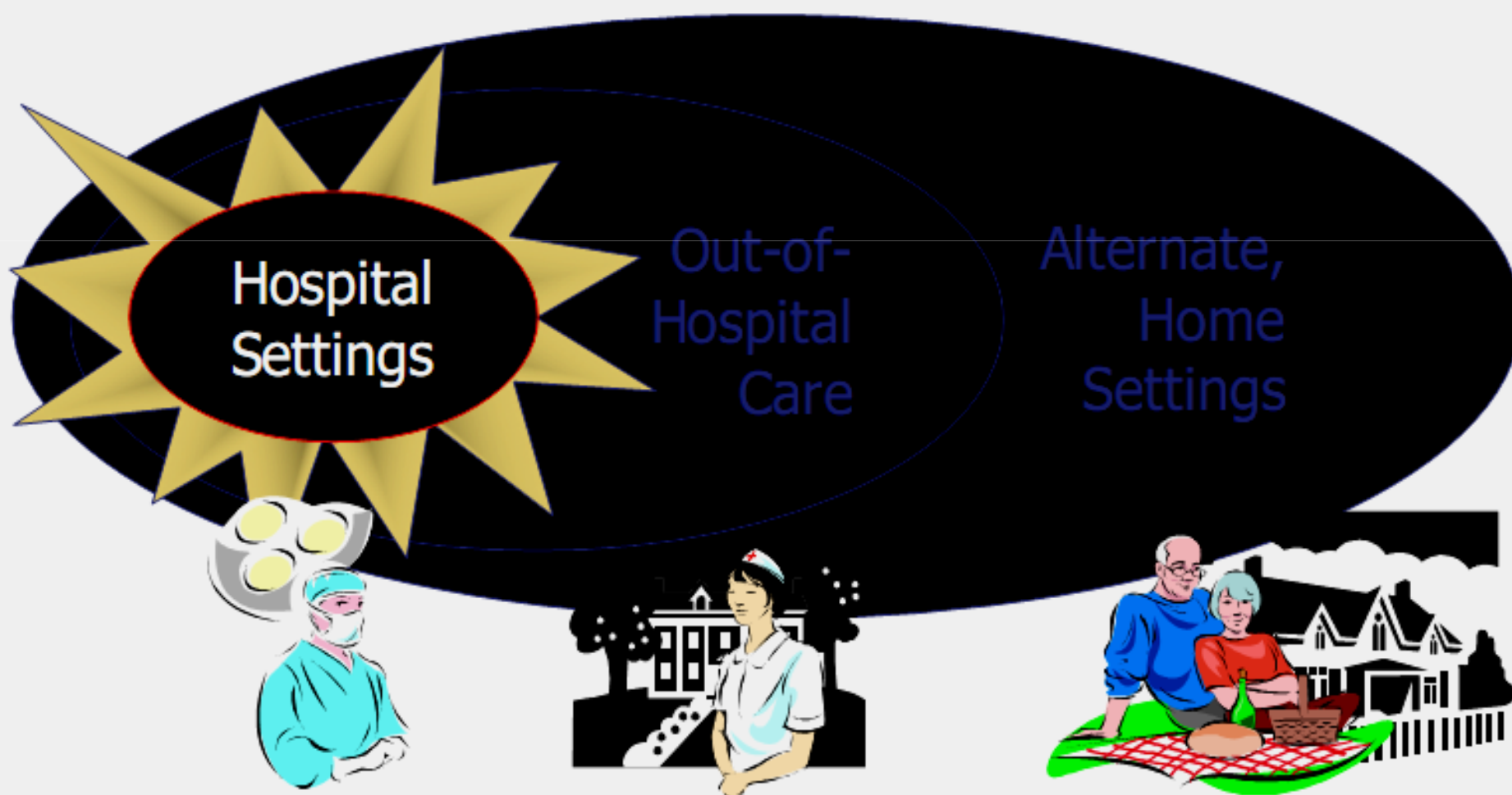


Not in the lab

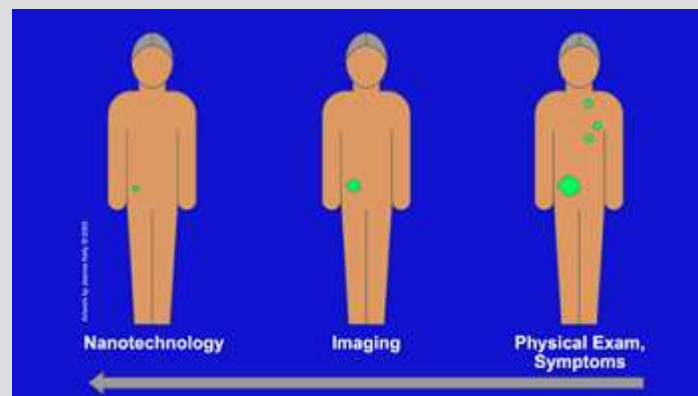
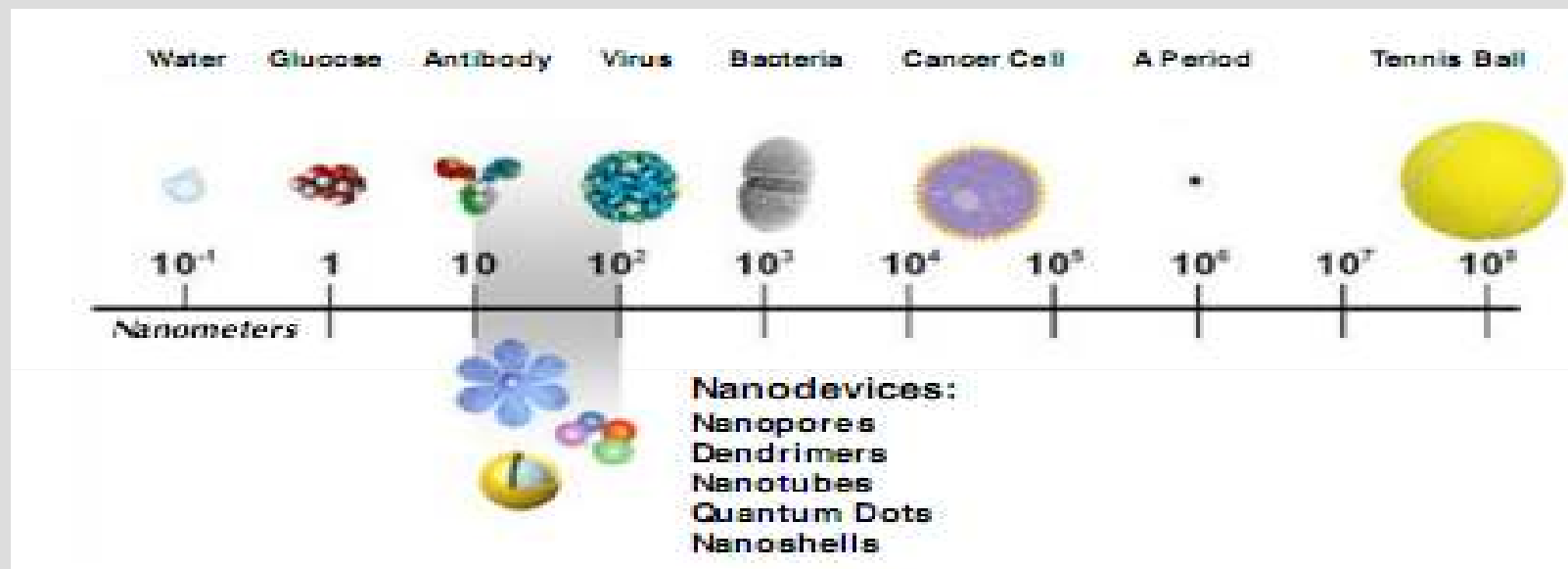


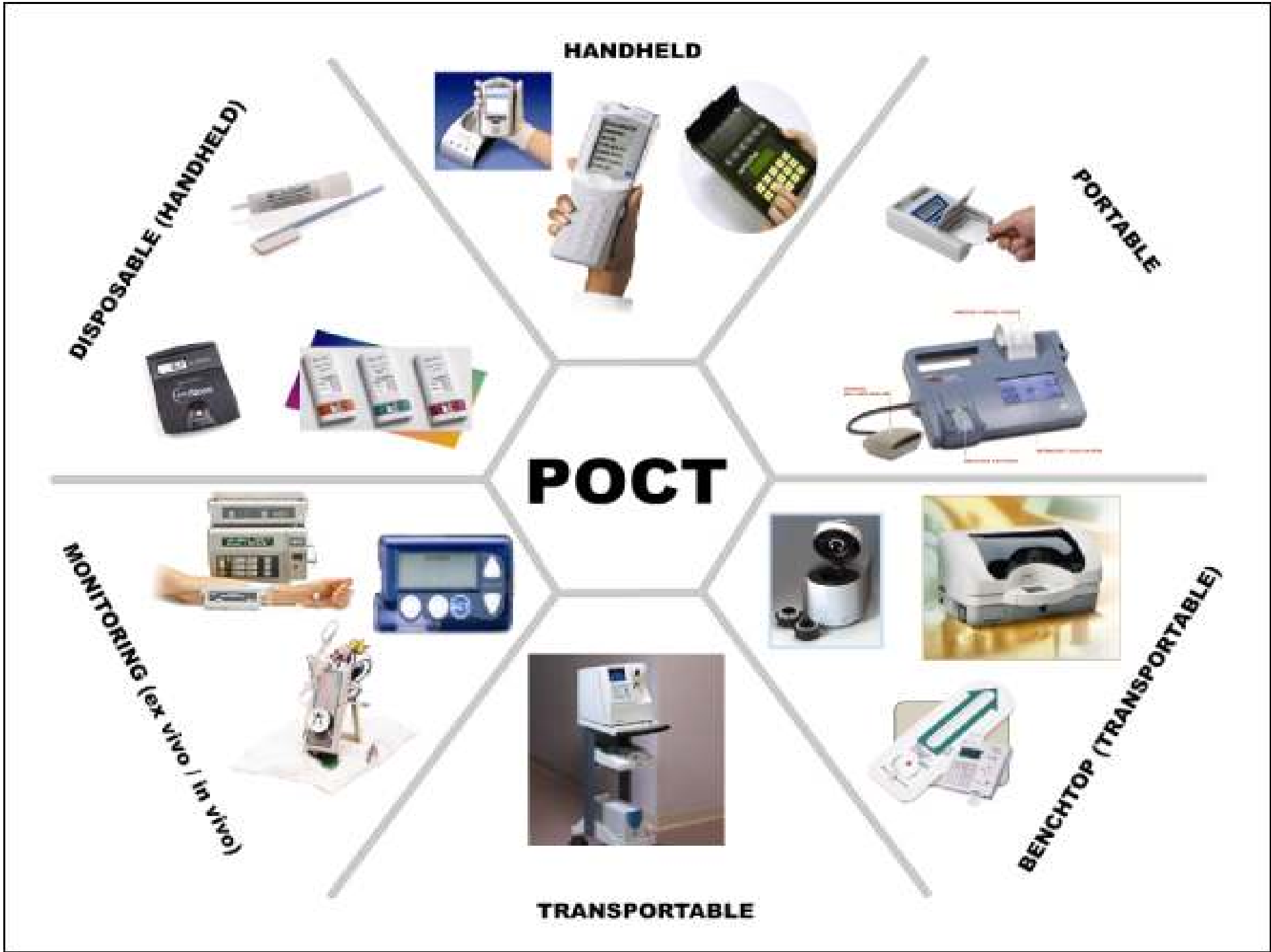
POC Testing Environments

Testing performed at the patient's side



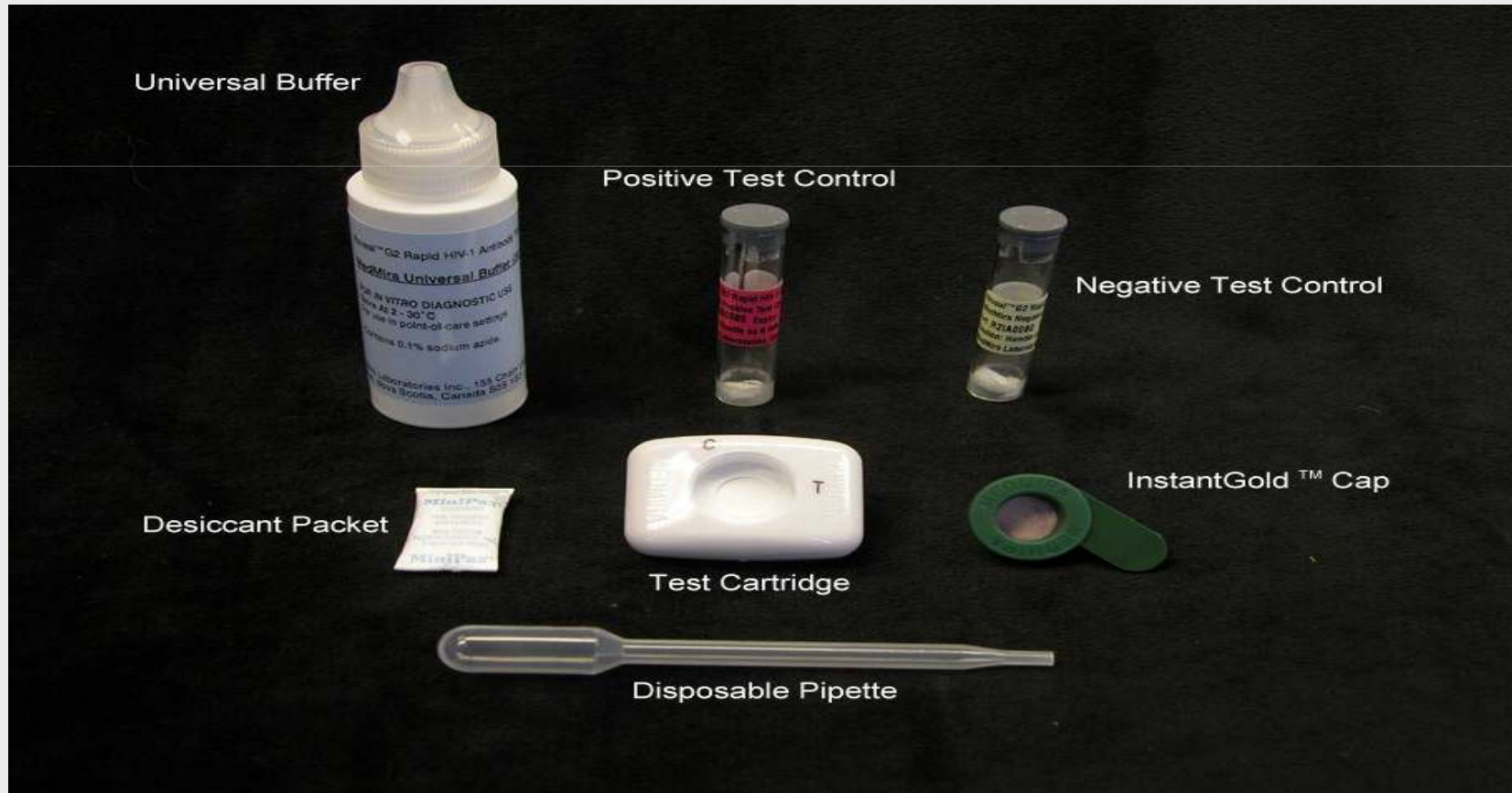
A Snapshot of Nanotechnology





Non-instrumental system (strip-based)

- Disposable system or device



Non-instrumental system (strip-based)

Test strip

- Simple analyte type
- Sophisticated multi-analyte reagent strip (with control)



Cartridge based instruments

- Single analysis
- Multiple analysis



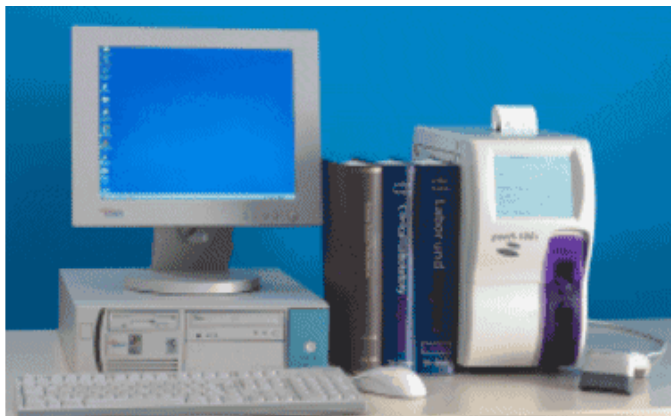
NHS Pathology Plus⁺ is a modern, tailored pathology solution...



NHS Pathology Plus⁺ has dedicated teams that support both technical, clinical, and governance issues across a range of "best-in-class" technologies.

We can provide a tailored package for you to provide Point of Care testing for your patients. Interpretation

Benchttop / Desktop analysis

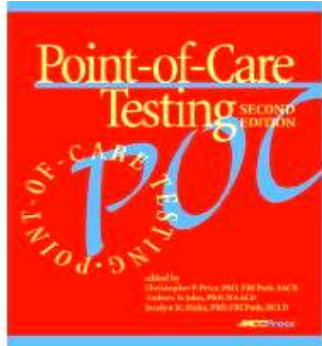




Simplified definition

POCT means a test performed close to the patient with quick result where patient care is given



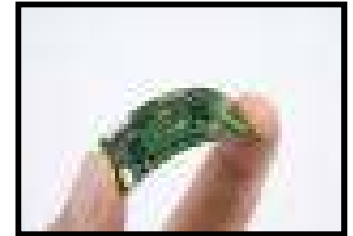


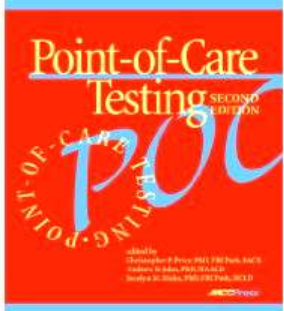
- **Rapidity**

- **validity**

Introduction

- Increasing interest
- Not a new concept
- Recent advances
 - Engineering
 - Innovation
 - Miniaturized devices
 - Lab-on-a-chip
 - Micro / nanoscale
- Simplification of blood handling
- Decreased TAT
- Transcription free delivery of reports





**POCT not a threat
rather
an opportunity to show our capabilities**

Key objectives

- **Results**
 - Quick
 - Reliable
 - Validated
- **Patient proximity**
- **Treatment**
 - Prompt treatment
 - Improving clinical and/or economic outcome
- **Patient reassurance**



**Cardio
Chek™
P•A**

Diabetes &
Lipid Panel



FAST
ACCURATE
FACTORY CALIBRATED
PORTABLE, TEST ANYWHERE

CardioChek ✓
CLIA - Waived CE

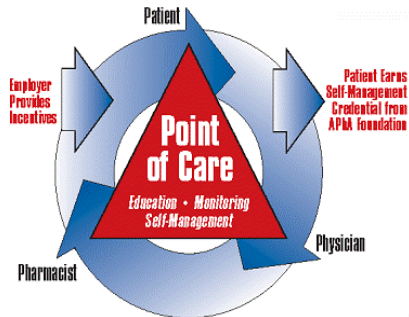
- **Non-invasive glucose measurement thru ear by INFRATEC DEVICE**
- **AMI detection (20 min) - Heart FABP**
- **Triage Cardiac Panel (15 min)**
 - **CK-MB**
 - **Myoglobin**
 - **Troponin I**
- **Cardio Chek P.A (2 min)**
 - **Unique POCT tool**
 - **Lipid profile**
 - **Diabetic profile**
- **Nova statsensor Creatinine meter (30 sec)**
 - **2 ul blood - fingerstick**
 - **Creatinine measurement with GFR**





- **Hemo Cue Albumin System (90 sec)**
 - **Immunoturbidimetric method (micro albumin)**
- **TOX / See (15 min)**
 - **Hand held POCT device**
 - **14 most abused drugs (urine sample)**
- **Toxicological screen - Saliva**
- **Breath Alcohol meter**
- **Intrapartum fetal surveillance (oximetry)**
- **POCT Coagulation meters**





Delivery forecast system (pregnancy)

- Transcutaneous Bilirubin measurement
 - Based on tissue optics
- NIRS (Near Infra-red spectroscopy) Tissue Oximetry
- Capnometry
- Equital Ambulatory Wearable System (physiological)
 - Heart rate
 - ECG
 - Respiratory rate & effort
 - Temperature
 - Body position
 - Oxygen saturation
 - Impact and fall detection



Point of Care Diagnostics and CLIA-Waived Testing

- **CLIA-Moderate Rapid Test Kits**

[CLIA-Moderate H. pylori Test Kits](#)
[CLIA-Moderate hCG Test Kits](#)
[CLIA-Moderate Mononucleosis \(Mono\) Test Kits](#)

- **CLIA-Waived Diagnostic Devices**

[Albumin Analyzers](#)
[CLIA-Waived Cholesterol Analyzers](#)
[CLIA-Waived Hemoglobin A1c Analyzers](#)
[CLIA-Waived Lipid Panel and Triglyceride Analyzers](#)
[CLIA-Waived Urine Analyzers](#)
[Glucose Analyzers](#)
[Hemoglobin Analyzers](#)
[Ketone Analyzers](#)
[Microhematocrit Centrifuges](#)
[Point of Care \(POC\) Data Management Systems](#)

- **CLIA-Waived Diagnostic Kits and Reagents**

[Alcohol \(Ethanol\) Saliva Test Kits](#)
[Amines Test Kits](#)
[Bladder Tumor Antigen \(NMP22\) Test Kits](#)
[CLIA-Waived Drugs of Abuse Test Kits](#)
[CLIA-Waived Fecal Occult Blood Test Kits](#)
[CLIA-Waived hCG Test Kits](#)
[CLIA-Waived Streptococcus Test Kits](#)
[Creatinine Test Strips](#)
[Erythrocyte Sedimentation Rate \(ESR\) Test Kits](#)
[Gastric Occult Blood and Gastric pH Test Kits](#)
[Gastric pH Test Kits](#)

- [Glucose Test Kits](#)
[Helicobacter pylori Antibody Kits](#)
[Helicobacter pylori Urease Test Kits](#)
[Influenza A, B Test Kits](#)
[Ketone Test Kits](#)
[Lyme Disease \(Borrelia\) Test Kits](#)
[Menopause and Fertility Impairment \(FSH\) Test Kits](#)
[Microalbumin Urine Test Kits](#)
[Mononucleosis Antibody \(MONO\) Test Kits](#)
[Ovulation "Fern" Test Kits](#)
[Ovulation \(Luteinizing Hormone\) Test Kits](#)
[Rapid HIV-1/2 Antibody Tests](#)
[Vaginal pH and Amine Test Kits](#)

- **Point-of-Care (POC) Diagnostic Devices**

[Albumin Analyzers](#)
[Bench-Top Clinical Chemistry Analyzers](#)
[CO-Oximeter](#)
[POC C-Reactive Protein \(CRP\) Analyzer](#)
[POC Cardiac Marker Analyzers](#)
[POC Coagulation Analyzers \(PT and INR\)](#)
[Point of Care \(POC\) Creatinine Monitors](#)
[Point of Care Albumin Creatinine Ratio \(ACR\) Analyzers](#)
[Pulse CO-Oximeters](#)



**POCT has to be accompanied
by
POCI**

ASCLS recommendations

ASCLS : American Society for Clinical Laboratory Science

POCT Pivotal role

- Instant result sharing
- Software interface enhancing communication
- Decreasing TAT
- Quick decision making
- Intervention
- Revision of treatment

Why has POCT re-emerged ?

- New health care trends
- Rising health costs
- To decrease hospital stay
- Movement from inpatient to outpatient or ambulatory settings

All want quick bedside results

Present scenario

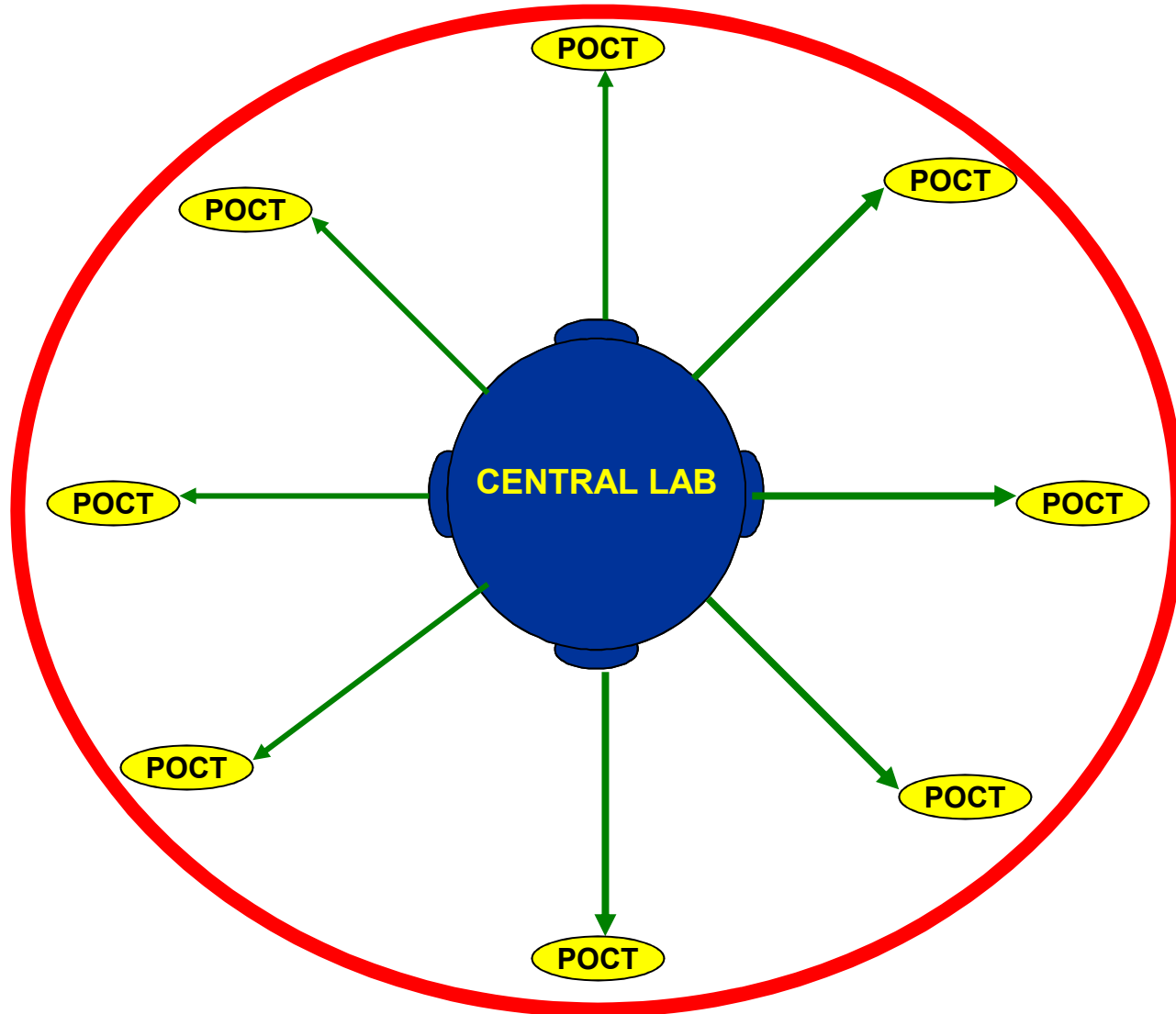
HOSPITALS

Treatment Centres
for acutely ill

Don't serve as
Diagnostic Centres

- Rapid advances in automation & technology

HUB & SPOKE MODEL



Is it possible to maintain quality test result ?

- While achieving shorter TAT
- Lowering costs through faster discharges
- Personnel shortage

Solution

POCT

Success of POCT

When all futuristic steps are backed by
QC & QA

POCT Package

- TQA plan
- POCT ownership
- POCT committee

POCT Quality

Right test with accurate results in
shortest possible time

Tailored QC programmes

Check the system as a whole

Switching over to POCT

Not easy

Are we ready for the challenge

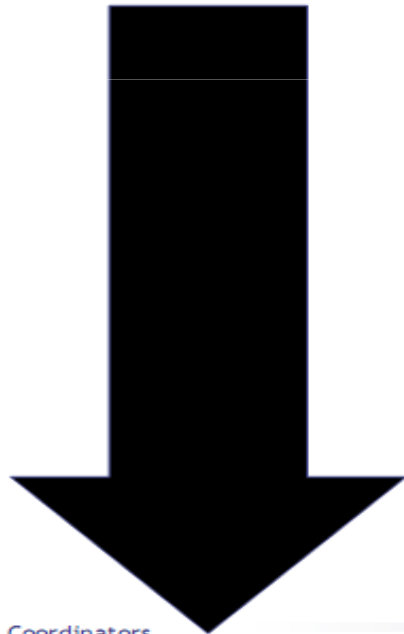


مہاجر شہداء کے ہاہر لٹاؤ جو کہ موقع پر کسی ہاؤسنگ اور واقعہ سے منسلک کیلئے پولیس اپکار اور بیڑ کی بجائے چار پائی لگا کر راستہ روکے گا ہے

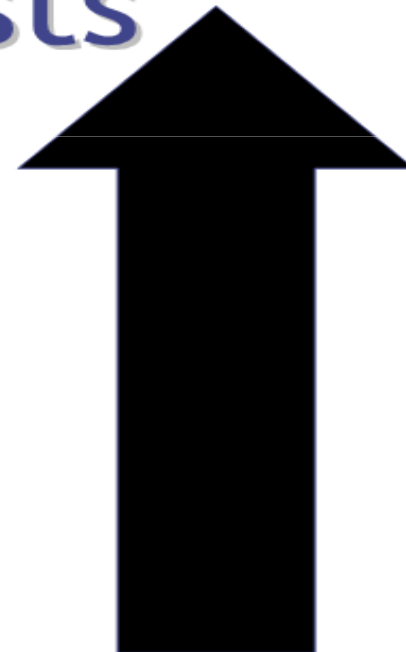
Technology can benefit quality

Laboratory Trends

Profits



Costs



- **Cost of instruments / reagents**
- **Hidden cost of accredited lab support**
- **Cost of training**
- **Device management**

POCT has changed the

- Testing site
- Technology
- personnel



QC Issues

- Central lab versus POCT
- Limited number of samples
- Discontinuous nature of testing process
- Pre-analytical quality assurance

POCT Audit

- All POCT results must be able to pass an audit i.e., the results be traced to:
 - The patient
 - The operator
 - The machine or process used
 - Relevant maintenance & QC logs
 - Date & time
 - Current competency record of operator
- All POCT must be quality controlled regularly

QC & QA

- Day to Day QC
- EQA (external quality assurance)
monthly
- PT (proficiency testing)

Accreditation

- Better quality
- Efficient POCT services
- Faster diagnosis
- Rapid treatment

How does hospital benefit from POCT

- Ability to process tests on site
- Printed lab style reports
- Saves staff time
- Reduces time spent chasing up / sorting results
- Eliminates transcription errors
- Immediate clinical decision
- May reduce extended length of stay

Where are we today ?

- My Hospital
- My POCT
- Tertiary care hospital of Provincial government

On the contrary

Reduction in morbidity and mortality with GDT(goal directed therapy) techniques has improved patient care in conjunction with POCT and EMR (electronic medical record)

Future of POCT

The new directions

Global markets & trends



- POCT market predictions estimate **10 Billion Dollar** market by the end of year 2010
- US national science foundation estimates **1 Trillion Dollar** annual global market for nano-related services by year 2015

“In the near future a large percentage of diagnostic testing will be done in front of the patients and not in the centralized labs, but this doesn't mean that high throughput laboratory testing is dead ”

Dr Simon Burnell ; Campaign managers at Cambridge

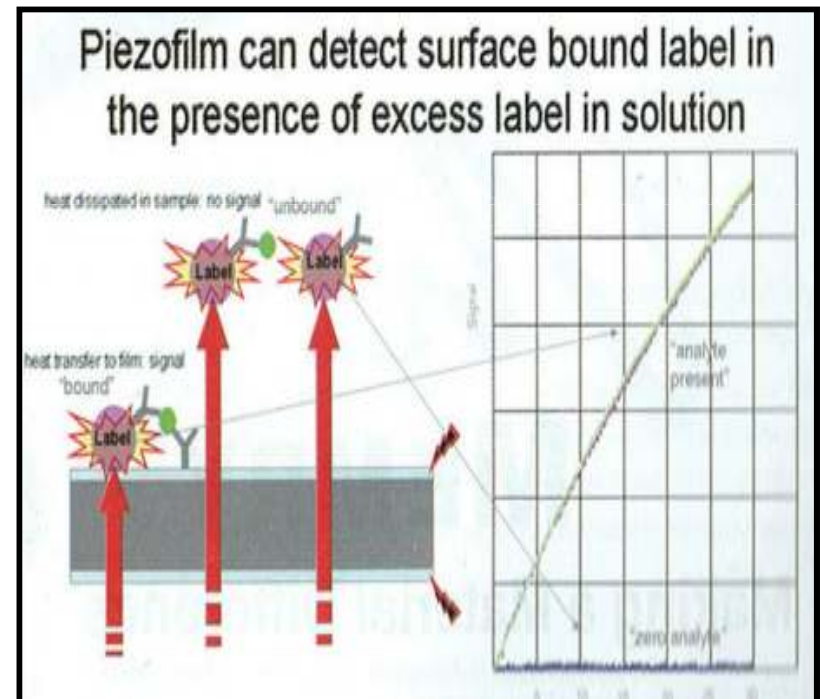
Low time-to-result

- **Magnetec Biosensor technology**
- **Single drop of blood**
- **Detailed biomarker detection / measurement**
 - **magnetic nanoparticles**
 - **measurement of target molecules**
 - **picomolar concentration**



Piezofilm technology

- 30 ul whole blood
- Result : 5 - 10 minutes



Lactate Monitors

- Miniaturized device(ear-clip)
- Nanopotentiostst based German techonology
- Result signal reception
 - Wrist watch
 - Cell phone



Temperature detection fabric

- Colour changing fabric
- Standard temperature threshold
- Fruit of
 - 6 years hard work
 - 700000 Pounds



Fitbit

- Miniaturized device
- 3 D motion sensor
- Tracks patterns of
 - Physical activity
 - Calories consumed
 - Sleep
- Data uploaded & synchronized



Digital Plaster



- Vital sign monitor
 - Acute care
 - Tele care
 - Chronic disease monitoring
- NSP (Nano sensor protocol)
- Continuous monitoring
- Wireless transmission
 - Temperature
 - Heart rate
 - Respiratory rate



Piccolo Express Analyzer

- Specialized POCT instrument
- Wide range of chemistry tests



Photon based Analyzers

- **Minimally invasive monitoring**
- **Critical / emergency care**
- **Capable of detecting**
 - **Cardiac biomarkers**
 - **Metabolites**
 - **vitals**

Lab in a drop

- Pocket sized PCR device
- Magnetic Nanoparticle technology
- Rapid test
- Sample processing



ABBOT i - stat

- Biosensor & advance micro fluidics technology
- Portable TRUE POCT analyser
- Sample requirement :
65 - 95 ul blood
- Result : within 2 minutes



Living chip

- No more blood draws
- Implantable tiny device
- Early detection
 - Physiologic changes
 - Chemical changes
- Fast
- Accurate
- Non-invasive testing



CONCLUSION