Confessions of a Microbiology Laboratory Director

Shopaholic: So Many Choices, So Little Time……and Money

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Disclosures
Nothing to Disclose

Objectives

• Review currently available rapid diagnostics, what is in the pipeline
• Discuss pros and cons of rapid diagnostics
• Discuss considerations for integration of new tests into the laboratory/hospital workflow

So What Is Out There??

1-3 Target Manual PCR Tests

Diasorin RT-PCR
8 well tube
FDA cleared: Group A Strep
Throat Swabs
1 hour

HSV 1 & 2
CSF, cutaneous and mucocutaneous swabs

Coming out this year: Bordetella (NP Swabs)
VX (CSF and cutaneous)
1-3 Target Automated PCR Amplification, Closed System

**Luminex/Aries**
- 6 cassette platform
- FDA cleared: HSV 1 & 2 cutaneous and mucocutaneous
- 1 hour
- Rs a/ORV
- Group A Strep
- C. difficile
- Bordetella

11/5/2018

**Cepheid**
- Platform: GeneXpert System (1, 2, 4, 16, Infinity)
- Xpert C. diff/Epi
- Xpert MGAs
- Xpert Flu/RSV
- Xpert CT/NG
- Xpert MTB/RIF
- Xpert Strep A
- Xpress Flu/RSV
- Xpert CT/NG
- FDA cleared for male/female urine, endocervical, self-collected vaginal, rectal and throat later this year.
- 90 minutes
- Xpert MTB/RIF
- Sputum, 2 hours
- Xpress Strep A
- CLIA waived as of May 2, 2018
- 18-24 minutes
- Throat (Eswab)
- No culture confirmation of negatives required
- Xpert Carba R
- Rectal Swab or bacterial isolate
- 50 minutes
- KPC, NDM, OXA-48, IMP

**GenMark; PCR Amplification**
- Platform: 3 bay tower or 6 bay tower
- Random and Continuous Access
- FDA cleared: Respiratory Pathogen Panel (17 targets)
- NP Swabs
- 1 hour, 40 minutes
- $160/test
- To FDA this year: Blood Panels (95% BC isolates)
- Gram – (21 pathogens, resistance genes and pan targets)
- Gram + (20 targets, resistance genes and pan targets)
- Fungal (14 targets)
- + Blood Cultures
- 1.5 hours
- Future: GI Panel
- CNS Panel
- HCV Genotyping Panel

**Luminex/Verigene; MicroArray Technology**
- Platform: 1 sample per instrument
- FDA cleared: Respiratory Pathogen (RP) Flex (16 targets)
- NP Swabs
- 45 minutes
- $129/test
- Future: Updating panels to TAT of 45 minutes

**Biofire; PCR Amplification**
- Platform: 1 module tower to start, (Cepheid) Torch
- FDA cleared: Revised Respiratory Panel (3 targets)
- NP Swabs
- 45 minutes
- $29/test
- Respiratory (2 targets)
- QID Microarray
- Blood Culture GI Panel (7 targets)
- Performed on + Blood Cultures
- 1 hour
- $29/test
- GI Panel (2 targets)
- Stool in Cary Blair from fecal swabs
- 1 hour
- $15/test
- Meningitis/Empyemiasis Panel (14 targets)
- 200 ul 600
- $15/test

**Accelerate Pheno System**
- FST for 85, 90 minutes (95 targets – Gen +, Gen –, Yeast)
- Morphological (Pheno: Time Lapse McPherson 447, 7 hours $250/test
- Positive Blood Culture
- Modular, 1 sample/instrument

**Blood Culture Targets:**
- **Gram Negative Organisms:**
  - Acinetobacter baumannii
  - Pseudomonas aeruginosa
  - E. coli
  - Klebsiella spp.
  - Enterobacter spp.
  - Proteus spp.
  - Citrobacter spp.
  - Serratia marcescens
- **Gram Positive Organisms:**
  - MRSA (Cefoxitin MLSb (Ery + Clind))

**Antibiotics:**
- Ampicillin
- Piptazobine
- Cefuroxime
- Ceftriaxone
- Ertapenem
- Vancomycin
- Gentamicin
- Tobramycin
- Ciprofloxacin
- Aztreonam
- Colistin (RUO)

**Resistance:**
- MRSA (Definitive MLSb-Emm4)

**Panels, Direct From Specimen, + Blood Culture**

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- Platform: 1 module tower to start, (Cepheid) Torch
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**Resistance:**
- MRSA (Definitive MLSb-Emm4)
Morphokinetic analysis

- Time-lapse imaging of live cells
- Proprietary algorithm converts images into graphic measurement of phenotypic features

E. coli vs. 4 μg/mL Pip/Taz. MIC=8 (S)
E. coli vs. 4 μg/mL Pip/Taz. MIC=128 (R)

T2 Direct Detection/ No Growth
Magnetic Resonance Technology
Platform: 7 sample capacity; random access

FDA cleared: Candida Panel (5 targets)
4 ml EDTA Blood
3-5 hours
$150-$200/test

Morphokinetic analysis

- Time-lapse imaging of live cells
- Proprietary algorithm converts images into graphic measurement of phenotypic features

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MALDI-TOF
Spotting of target plates with isolates from culture
Identifies large number of organisms from all sources
Very inexpensive

Bruker
Small footprint
Identification from culture isolate
Aerobic, anaerobic bacteria, Yeast
Separates V/I Kits CE marked, direct from vBC

Vitek
Large footprint
Identification from culture isolate
Aerobic, anaerobic bacteria, Yeast, AFB, Molds
Future: Adding more organisms to library. Direct from positive blood culture detection to go with future direct from blood AST

Near Patient/POC Tests

- Influenza A/B
- RSV
- Group A Strept
- Chlamydia trachomatis
- Neisseria gonorrhoeae
- Trichomonas
- C. difficile
- MRSA
- Enterovirus
- Group B Streptococcus
- M. tuberculosis

Traditional Microbiology Diagnostics

- Influenza A/B
- RSV
- Group A Strept
- Chlamydia trachomatis
- Neisseria gonorrhoeae
- Trichomonas
- C. difficile
- MRSA
- Enterovirus
- Group B Streptococcus
- M. tuberculosis

Future: Lyme Panel
Gram Negative Resistance Panel (direct from whole blood)
The Problem

- Total time: 3-4 days
- Appropriate and rapid delivery of targeted antibacterials is the most critical factor of all Surviving Sepsis attributes
- Wrong empiric therapy = 5x higher mortality
- Increase in survival for every hour of delay prior to proper therapy (hypotension onset)
- Indications for therapy: 10% decrease in survival for every hour of delay prior to proper therapy (hypotension onset)
- 100 of patients receive ineffective empiric therapy
- 60% of septic patients have negative blood cultures
- Up to 5% of explants patients have negative blood cultures
- Some organisms sensitive cultured
- Some organisms sensitive cultured
- fined antioxidants and susceptible

Current Approach to Microbiology Diagnostics

- ID + AST
- ID + resistance genes
- ID + AST
- ID + MICs
- ID only: MALDI

Next Generation Sequencing (NGS)

- Technology exists
- Faster
- More automated - Minimal hands-on time
- Easy to perform
- Closed systems – Decreased contamination
- More comprehensive
- CLIA waived – Performed near patient
- Highly sensitive and specific
- Provides actionable results earlier on in course of infection/disease
- Organism ID
- Organism susceptibility profile

Karius Reference Laboratory Assay

- Quantitative NGS to diagnose infection from microbial cell free DNA in plasma/LV, blood cultures, lungs, prostate
- Next day results
- $2,000/test
- FDA approved lower resp. pneumonia panel; ID and resistance genes
- Technology exists
- $2,000/test

Future Microbiology Diagnostics

- ID + resistance genes
- ID + AST
- ID only: MALDI
- ID + MICs: Accelerate PhenoTest BC

Next Generation Approach to Microbiology Diagnostics

<table>
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<th>Results</th>
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<td>Microarray Genotypic detection of Bacteria, Candida, resistance genes (LOD 1 CFU/mL), direct from blood in 40 min; RT-PCR ribosomal targets</td>
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<tr>
<td>Curves</td>
<td>1° FDA approved, lower resp., pneumonia panel; ID and resistance genes; SDDK instrument, $300/cartridge; tissue and implant targets</td>
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<td>SpecifID</td>
<td>ID and MIC 6 hours; measures small volatile metabolites; 4 samples/instrument; 96-well inoculation plates</td>
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<tr>
<td>BacteriaScan</td>
<td>FDA approved for urines; identifies negative urine specimens in a 3 hour turnaround time; 16 samples/instrument; AST (S, I, R) to come; $254K instrument, $50/cartridge</td>
</tr>
<tr>
<td>OpGen</td>
<td>Semi-quant 5 logs ID and resistance markers; Complicated UTIs, 3 hours; 4 samples at a time; $150/test</td>
</tr>
<tr>
<td>Lifescale</td>
<td>AST only from BC 3-4 hours; $100K instrument, $100/test; 5 ASTs at a time (No ID)</td>
</tr>
<tr>
<td>AncestrySmarts</td>
<td>ID and AST</td>
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Microbiology Diagnostics Trends

- Faster
- More automated - Minimal hands-on time
- Easy to perform
- Closed systems – Decreased contamination
- More comprehensive
- CLIA waived – Performed near patient
- Highly sensitive and specific
- Provides actionable results earlier on in course of infection/disease
- Organism ID
- Organism susceptibility profile
Pros of Currently Available Microbiology Diagnostics

- Faster
- More automated - Minimal hands on time
- Easy to perform
- Closed systems – Decreased contamination
- More comprehensive
- CLIA waived - Performed near patient
- Highly sensitive and specific
- Potential to provide actionable results earlier in course of infection/disease
- Small footprint
- Modular and scalable
- Mechanisms for reporting, transmitting results
  * Accelerate's Smart Reporting – results direct to client via email or via text to mobile phone

Cons of Currently Available Microbiology Diagnostics

- More expensive (but getting cheaper)
- Reimbursement issues
- Faster test ≠ Timely result ≠ Action
- Genotypic vs Phenotypic
- Result interpretation
  - False negs and false pos
  - Multiple pos – what should we do with that?
  - Expertise needed?

Reimbursement Challenges – Multiplex Testing

- “One size fits all testing approach is screening and not a Medicare benefit”
- “Contributes to test over-utilization, and increased cost to health care without specific benefit to a given patient”
- Palmetto denied coverage to large respiratory panels
  - Small panels (3-5 analytes, CPT 87631) covered in limited circumstances
  - Highly multiplexed tests (6-11 analytes, CPT 87632 and 12-25 analytes, CPT 87633) will not be covered
- Ruling of GI Panels soon
  - Prior draft proposed coverage limited to 5 most common food-borne bacterial pathogens (Salmonella, Campylobacter, Shigella, Cryptosporidium, Shiga-t0xin producing E. coli)
  - Excludes viruses due to lack of virus-specific treatment options

Screening

- Blood, Urine, Stool
- Low percentage positive
- Will a patient be ok with a $1000 charge for a negative result, esp if feeling better without intervention?

Health Care Coverage & Health Care Expenditures in the U.S., 2015

Healthcare Coverage

- Total = 311.4 Million
- Employees 80% (80.4 Million)
- Retirees 12% (37.7 Million)
- Medicaid 4% (12.5 Million)
- Medicare 22% (68.3 Million)
- Other Public Funds 4% (12.9 Million)
- Other Private Funds 4% (12.9 Million)
- Other Govt Programs 8% (24.9 Million)
- Total = 311.4 Million

Health Expenditures

- Total = $2.7 Trillion
- Private Health Insurance 35% ($954 Billion)
- Medicare 22% ($600 Billion)
- Medicaid 18% ($486 Billion)
- Other Public Programs 8% ($216 Billion)
- Other Private Funds 4% ($138 Billion)
- Other Govt Programs 4% ($138 Billion)
- Total = $2.7 Trillion

NOTE: Health spending total does not include administrative spending.

Private Health Insurance 35%

Medicare 22%

Medicaid 18%

Other Public Programs 8%

Other Private Funds 4%

Other Govt Programs 4%

Health Care Coverage

Total = 311.4 Million

Health Expenditures

Total = $2.7 Trillion

$338 Billion out-of-pocket Expenditures!!
Test Stewardship (GI)

- Most diarrheal illnesses are self-limited
- Suggest testing if diarrhea accompanied by fever, bloody stools, systemic illness, recent antibiotic usage, day-care attendance, dehydration

Practice Guidelines for the Management of Infectious Diarrhea, IDSA 2001

Cost savings of flex testing

- Cost savings of flex testing

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Presenting complaint  | NAAT result  | Time to treatment for CT/GC or treatment not received
--- | --- | ---
Asymptomatic  | 77 (54.4%) Positive  | 16 (21.6%) at consultation
  | 22 (14.9%) Negative  | 18 (24.6%) at a later date
Sympotomatic of CT/GC  | 92 (21.9%) Negative  | 19 (42.6%) at consultation
  | 28 (6.7%) Positive  | 12 (26.7%) at a later date
  | 3 (0.7%) not treated
Sympotomatic of other STI  | 100 (7.9%) Negative  | 13 (13%) treated unnecessarily
  | 4 (3.1%) Positive  | 1 (10.0%) at consultation
  | 11 (84.4%) at a later date
  | 2 (1.6%) not treated

Minimal benefit of rapid blood culture testing without the necessary players

- Use of 90 minute mPOC test for Chlamydia trachomatis and Neisseria gonorrhoeae


Questionnaire: Maximum time willing to wait for a mPOCT (N=1356)
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Do resistance marker tests get results?

- ONLY one randomized controlled trial:
  - N= 361 patients

  YES
  - Reduces treatment of contaminants
  - Reduces use of broad spectrum antimicrobials
  - Sooner escalation of therapy
  - Sooner de-escalation (with stewardship team)

  - No impact on management of Gram-negative infections

Genotypic Rapid Methods

- Blood Culture Panels
- meCA, vanA, vanB
- CTX-M(ESBL)
- Carbapenemases: IMP, KPC, NDM, OXA, VIM
  - Blood culture
  - ID (Gram +/-) and presence/absence of gene targets in 1-2 hours
  - Only detects the specific genes being targeted for
  - No MICs (SDD could still treat)
  - Doesn’t indicate expression
  - No other drugs tested
  - Guides physician against drugs if positive, but doesn’t tell physician what drugs could work

Challenge of genotype for Gram negatives

- Specimen: Blood
- Organism: Klebsiella pneumoniae

  “This Klebsiella does not harbor the blaKPC gene”

  Carbapenemase-negative K. pneumoniae
  IMP, NDM, KPC, VIM, OXA

How this could be a problem…

**Plasmid AmpC + porin mutations by WGS**

Even if we had a PCR for AmpC, would assume “S” to carbapenems...

Cons of Currently Available Microbiology Diagnostics

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Need to Understand Limitations of Test

- Tuberculosis meningitis misdiagnosed as HSV-1 due to HSV-1 positive FilmArray Meningitis/Encephalitis panel result
- Pre-test probability of disease
- Chemistries
- Cell counts
- Positive Predicted Value
- No melting curve to determine if transient, on edge

Test Stewardship (CNS)

Point-counterpoint paper on utilization of large multiplex panels

- Points of agreement
  - Highly multiplexed molecular tests have clinical value
  - The use of highly multiplexed tests is more closely aligned with traditional culture methods
  - Multiplex tests should be developed in consultation with clinical microbiologists and clinicians so that the panel members reflect clinical reality.
  - Implementation of panel tests should be done in consultation with clinicians for clear understanding of appropriate use and interpretation of test results.

Point-counterpoint paper on utilization of large multiplex panels

- Issues to be resolved
  - Outcome studies needed
  - The value of using highly multiplexed tests as front-line diagnostics will depend on the clinical situation
    - more difficult when the panel includes pathogens that are very rare, when all pathogens in the panel do not cause overlapping clinical syndromes, or when some pathogens are found only in specific patient populations (immunocompromised patients)
  - Understanding performance characteristics of all members of the panel is essential, sensitivity and specificity for the detection of each pathogen may vary.
  - Colonization vs infection
    - C. difficile
    - Long-term shedding
    - Norovirus
    - Rotavirus
    - Latency
  - HIV

Which Test Should We Bring In??

Does One Size Fit All? What Happens if We Don’t Use the Test Correctly?

- Helmets are estimated to reduce odds of head injury by 50 percent, odds of head, face, or neck injury by 33 percent
- Twenty-one states and the District of Columbia have helmet laws applying to young bicyclists; none of these laws applies to all riders.
- Local ordinances in a few states require some or all bicyclists to wear helmets.
- The odds that a bicyclist will wear a helmet are 4 times higher after a helmet law is enacted than before a law is passed.
- Helmets are important for riders of all ages, not just young bicyclists.
- Eighty-six percent of bicyclist deaths are persons ages 20 and older.
- During the past few years, no more than 17 percent of fatally injured bicyclists were wearing helmets.
Right-Sizing Technology

Right test is offered at the right time for the right patient with maximal operational efficiency and cost-effectiveness.

Goal: To provide results with the potential to inform therapeutic and infection control decisions for improved care, better outcomes, and ultimately, reduced downstream costs.

Respiratory Testing: One Size Does Not Fit All

Right Test and Right Time – For the Patient? For the Laboratory? For the Hospital?

• For the patient
  • Are there ways that we can effectively use resistance markers for Gram-Negative organisms?
  • Sensitivity/Specificity
  • Prevalence in the population being tested – PPV/NPV?
  • Will we be able to trust the results?
  • How long has the patient been sick?
  • Dengue – virus disappears shortly after symptom onset, is the FCR useful?
  • How fast does the test need to be to make a difference?
  • Can we logically pair the tests where it would be effective as in a triplex card (CA)?
  • Will the sample need to be transported to a central lab with pickup only at specific times?
  • How far away is the central lab?
  • Will it be batched once it gets to the lab?
  • Is the lab 24/7?
  • Is there a system for communicating results in a timely fashion and will the doctor immediately act on the results?
  • Susceptibility testing – is U, I, R good enough or do we need MIC values?

• For the laboratory - Operational Efficiency
  • Kaiser comprised of 21 hospitals and over 200 medical offices spread over a very wide geographic area with over 3.5 million members serviced by a central laboratory
  • Santa Clara Valley Medical Center county hospital lab located in the hospital, serviced some outreach clinics
  • Washington Hospital
  • What platform?
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Typical Verification Costs of a Laboratory Developed, Quantitative, real-time PCR Assay or LDT Performance Category

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Right Test – For the Patient? For the Laboratory? For the Hospital?

- For the hospital
  - Cost Beneﬁt?
  - What is the need & what is driving it?
  - What is the acquisition beneﬁt (ie faster TAT = decreased LOS)?
  - Does the technology provide an additional beneﬁt to laboratory operations (ie new test volume, workflow, staff)?
  - How is test volume trending?
  - What is the return on investment?
  - Does it improve patient, employee, and physician satisfaction?
  - Does it support performance improvement (quality & cost savings) somewhere else in the continuum of care?
  - What is the beneﬁt to the patient?

Right Patient

- Test Stewardship
  - Everyone?
  - Inpatient vs Outpatient?
  - Specialty Clinics
    - STIs
  - Symptomatic vs non-symptomatic?
  - Extent of clinical presentation?
  - Potential improved outcomes?
  - Determine how convey/communicate algorithm to the physicians so ordering correctly, way we intend it to be ordered.
  - What tends to happen is that people order what’s easy ie alphabetically.
  - Physician education and decision support.

Summary

- Technology has provided a wealth of diagnostic solutions
- Newer diagnostic tools enable diagnosing/appropriate therapeutics earlier on in infection
- Newer tests/platforms can be very expensive
- Placement, utilization & oversight remain a challenge for implementation
- It’s important to right-size technology

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