

Cepheid Molecular Diagnostics

Delivering A Better Way



 **Cepheid®**
A better way.

Agenda

Company Overview

A Better Way

What It Means for Your Institution

Why partner with Cepheid?

Closer Look at Current Tests

An Established, Innovative Company

+550 Employees

Including 120 R&D Scientists

11

CE-IVD Tests

+60 Countries

with a Distribution Presence

+9 Years

as a Public Company

**1,375 GX
worldwide**

9

FDA Cleared Tests

+8 Million

Anthrax tests with no false positives; only technology selected by gov't

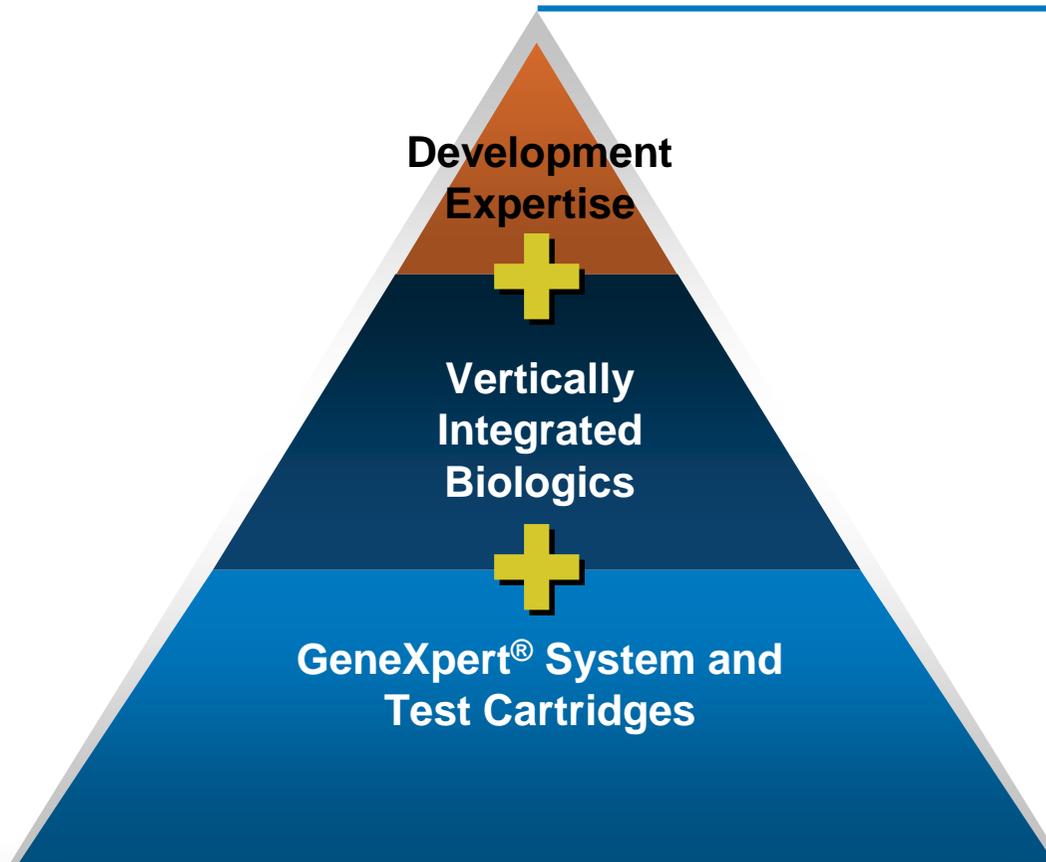
14 Years

Operating History



Information as of Q4 '09

Building Quality from the Ground Up



A **FULLY INTEGRATED**
Molecular Diagnostics
Company

Delivering A Better Way



Delivering a Better Way to Realize the Benefits of Molecular Diagnostics



ACCURATE

Results



FAST

Answers



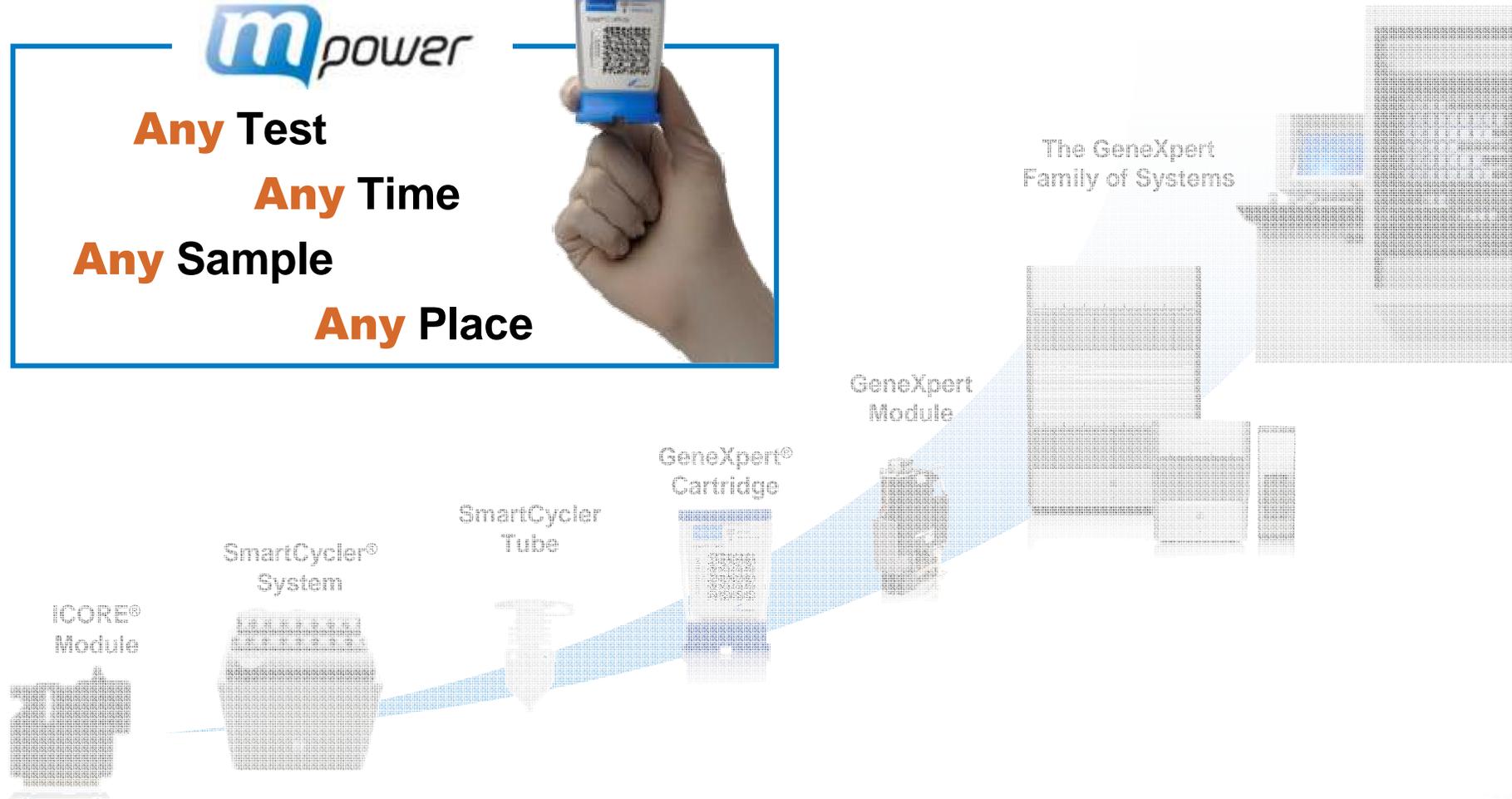
EASY

To Use

Defining Molecular Diagnostics



Any Test
Any Time
Any Sample
Any Place



A Better Way to Platform Design

GeneXpert®
Module



GX-1



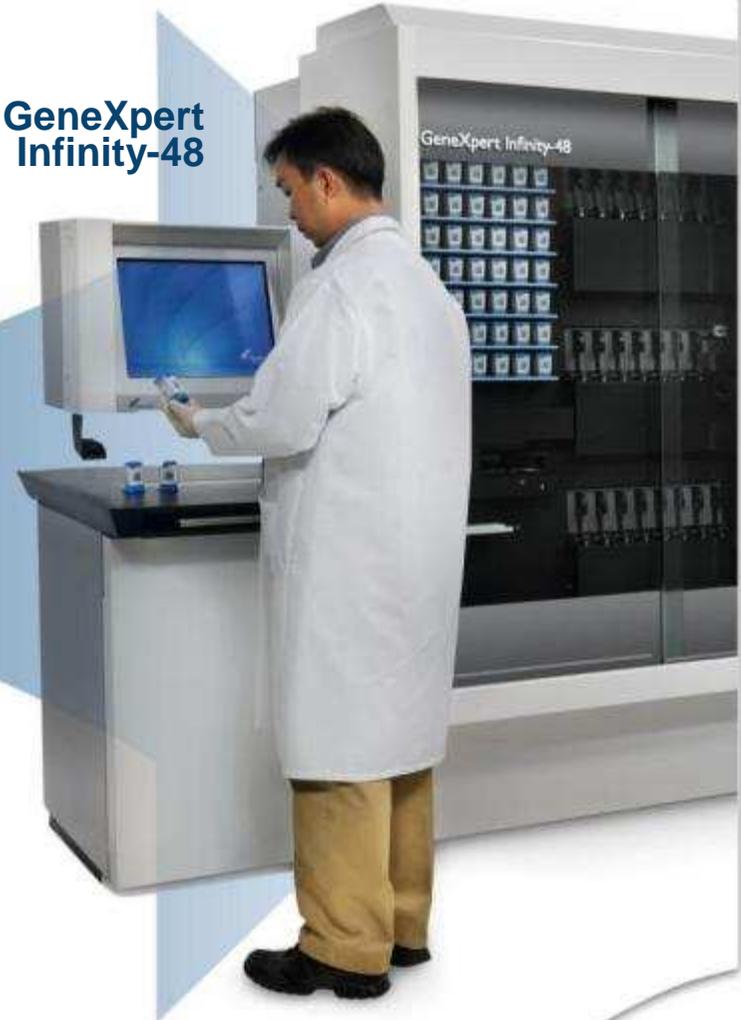
GX-4



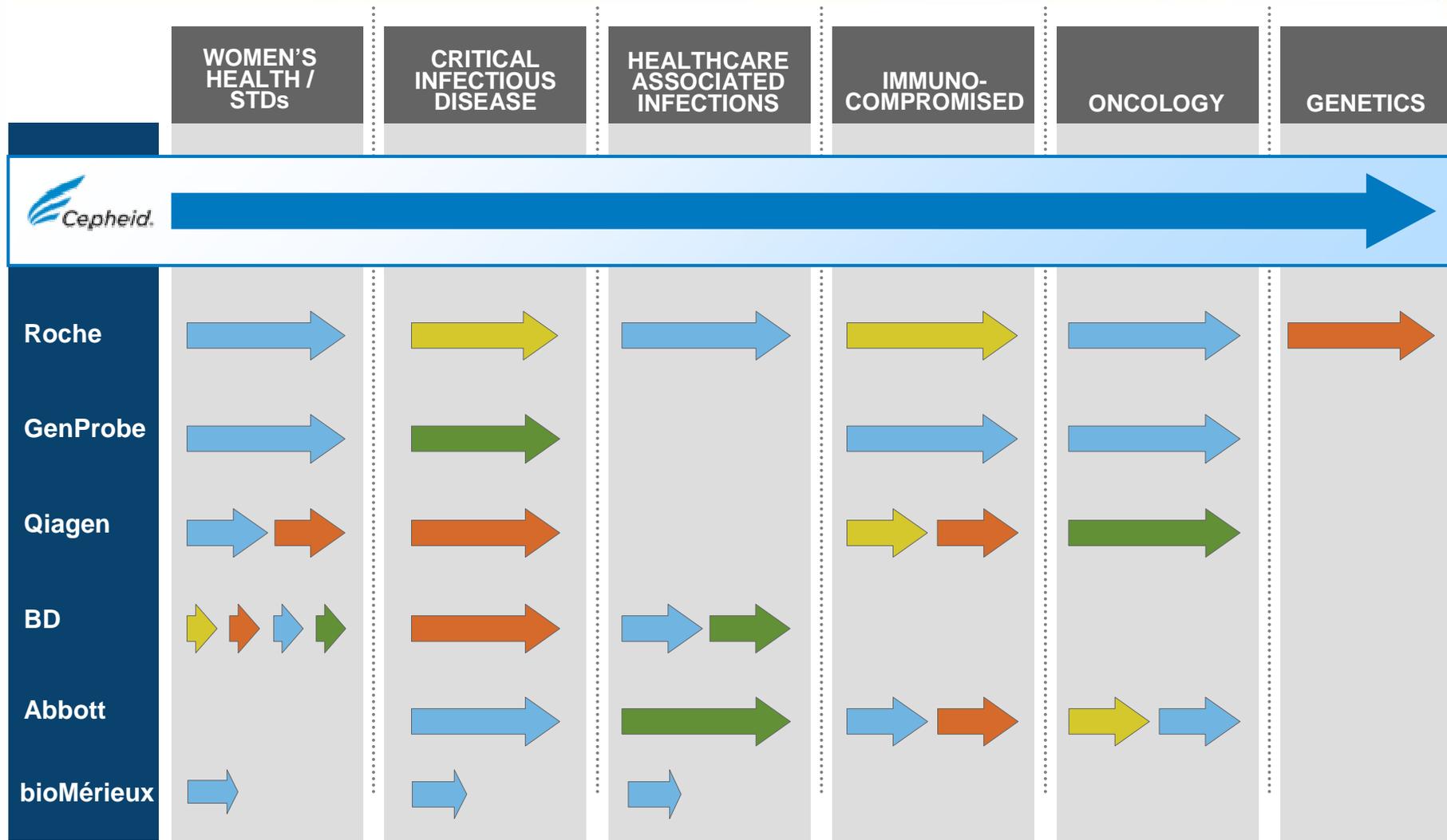
GX-16



GeneXpert
Infinity-48



Unique Ability to Meet Diverse Testing Needs



Each color denotes separate platform.

Strategic Market Development

REFERENCE LABS

REFERENCE LAB

HOSPITALS

CORE LAB

DISSEMINATED
(ICU, ED, Admissions, L&D, STAT)

ALTERNATE SITES

PHYSICIAN OFFICE LABS
(GPs, Urology, OB/GYN)

SURGERY CENTERS

LONG TERM HEALTH CARE

RETAIL PHARMACY/ URGENT CARE



Each color denotes separate platform.



A Better Way: *The Molecular Lab in a Cartridge*



- **Universal Medical & Market Utility**
 - Infectious Disease
 - Oncology
 - Genetic Disease
- **All Testing Done Within Cartridge**
 - Sample Prep
 - Amplification
 - Detection
- **Same Basic Cartridge Works With all Tests and GeneXpert® Systems**

A Disruptive Technology: What it Means

- **Optimal Implementation Requires Change**
 - Change in the Way of Thinking
 - Change of Diagnostic Pathway
 - Change of Guidelines and Recommendations
 - Change in Power and Budgets
 - Change of Quality Control Procedures and “Control”
 - Change in Reimbursement
 - Change in the Way of Selling IVD, or Better “Detection Systems” ...
 - Redefines “Competition”



No Specialized Training Required to Achieve Reliable, Reproducible Results

INTEGRATED PLATFORM AND TEST

Insert Swab into
Elution Reagent Vial and
Break at Scope



1

Vortex and Dispense
Sample into Port S



2

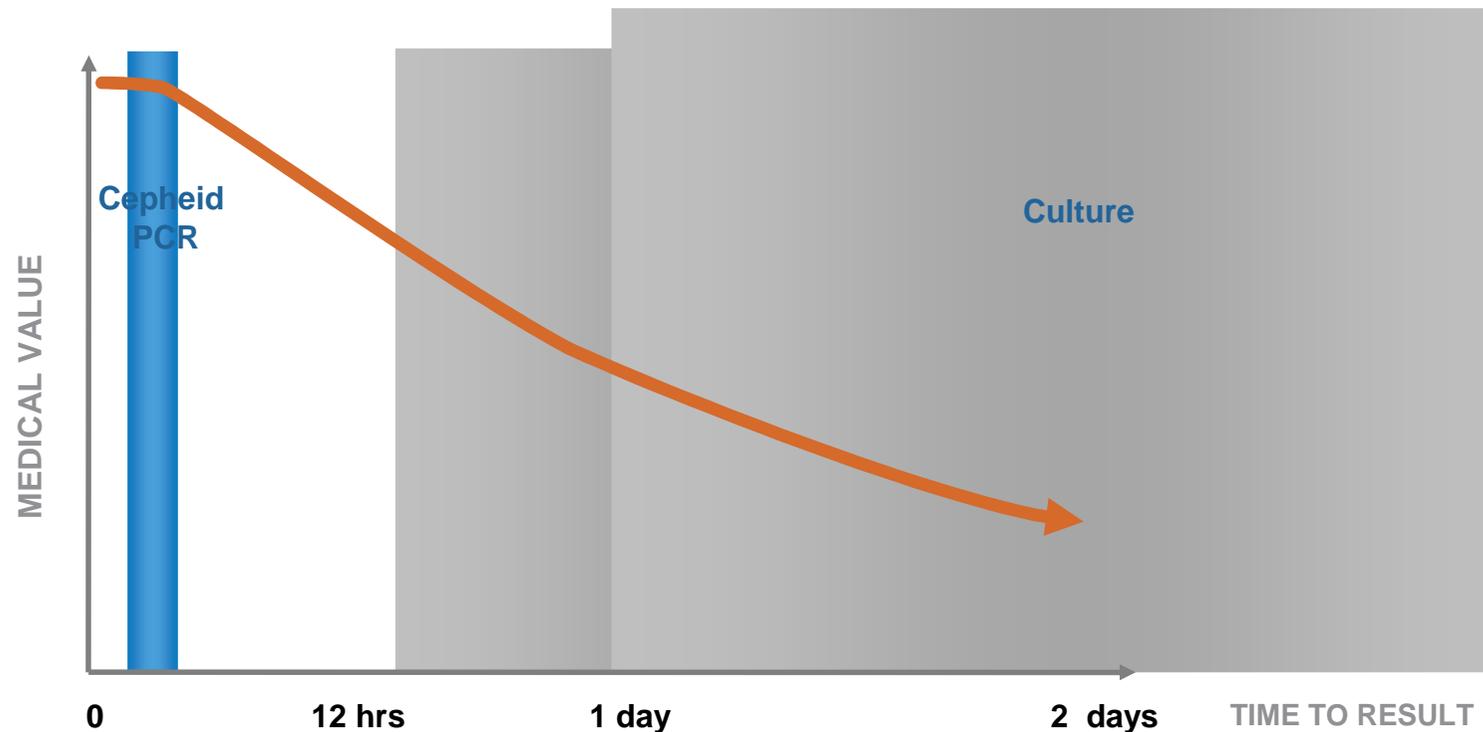
Insert Cartridge and
Start Assay



3

Total Hands-On time <1 Minute

Medical Value: Time to Result is Crucial



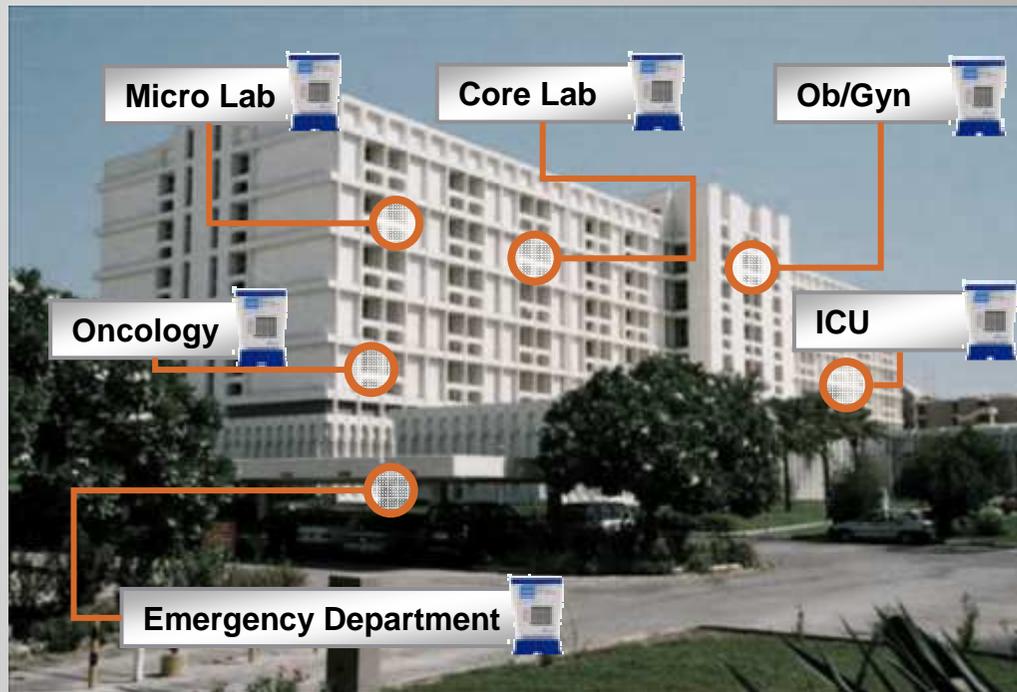
Cepheid *m*Power vs. Batch PCR and Culture

Articles that look at time to result as crucial to maximizing diagnostic value:

1. Lance R. Peterson, M.D., Donna M. Hacek, M.T. (A.S.C.P.), Ari Robicsek, M.D., Case Study: An MRSA Intervention at Evanston Northwestern Healthcare, printed in *The Joint Commission Journal on Quality and Patient Safety* Volume 33 Number 12, December 2007
2. Lance R. Peterson, M.D., *Rapid Diagnosis of Community-Acquired MRSA*, printed in *Clinical Updates in Infectious Diseases*, Volume Issue 3, October 2008
3. Eli N. Perencevich, MD, MS et al., SHEA Guideline: Raising Standards While Watching the Bottom Line: Making a Business Case for Infection Control, *Infection Control and Hospital Epidemiology*, Volume 28, Number 10, October 2007

mPower: Diagnostic Value Within and Beyond Hospitals

Within



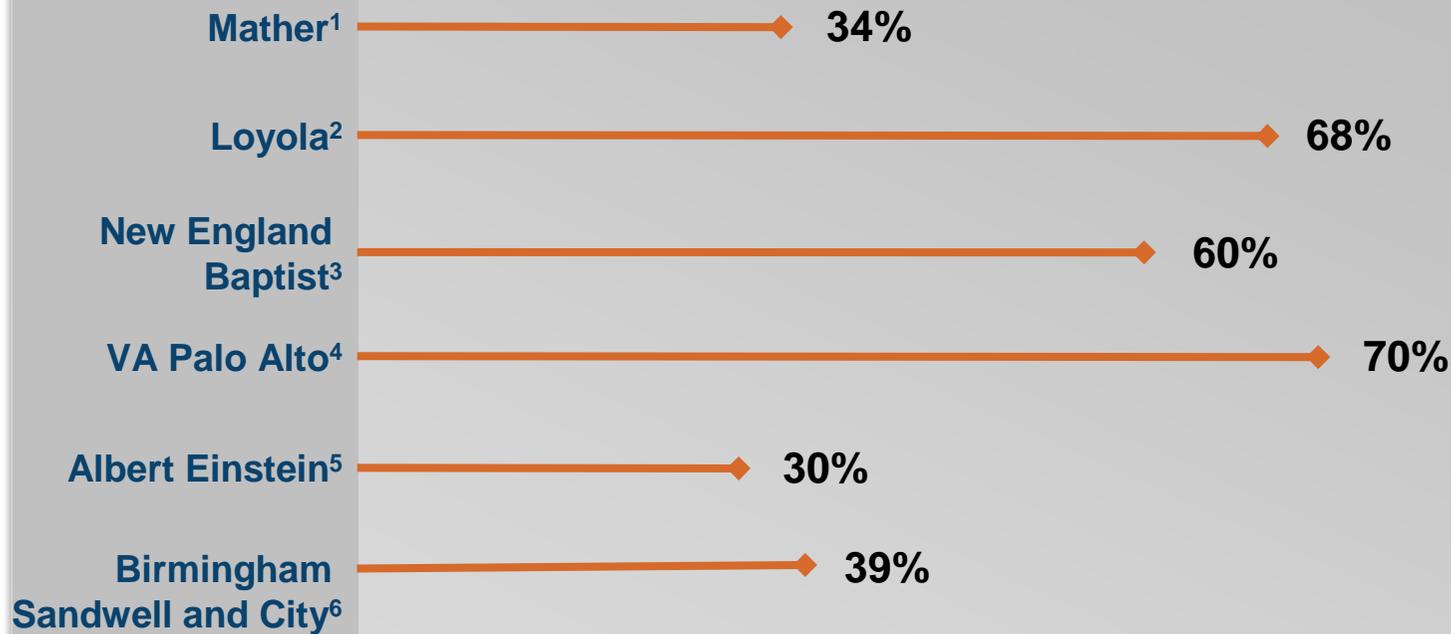
Beyond



- Satellite/Reference Labs
- Clinics
- Surgery Centers
- Retail Pharmacy
- Urgent Care

GeneXpert[®] Customers Are Improving Patient Safety

PROVEN REDUCTION OF MRSA INFECTIONS



1. In house data as reported in J.T. Mather Hospital, 2008 Annual Report.

2. Parada, J et al. Universal Inpatient Screening with Rapid PCR Based Technology Reduces Nosocomial Methicillin Resistant Staphylococcus aureus (MRSA) Rates. Poster presented at SHEA 2009.

3. Spencer, MP et al. Eradication of Methicillin Sensitive Staphylococcus aureus and Methicillin Resistant Staphylococcus aureus Before Orthopedic Surgery. Poster presented at SHEA 2008.

4. Are California Hospitals Doing Enough To Stop MRSA?. CBS 5 News. Accessed August 20, 2008.

5. Einstein Honored for MRSA Initiative. Albert Einstein Healthcare Network. Accessed August 20, 2008.

6. To be published

Projected Xpert® Test Menu — CE-IVD

	Now Available	Near Term 2011	Mid-Term 2012 - 2013	Longer Term 2014 - 2015
Women's Health / Sexually Transmitted Diseases	GBS	CT/NG (2011)	CT/NG FluroQ Resistant Vaginitis Panel Trichomonas HPV	HSV-CSF
Healthcare Associated Infections	MRSA MRSA/SA BC MRSA/SA SSTI MRSA/SA Nasal <i>C. difficile</i> vanA/vanB	MRSA Nasal Next Gen (2011)		Norovirus
Critical Infectious Disease	EV Flu MTB/RIF		RSV/Metapneumovirus Group A Strep	HSV Typing Lesion
Immuno-Compromised			HIV Quant HCV Quant	HCV Genotype HBV Quant EBV Quant CMV Quant
Oncology	BCR ABL		Bladder CA Symptomatic Bladder CA Monitor/Recur. Lung CA	Bladder CA Asymptomatic
Genetics	HemosIL FII, FV*		2C19	

Why Partner with Cepheid?

- ✓ Automated, Scalable, Easy-to-Use
- ✓ Operational Efficiency
- ✓ Better Patient Care
- ✓ Ability to Multiplex
- ✓ Broad & Expanding Test Menu
- ✓ Actionable Results
- ✓ Proven Quality



Current Test Menu: A Closer Look



Xpert MRSA



**On Demand Testing Improves
Infection Control**

CHALLENGES

- **Patients colonized with MRSA not accurately identified create opportunities for:**
 - Spread of infection to other patients
 - Spread of infection to hospital personnel
 - Potential spread to family members and the community

LESS THAN 1 HOUR WITH Xpert® MRSA

- **Rapid and Accurate detection of MRSA colonization in 66 minutes or less means:**
 - Quickly identify patients requiring contact precautions
 - Improve resource utilization and reduce IC costs
 - Detect breakdown in infection control sooner and reduce the risk of potential outbreak
 - Patient counseling to reduce transmission to family and community

Clostridium Difficile



**Rapid & Accurate CDI detection
Improves Infection Control**

CHALLENGES

- **Test Result for Highly Suspicious Patient Often Comes Back as “*C. difficile* Negative”**
- **Additional Tests Are Needed to Confirm *C. difficile* Infection**
- **Significant Impact from Diagnostic Delay**
 - Incremental Cost
 - Incremental LOS
 - Increased Mortality Rate

45 MINUTES WITH Xpert® *C. difficile*

- **Diagnosis of CDI & presumptive 027 in 45 Minutes**
- **Determine Whether to Isolate or Not**
- **Determine Optimal Therapy Options**
- **Reduce Number of Patient Follow-Ups**
- **Patient Counseling to Reduce Transmission to Family and Community**

Tuberculosis and MDR Tuberculosis



Rapid pathogen detection enables clinicians to make appropriate decisions on patient isolation and treatment.

CHALLENGES

- According to the WHO, MTB is vastly under-diagnosed
- Current assays either lack sensitivity or take too long
- There is an emerging problem with drug-resistant strains.
- Early implementation of appropriate treatment is important but difficult to realize

2 HOUR TEST WITH Xpert[®] MTB/RIF

- Simultaneous detection of both MTB and rifampicin resistance: marker for MDR strains
- Unprecedented sensitivity for detecting MTB — even in smear negative, culture positive specimens
- Results in two hours; requires no instrumentation other than the GeneXpert[®] System
- On-demand results enable physicians to treat rapidly and effectively

Pre-surgical *S. aureus* screening



Identify Patients in Need of
Pre-operative Decolonization

CHALLENGES

- Patients colonized with *S. aureus* are at a 2- to 9-fold increased risk for a post-operative surgical site infection (SSI).
- Not knowing on time who is *S. aureus* carrier before clean surgery, means not being able to optimally prepare the patient for the operation, in order to avoid unnecessary SSI.

<50 MIN. WITH Xpert® MRSA/SA Nasal

- Prevent SSI effectively
- Improve resource utilization
- Optimize pre-admission workflow and timely pre-operative decolonization
- Optimally prepare emergency operation with best antibiotic stewardship

MRSA/SA Skin and Soft Tissue Infections



**On-Demand Testing Improves
Infection Control**

CHALLENGES

- The cost for cure of skin and soft tissue infections (SSTI) has been rising constantly in parallel with increasing antibiotic resistance.
- For key therapeutic decisions physicians need to know whether wounds contain MSSA or MRSA.
- With current culture methods, it takes from 30 to 72 hours to get an answer.

< 1 HOUR WITH Xpert[®] MRSA/SA SSTI

- Enables Improved Infection Control, Lower Costs & Shorter LOS
- Allows for Appropriate Treatment Sooner, Better Management in ED, and Better Clinical Outcomes
- Ensures Proper Patient Education to Reduce Transmission of MRSA to Family and Community

MRSA/SA Blood Culture



Prescription of Targeted Active Antimicrobial Therapy Days Sooner

CHALLENGES

- *S. aureus* is one of the two most common pathogens causing bacteraemia and sepsis
- Sepsis is the main cause of mortality in hospitals
- Current Sepsis Triage Protocols Begin With Empiric Antimicrobial Therapy; Empiric Therapy is Often Suboptimal, Resulting in Advancing Infections
- Current laboratory methods require 30 to 72 hours to get an answer

< ONE HOUR WITH Xpert® MRSA/SA BC

- Prescription of Targeted Active Antimicrobial Therapy Days Sooner
- Improved Patient Management
- Decreased Length of Stay

vanA/vanB



**Identify Patients in Need of
Contact Precautions**

CHALLENGES

- Patients colonized with VRE not accurately identified create opportunities for additional infection
- 28.5% of enterococci causing HAI in intensive care units (ICU) were VRE*
- Current VRE surveillance tests are based on culture method requiring 24-48 hours to generate a result

45 MINUTES WITH Xpert® vanA/vanB

- Rapid identification of patients requiring contact precautions
- Improve resource utilization and reduce IC costs
- Detect breakdown in infection control sooner and reduce the risk of potential outbreak
- Patient counseling to reduce transmission to family and community

* American Journal of Infection Control. 2004; 32: 470-85

Group B Streptococcus



Rapid Testing Upon Arrival Can Help Determine Appropriate Treatment

CHALLENGES

- **Leading Cause of Neonatal Morbidity and Mortality**
- **Culture is Time Consuming**
- **Culture Not an Option for Preterm Births, Women with no Prenatal Care or When Results Are Unavailable (15-35% of Births)**
- **Prophylactic Antibiotics Prescribed Unnecessarily—Potential for Increasing Antibiotic Resistance**

32-50 MINUTE TEST WITH Xpert[®] GBS

- **Ability to Test Mother Upon Arrival**
- **Timely Information to Determine Appropriate Treatment**

Sources MMWR Weekly; August 16, 2002; 1001.51; No. RR-11

Enterovirus Meningitis



**On-Demand Testing
Reduces Unnecessary Admissions**

CHALLENGES

- **No Acceptable Non-Molecular Test**
- **Existing Molecular Tests Too Slow/
Unavailable to Prevent Most Admissions**
- **Slow and Expensive Conventional
Diagnosis and Treatment**
- **Unnecessary Antibiotic Treatment due to
Uncertainty**

2½ HOUR TEST WITH Xpert® EV

- **Improved Detection**
- **Provides 24/7 Testing Access**
- **Reduced Need for Ancillary Tests and
Unnecessary Antibiotics**

Influenza



Rapid & Accurate Identification of 2009 H1N1 improves patient management

CHALLENGES

- Antigen Tests are Not Accurate
- Accurate Test Takes Too Long for a Result
- Currently Available Rapid Tests Do Not Call Out for 2009 H1N1 Which Has a Different Antiviral Susceptibility Profile

< ONE HOUR WITH Xpert® Flu A Panel

- Accurate Determination of 2009 H1N1
- Rapid Identification of Patients Requiring Contact Precautions
- Improve Resource Utilization / Reduce Costs
- Prescribe Appropriate Therapy
- Patient Counseling to Reduce Transmission to Family and Community

BCR/ABL

CHALLENGES

- In Europe, every year ~4000 patients are newly diagnosed with Chronic Myeloid Leukemia.
- Molecular monitoring of bcr-abl in CML patients is recommended (European Leukemia Network)
- Current molecular assays require many manual steps, and extensive hands-on time with the risk of user-variation, errors and contamination.

2 ½ HOUR TEST WITH Xpert® BCR/ABL

- Standardized molecular monitoring to determine correct dosage adjustments
- Ability to test during consultation



Simplified testing for improved CML patient management

FII & FV Leiden



CHALLENGES

- Factor II and Factor V mutations represent significant independent risk factors for deep venous thrombosis and associated complications for patients with hemostasis disorders
- Batch testing or send-outs resulting in TAT of often 2-3 weeks
- Patients & physicians are left waiting for important results, while the other parameters of the thrombophilia panel are available in hours



Instrumentation Laboratory



Molecular FII, FV testing for a complete thrombophilia panel assessment based on (in-house) immediate results

~32 MINUTE TEST WITH Xpert® FII/FV

- Easy-to-use assay: Enables daily testing
- Timely information empowers physicians with rapid actionable information
- Requires no instrumentation other than the GeneXpert® System

Xpert HemosIL Factor II & V exclusively distributed worldwide by Instrumentation Laboratory

A Better Way: Immediate Answers to Make Better Clinical Decisions, Faster

Detect
More Carriers

Decrease
Length of Stay

Lower
Hospital Costs



Reduce
Infection Rates

Optimize
Antibiotic Utilization

Promote
Community Leadership



mpower