DISASTER POINT OF CARE TESTING: FUNDAMENTAL CONCEPTS TO ENHANCE CRISIS STANDARDS OF CARE

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[Disclaimer: Device use must adhere to federal, national, and state regulations within the context of appropriate accreditation. Illustration of devices, including suggestions for disaster caches, does not imply endorsement. Research results may be preliminary. Final conclusions may differ. Please consult published papers.]

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Please visit our YouTube site at http://www.youtube.com/POCTCTR
http://www.ucdmc.ucdavis.edu/pathology/poctcenter/
LEARNING OBJECTIVES

• To understand the role of needs assessment in formulating point-of-care (POC) resources for complex emergencies and disasters.
• To become familiar with environmental factors that can affect diagnostic testing performance.
• To prepare the POC Coordinator for crisis leadership in small-world networks.
• To gain knowledge that will enhance crisis standards of care, prepare the audience to comment on new guidelines, and help adapt them to local, national, and global needs.
• To learn about POC disaster caches and interactively design contents, plan use, and deploy successfully.
THE GLOBAL VISION

“Point-of-care testing will improve crisis standards of care,* disaster preparedness, and at the same time, healthcare in small-world networks.”

*The fundamental concept of the standard of care is based on the US case, *Vaughan v Menlove* (1837), wherein the judge instructed the jury to reason whether the defendant “proceed[ed] with such reasonable caution as a prudent man would have exercised under such circumstances.”

Point-of-Care Testing (POCT)

• **Definition**
  
  *POCT is medical testing at or near the site of care.*

• **Fundamental Goals**
  
  **Significance** Identify critical diagnoses, screen quickly
  **Evidence** Produce test results for decision-making
  **Speed** Accelerate triage and treatment
  **Approach** Enhance response using new technologies
  **Impact** Improve medical and economic outcomes

**Resources**

3. *Point of Care*—the primary journal in the field, 11th year of production.
PRINCIPLES: 3 FUNDAMENTALS—SOLUTION, BALANCE, EFFICIENCY

- **Solution:** Past disasters demonstrate the role and feasibility of using POC testing.

- **Balance:** Needs assessment guides POC invention, innovation, and technology development.

- **Efficiency:** POC test clusters allow “mission matching”—one can select instruments and tests for triage, diagnosis, treatment, and/or monitoring.
PRINCIPLES: 3 LEVELS—EVIDENCE, INTEGRATION, SYNTHESIS

• **Evidence**: POC technologies enable evidence-based decision-making at the point of need.

• **Integration**: Strategic planning optimizes small-world networks where healthcare teams and patients become experienced with POC testing through education, training, and everyday use.

• **Synthesis**: Value propositions generate tactics for placing POC testing appropriately in physical, demographic, and geographic settings, and for designing disaster caches (e.g., USA).
Past disasters demonstrate the role and feasibility of using POC testing.

Examples—

– Hurricane Katrina in New Orleans, 2005
– Bangkok Flood, 2011
– Hurricane Sandy in New York, 2012
Shelters: Acute Monitoring, Chronic Diseases, and Public Health

OraQuick ADVANCE
HIV-1
HIV-2

Onyx II
Pulse Oximetry

StatStrip Glucose

[Images of shelters with various medical equipment and people]
NEWDEMICS: The Future is now!

Definition: “Unexpected and disruptive problems that affect the health of large numbers of individuals in a crowded world.”

World population is 7 billion, 7 million children who did not exist found in China (parents hide children), humans reproduce at a rate of 25,000 every 10 seconds, first UN count started with 2.5 billion in 1950, & expect 9 billion in 2050, slowing to 10 billion by 2100.

Flood perils and tests: contamination (Leptospirosis, fungi), bites (centipedes, reptiles, crocodiles), infections (Hepatitis A, E. Coli, Staphylococcus endotoxin, enteroviruses, typhoid fever, cholera, poliomyelitis, malaria, Dengue fever), and stress (e.g., chest pain in ERs in Queensland, Australia--R/O AMI).

References
PRINCIPLE #2

Needs assessment guides POC invention, innovation, and technology development... ...but as Henry Ford said, “If I had asked people what they wanted, they would have said a faster horse!”

References
Quote:
Respondents preferred disaster-ready POC devices that sample blood directly into a test cassette, which stores all biohazard material for easy disposal.

When asked to explain, they said minimize contamination when performing infectious disease testing outside of the laboratory.

Respondents also wanted to draw a single sample and have multiple testing options to fully evaluate each patient.

They wanted fast results, battery operation, handheld devices, and high sensitivity testing that they could perform themselves.

PRINCIPLE #3

POC test clusters allow “mission matching”—one can select instruments and tests for triage, diagnosis, treatment, and/or monitoring…but devices and reagents must be operated within environmental tolerances and legal constraints specified by the manufacturer.
<table>
<thead>
<tr>
<th>Function/Target</th>
<th>Point of Care Pivot(s) or Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Energy</td>
<td>Glucose, β-hydroxybutyrate</td>
</tr>
<tr>
<td></td>
<td>Hemoglobin</td>
</tr>
<tr>
<td></td>
<td>pO₂, O₂ saturation</td>
</tr>
<tr>
<td>Conduction</td>
<td>Potassium</td>
</tr>
<tr>
<td></td>
<td>Sodium</td>
</tr>
<tr>
<td></td>
<td>Ionized calcium (free calcium, Ca^{2+}), ionized magnesium (Mg^{2+})</td>
</tr>
<tr>
<td>Contraction</td>
<td>Ionized calcium, ionized magnesium</td>
</tr>
<tr>
<td>Perfusion</td>
<td>Lactate</td>
</tr>
<tr>
<td>Acid-Base</td>
<td>pH</td>
</tr>
<tr>
<td></td>
<td>CO₂ content (TCO₂), pCO₂</td>
</tr>
<tr>
<td></td>
<td>End-tidal CO₂ tension</td>
</tr>
<tr>
<td></td>
<td>Bicarbonate (calculated HCO₃⁻)*</td>
</tr>
<tr>
<td>Osmolality</td>
<td>Measured osmolality</td>
</tr>
<tr>
<td></td>
<td>Calculated osmolality</td>
</tr>
</tbody>
</table>
# Crisis Care Profile

<table>
<thead>
<tr>
<th>Function/Target</th>
<th>Point of Care Pivot(s) or Rationale</th>
</tr>
</thead>
</table>
| Hemostasis      | Hematocrit, hemoglobin
                | Prothrombin time (PT), international normalized ratio (INR)
                | Activated partial thromboplastin time (aPTT)
                | Activated clotting time (ACT)
                | D-dimer
                | Platelet count and function (thromboelastogram) |
| Homeostasis     | Creatinine, urea nitrogen
                | B-type natriuretic peptide (BNP)
                | Chloride, inorganic phosphate
                | White blood cell count, hemoglobin E, fragility (thalassemia)
                | Co-oximetry variables |
| Biomarker       | Cardiovascular risk (cholesterol, HDL, LDL, tryglycerides; CRP, hs-CRP)
                | Bone formation (bone-specific Alk Phos)* and resorption (NTx)*
                | Cancer (prostate-specific antigen, urine NMP22– bladder cancer)
                | Cardiac injury (troponin I/T, myoglobin, CK-MB mass/isoforms)
                | Endocrine (intraoperative parathyroid hormone)
                | Trauma (S100 [brain injury marker]) |
| Sepsis          | Lactate, procalcitonin*, C-reactive protein* |
## Crisis Care Profile

<table>
<thead>
<tr>
<th>Function/Target</th>
<th>Point of Care Pivot(s) or Rationale</th>
</tr>
</thead>
</table>
| **Birthing**          | Prenatal testing (*glucose, urine protein, sexually transmitted diseases*)  
Antenatal screening (genetic disorders)  
Delivery monitoring (fetal heart rate, group B *Streptococcus*) and transcutaneous neonatal bilirubin, pO₂, and pCO₂                                                                 |
| **Women’s Health**    | Fertility (*FSH*)  
Pregnancy (*β-hCG*)  
Bone resorption (*NTx)*  
Human papillomavirus*  
Cervical cancer*                                                                                                                                  |
| **Emergency Blood Donor Screening** | HIV-1/2, Hepatitis B, and Hepatitis C                                                                                                                                                                                               |
| **Transfusion**       | ABO blood typing, Rh class                                                                                                                                                                                                         |
| **Infectious Disease**| HIV-1/2, *H. pylori*, Vibrio cholerae, leptospirosis, Dengue, *others*—rapid Dx-Rx with multiplex assays  
Primary care, public health, surveillance—prevention and control                                                                                         |
| **Influenza Pandemic**| *Influenza A, influenza B*, and subtypes (H1N1, 2009 H1N1, H3, H5N1)  
Drug resistance (oseltamivir, zanamivir, amantadine, rimantadine)                                                                                          |
### Crisis Care Profile

<table>
<thead>
<tr>
<th>Function/Target</th>
<th>Point of Care Pivot(s) or Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Epidemic</strong></td>
<td>Cholera (stool test, rectal swab)</td>
</tr>
<tr>
<td></td>
<td>Tuberculosis (PPD skin test)</td>
</tr>
<tr>
<td></td>
<td>Avian influenza* (FDA emergency use authorization, EUA)</td>
</tr>
<tr>
<td><strong>Newdemic</strong></td>
<td>Diabetes: glucose, hemoglobin A1c, estimated average glucose (eAG), urine albumin to creatinine ratio (ACR), fructosamine*</td>
</tr>
<tr>
<td><strong>Biothreat</strong></td>
<td>Anthrax, botulism, plague, tularemia, Ebola, West Nile</td>
</tr>
</tbody>
</table>

An asterisk ("*") indicates that a POC test is needed or in development. CLIA-waived test are indicated by the green lettering.

## Point-of-Care Device Requirements for Simplicity

<table>
<thead>
<tr>
<th>Knowledge</th>
<th>Training and Experience</th>
<th>Reagents and Materials Preparation</th>
<th>Characteristics of Operational Steps</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimal scientific and technical knowledge is required to perform the test; and Knowledge required to perform the test may be obtained through on-the-job instruction.</td>
<td>Minimal training is required for preanalytic, analytic and postanalytic phases of the testing process; and Limited experience is required to perform the test.</td>
<td>Reagents and materials are generally stable and reliable; and Reagents and materials are prepackaged, or premeasured, or require no special handling, precautions or storage conditions</td>
<td>Operational steps are either automatically executed (such as pipetting, temperature monitoring, or timing of steps), or are easily controlled</td>
</tr>
</tbody>
</table>

## Calibration, Quality Control, and Proficiency Testing Materials
- Calibration materials are stable and readily available; Quality control materials are stable and readily available; and External proficiency testing materials, when available, are stable

## Test System Troubleshooting and Equipment Maintenance
- Test system troubleshooting is automatic or self-correcting, or clearly described or requires minimal judgment; and Equipment maintenance is provided by the manufacturer, is seldom needed, or can easily be performed

## Interpretation and Judgment
- Minimal interpretation and judgment are required to perform preanalytic, analytic and postanalytic processes; and Resolution of problems requires limited independent interpretation and judgment

Temperature Extremes in Disasters

Hurricane Katrina¹, 2005

Temp: 20 to 43.3°C


Haiti Earthquake², 2010

Temp: 20 to 35°C

² Cavallo EA, et al. Inter-American Development Bank. 2010

Japan Earthquake³, 2011

Temp: -5 to 20°C

³ http://www.npa.go.jp/archive/keibi/biki/higaijokyo_e.pdf
Point-of-need Challenges

• During Hurricane Katrina new shipments of POCT failed after one week of use. (43.3ºC)

• In Springfield, Massachusetts, paramedics complained that cold temperatures caused glucose meter systems to shutdown during emergency response. (<12.8ºC)

• In Port-au-Prince, Haiti, i-STAT whole blood analyzers were inoperable due to high temperatures. (35ºC)

3) Case Study, Courtesy of Dr. James Nichols, Baystate Health, Springfield, MA
Hot, Cold, and Humid Profiles

Banda Aceh, Indonesia

Hurricane Katrina, New Orleans

Springfield, Massachusetts

Port-au-Prince, Haiti
Environmental Stress Testing

- POC Reagent Test Strips & Cartridges
- Environmental Stress Testing Chamber & Profile
- Evaluate Test Strips & Cartridges
- Tenney T2RC

- Facilitate Device Design
- Enhance Development of Disaster Guideline

Hurricane Katrina
Environmental Stress Testing

**Thermal stress and point-of-care testing performance: Suitability of glucose test strips and blood gas cartridges for disaster response**

**Conclusions:** The performance of glucose test strips and blood gas cartridges was affected adversely by thermal stresses. Heating generated elevated results, and cooling depressed results. Disaster medical assistance teams and emergency medical responders should be aware of these risks. Field POCT devices must be robust to withstand adverse conditions. We recommend that industry produce POCT devices and reagents suitable for disaster medical assistance teams.


**Ensuring quality control of point-of-care technologies: effects of dynamic temperature and humidity stresses on glucose quality control solutions**

**Conclusions:** Dynamic stresses affected the performance of QC solutions and, consequently, results given by GMS1 and GMS2. To protect the efficacy and accuracy of POC technologies in emergency and disaster settings, proper monitoring, handling, and storage of QC reagents must be assured.


**Preliminary evaluation of a point-of-care blood gas-electrolyte analyzer potentially robust in cold during emergencies and disasters: Evidence from evaluation of reagents in stress testing chambers**

**Conclusions:** The epoc test cards do not appear to be affected significantly by the dynamic cold conditions observed during the 2011 Great East Japan Earthquake. Therefore, use of epoc blood gas systems may be feasible and should be explored with field trials.


**Effects of Dynamic Temperature and Humidity Stresses on Point-of-Care Glucose Testing for Disaster Care**

**Conclusions:** The duration of dynamic stress affected the performance of both GMS1 and GMS2 glucose test strips. Therefore, proper monitoring, handling, and storage of point-of-care (POC) reagents are needed to ensure their integrity and quality of actionable results, thereby minimizing treatment errors in emergency and disaster settings.

Japan—A Cold Disaster!

- Magnitude 9.0 earthquake followed by tsunami and nuclear accidents on March 11, 2011
- Over 15,000 deaths and more than 125,000 buildings damaged or destroyed
- About 80 percent of the combined 380 hospitals in Iwate, Miyagi, and Fukushima prefectures were completely or partially incapacitated
- The temperature dropped to -5°C
- Scheduled power outages caused problems for the medical institutions in the disaster area
- POCT was not adequately prepared

1 http://www.npa.go.jp/archive/keibi/biki/higaijokyo_e.pdf
2 http://search.japantimes.co.jp/cgi-bin/nn20110609a1.html
3 National Climate Data Center
4 http://www.med.or.jp/english/report/20110324.html
Epoc Blood Analysis System

- Handheld device heats test cards to 37°C before measurements are performed

- Test cluster includes pH, pCO₂, pO₂, Na⁺, K⁺, Ca++, glucose, and hematocrit

- Storage temperature for test cards is 15-30°C
Thermomodulating Container

1st Generation container

Wiring Schematic

Figure 2: Rust MJ, Carlson NA, Nichols JH. A thermo-modulating container for transport and storage of glucose meters in a cold weather environment. *Point Care*. 2012;11:157-160.
POC technologies enable evidence-based decision-making at the point of need...and also can transfer ownership for personalized medicine there!
MMU Regional Span in Province SWN

Legend
- MMU Service Areas
- Naresuan University
Mobile Medical Unit (MMU): Rural Thailand
Empirical Judgment -> POCT -> Evidence-based Medicine
MMU Ownership and Empowerment
POC Testing is Adaptable and Transferable

......at a local Aboriginal Women’s Centre in Australia

... in a tin shed !!!
HbA1c & Lipid Profile—Cobas 101
Point of Care Culture—The Final Frontier!

*Point of care (POC) culture* is medical empowerment of the individual and family nucleus integrated with norms, behaviors, beliefs, attitudes, expectations, technology, and outcomes.

PRINCIPLE #5

Strategic planning optimizes small-world networks where healthcare teams and patients become experienced with POC testing through education, training, and everyday use.
Roadmap of Khon Kaen Regional Hospital and Heart Center Referral System in Isaan, Northeast Thailand.

Small-World Network Integration

Orange: SWNs
Green: Route to Khon Kaen Heart Center
Red: Ambulance connector
Small-World Networks…

…are “like your family and friends…you have fun and work with them every day, and in times of need, you call on them for assistance!”

Examples—six degrees of separation between people, social influence networks, food chains, electric power grids, airline flights, and road maps.

Attributes—most network nodes connected by at least one short path, over abundance of hubs with high number of connections, and common connections mediating short path lengths between edges.

Features—develop demographically, match geography, interconnect regionally, reveal health resource disparities, and guide POCT allocations.
Value propositions generate tactics for placing POC testing appropriately in physical, demographic, and geographic settings.

Corollary
If POC testing does not impact decision-making or add value, then do not use it!
Value Proposition
Reduce Therapeutic Turnaround Time (TTAT) to Speed Critical Paths

Evidence-based research shows that POC testing and \textit{in vivo} monitoring decrease TTAT. Fast TTAT improves field and emergency room patient triage, treatment, and transfer, which observers deemed important during the Thai Tsunami response. Thus, rapid TTAT adds value and preparedness to the SWN.
Monitoring $O_2$ Saturation and Hemoglobin

Cordless, Fingertip Post-Tsunami, Thailand (Nonin Onyx II 9550)

O2 Pulse Oximeters for adult and neonate (Nellcor OxiMax N-600x)

Embedded Printer (BCI FingerPrint)
Pulse Oximeter with Bluetooth Module (Alive Pulse Oximeter)

plethsmograph variability index hemoglobin
carboxyhemoglobin methemoglobin perfusion index
(Masimo Rad-57)

wireless connectivity perfusion index hemoglobin
(Masimo Pronto 7)

Value Proposition
Optimize Practitioner Experience with POCT

Tactical POCT should—

• complement healthcare delivery resources,
• fulfill needs for simultaneous emergency care and disaster preparedness, and
• match geographic isolation, current or anticipated.

Therefore, routine daily use of POCT assures the high quality of trained operators, who become “POC Coordinators” and integrate POCT within and between small-world networks.
POC Coordinator preparedness, post-disaster functions, leadership roles, duties, and telecertification

Operators
QC
Products/Devices

Test Site Management
Test Site ‘Compliance’
Standards & Regulations

Audit QC and patient results in EMR
Re-certification/validation
Support – coaching and troubleshooting
Initial training/competency validation, update operator database

Maintenance of instruments

Other: Industry liaison, technology advisor, coordinates & conducts lab studies, handles product recalls & alerts, Chair or representative for institutional committees, networks on behalf of institution, publishes & contributes to professional societies and listserves

POCC Manager & Leader

Implementation

Formulary

Training-Competency Validation

Test Menu
Pre- and post-disaster

- POC A1c
- POC Hct
- POC Creatinine
- POC Hgb
- POC Glucose
- POC INR
- POC Occult Blood
- POC Rapid Streps
- POC Rapid Flu
- POC UA
- POC Urine hcg
- Non-invasive Bilirubin (Clia Exempt)

Essential Skills of the POC Coordinator for Readiness

• Perform needs assessment in advance of a crisis
• Participate in writing the emergency plan
• Periodically drill the emergency plan ➔ assess response ➔ revise plan
• Do annual “gap analysis” to identify and eliminate weak preparedness areas of high risk
• Communicate with surrounding communities in the small-world network and regionally
• Guarantee the competency of operators who respond outside the hospital
• Outline what is the process, who is in charge, and where is the command center
Essential Skills of the POCC (cont.)

• Include offsite training programs, telecertification, and validation

• Examine requirements such as power, durability, scan functions, and victim identification

• Standardize supplies for interchangeability during responses

• Consider the impact of environmental conditions on supplies and test performance

• Assess periodically the quality control of materials in caches

• Solve problems and troubleshoot

• Alert colleagues to username and password preservation and accessibility
Essential Skills of the POCC (cont.)

• Adapt resources to meet the needs of health care teams in the field

• Be mindful of regulatory requirements and any practice exceptions that occur

• Connect test results with the electronic medical record in real time and after the event

• Preplan using a reference laboratory and the supply chain for specimen transport

• Conduct table top all hazards disaster and pandemic isolation drills

• Maintain personnel, government agencies, and industry contact lists

• Practice communicating via text, long-range radios, and analog phones
Emergency Plan

1. Written plan
2. Event or Drill
3. Document effectiveness or corrective action needed
4. Drill plan to include changes
5. If ‘pass’, accept changes
6. Revise plan with changes

Value Proposition
Use POC Testing in High Impact Sites During Emergencies and Disasters

**Physical:** Community hospitals, alternate care facilities, and shelters

**Demographic:** Rural areas, primary care, and regions with poor health resource scores

**Geographic:** Healthcare systems with challenging regional topographies at high risk of isolation
CONCLUSIONS AND IMPACT!

- Point-of-care coordinators can and should take responsibility for proper training, quality assurance, and test performance that will enhance standards of care, both routinely and during crises.

- Needs assessment and research a) describe point-of-care designs for emergency and disaster settings, b) reveal which devices and reagents can be used in different climates, and c) identify test clusters necessary for critical decision-making.

- Regardless of location, innovative point-of-care technologies empower people for personalized medicine and evidence-based practice, even under dire circumstances, and therefore, should be harmonized globally.

- Small-world networks + flexibly equipped hubs + strategically placed POC testing *create value*, that is, efficient urgent-emergency care, cost-effective disaster preparedness, and appropriate national disaster caches.

- The *Emergency and Disaster POC Testing* CLSI guideline (POCT15) soon will be available for public comment, so please review and contribute!
National Disaster Caches: United States

We recommend enhancing US disaster point of care caches. Consider what resources should be available in other countries! We recommend that country caches be harmonized globally, accompanied by free Web tutorials for operator competency.
Lab Basic
[Briefcase ≤ 50 lbs]

- i-STAT® with 25 Chem 8+ and 25 G3+ Cartridges
- 5 Pregnancy Test Strips
- 1 Box of CLINITEK® Urinalysis Test Strips
- 5 LifeSign® MI Cartridges (Qualitative)
- OneTouch® Ultra®
Value Proposition for POC Cardiac Biomarker Testing

![Diagram showing the AUGMENTED VALUE process leading to KNOWLEDGE OPTIMIZATION through various stages including High Clinical Risk, Problem-Focused Strategy, Small-World Networks, and Early Treatment Cost-Effectiveness Improved Outcomes.](image-url)
POC and NPT for Acute Coronary Syndrome

- **i-STAT** [1.4 lbs (0.6 kg)]
  - Abbott Laboratories
  - cTnI, CK-MB, BNP

- **Cobas h232** [1.4 lbs (0.6 kg)]
  - Roche Diagnostics
  - cTnT, NT-proBNP, CK-MB, Myoglobin, D-Dimer
  - (Not available in USA)

- **RAMP® Reader** [4.6 lbs (2.1 kg)]
  - Response Biomedical
  - cTnI, NT-proBNP, CK-MB, Myoglobin, D-Dimer

- **Triage® MeterPro** [1.5 lbs (0.7 kg)]
  - Alere™
  - cTnI, BNP, CK-MB, Myoglobin, D-Dimer

- **PATHFAST®** [72.8 lbs (33 kg)]
  - Mitsubishi Chemical USA, Inc.
  - cTnI, NT-proBNP, CK-MB, Myoglobin, hsCRP, D-Dimer

- **mini VIDAS®** [88 lbs (39.9 kg)]
  - bioMérieux
  - cTnI, NT-proBNP, D-dimer, Procalcitonin

- **AQT90 FLEX** [77.2 lbs (35 kg)]
  - Radiometer
  - cTnI, cTnT, NT-proBNP, CK-MB, Myoglobin, D-dimer, CRP, βhCG

- **Stratus® CS** [150 lbs (68 kg)]
  - Siemens
  - cTnI, NT-proBNP, CK-MB, Myoglobin, D-Dimer, hsCRP, βhCG
## POC Cardiac Troponin I Sensitivity

<table>
<thead>
<tr>
<th>Device</th>
<th>Limit of Detection (ng/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mitsubishi PATHFAST®</td>
<td>8</td>
</tr>
<tr>
<td>Alere Triage®</td>
<td>10</td>
</tr>
<tr>
<td>Abbott i-STAT</td>
<td>20</td>
</tr>
<tr>
<td>Response Biomedical RAMP® Reader</td>
<td>30</td>
</tr>
<tr>
<td>Siemens Stratus CS</td>
<td>30</td>
</tr>
<tr>
<td>Roche Cardiac Reader</td>
<td>30 (cTnT Semi-Quantitative)</td>
</tr>
<tr>
<td>Roche Cobas h232</td>
<td>50 (cTnT Semi-Quantitative)</td>
</tr>
<tr>
<td>LifeSign MI®</td>
<td>1,500 (Qualitative)</td>
</tr>
</tbody>
</table>
Lab Basic Included

Lab Plus Package [~400 lbs]

Rapid tests for: Strep Throat, Mono, and D-dimer

- Hemoccult Immunochemical Chromatography Test
- Piccolo Chemistry Analyzer General Chem 13 Liver Panel
- PT/INR Cartridge (i-STAT)
- Coulter AcT diff 2
- Triage TOX Drug Screen
- Clinitek 50 Urine Analyzer
New Hematology Device
Ativa MicroCBC

- Three detection methods:
  - optical light scatter
  - colorimetric
  - electrochemical

- Single-use disposable test cards

Reference: www.ativamed.com
MicroCBC Technology

CBC results in 3-5 minutes

- Microfluidic flow control through channels sandwiched between two plastic plates.

Reference: www.ativamed.com
Value Proposition
Assess POC Testing in Context

Critical information has value exceeding the costs of tests. Physicians assign high value because test results impact decisions. Nurses assign higher value than laboratorians. Speed has value, and often is life-saving. Patient self-care and responder welfare garner value as well! Total value depends on the sum of benefits minus costs—

Value = Σ [Benefits – Costs]
Disaster Point of Care

- **i-STAT® 1 Wireless** with G3+ (blood gases), Chem 8+ (Electrolytes), PT/INR and cTnI Cartridges
- **Sure-Vue® Urine hCG Cartridge**
- **Oraquick ADVANCE® HIV 1/2**
- **Onyx® II 9560 Fingertip Pulse Oximeter**
- **MicroCBC: RBC, WBC, neutrophil, lymphocyte, monocytes, Hb, PLT, MPV and MCV Hematology Analyzer (investigational use only)**
- **Hemoccult®-Immunochromatographic Fecal Occult Blood Test**
- **Hemoccult® ICT**
- **QuickVue® Influenza Test**
- **CLINITEK® Urinalysis:** Alb, Blood, Crea, Ketone, Leukocyte, Nitrite, pH, Protein, Alb to Crea ratio and Protein to Crea ratio
- **Min-Max Temp**
- **Triage® Drugs of Abuse Test Card**
- **Statstrip** Glucose, Lactate, β-hydroxybutyrate and Creatinine
- **Masimo Rad-57™ Oxygen Saturation, Hgb plus pediatric probes**
Point-of-care “Clusterettes”—Customized for Decision-Making

- Disaster Point of Care
  - Radiation exposure—detection, monitoring, and treatment
  - Crush Injury—electrolytes, hct/hgb, creatinine (renal failure)

- Infectious Diseases/Pandemic
  - MRSA, *S. aureus*, influenza (H7N9, “SARS-like” virus)

- Chemical and Biothreats
  - Anthrax, Tularemia, nerve agents

- Alternate Care Facility
  - Whole-blood analysis—multiplex blood gases, pH, Hct/Hgb, and electrolytes, including Ca\(^{+2}\)
  - Glucose, Glu/βOH butyrate, creatinine, lactate

- Imaging
  - Portable ultrasound
WHAT DO YOU THINK IS MISSING?
NEW YORK CITY HEALTHCARE WORKERS:
H7N9—128 cases, 27 dead; SARS-like—30, 18 (May 7)
New Influenza POC Device

- Automated
- Integrated POC platform for molecular diagnostic testing
- Influenza subtyping
- Antiviral resistance testing (i.e., Tamiflu)

Provided Courtesy of David Kelso at Northwestern University & Karen Kaul at NorthShore University Health System
Novel Design
Alternate Care Facility

...what is missing?

Point-of-Care!

Test Clusters and Isolation

Disaster setting and bloodstream infections
MRSA, *Salmonella typhi*, *Vibrio cholerae*, *E. coli*, *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Streptococcus pneumoniae*, and carbapenem-resistant enterobacteriaceae (*POC* 2012;11:119)

Whole-blood analysis
Electrolytes and blood gases (Cobas b123), viruses

Blood donor screening
HIV, Hepatitis B and C virus (*POC* 2012;11:119)

CONCLUSIONS AND IMPACT!

• Point-of-care coordinators can and should take responsibility for proper training, quality assurance, and test performance that will enhance standards of care, both routinely and during crises.

• Needs assessment and research a) describe point-of-care designs for emergency and disaster settings, b) reveal which devices and reagents can be used in different climates, and c) identify test clusters necessary for critical decision-making.

• Regardless of location, innovative point-of-care technologies empower people for personalized medicine and evidence-based practice, even under dire circumstances, and therefore, should be harmonized globally.

• Small-world networks + flexibly equipped hubs + strategically placed POC testing create value, that is, efficient urgent-emergency care, cost-effective disaster preparedness, and appropriate national disaster caches.

• The Emergency and Disaster POC Testing CLSI guideline (POCT15) soon will be available for public comment, so please review and contribute!
Guidelines (recent & in progress)
Clinical and Laboratory Standards Institute

- POCT10-A2. 31;24. Physician and Nonphysician Provider-Performed Microscopy Testing
- POCT11-A2. 31;9. Pulse Oximetry
- POCT12-A3. [in progress] Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities
- POCT14-P. [in progress] Point-of-Care Testing for Infectious Diseases
- GP36. [in progress] Planning for Laboratory Operations During a Disaster
Sarah Brown, PhD, Symposium Chair
“Clinical Chemistry in Disaster Response and Resource-Poor Environments”

Dr. Kost, Speaker
“The Use of Small-World Networks and Technological Advances in Point of Care for Disaster Preparedness, Response, and Resilience”

Two Other Speakers
Carla Orner, MBA, MT, of Heart-to-Heart International, will present her experience with mobile laboratories in the U.S. and with quality assurance initiatives in Haiti. Sarah Halcomb, MD, will speak about test utilization by emergency physicians in disaster response and low-resource settings, share examples of what was available after the Haiti earthquake, and contrast them to ideal laboratory support.

Session 32214, Monday, July 29, 2:30 - 5:00pm
George R. Brown Convention Center


