

# Breakthrough Sepsis Pathogen Detection

Corporate Presentation  
October 2019  
(NASDAQ: T2OO)

# Forward-Looking Statements

This presentation contains forward-looking statements. Such statements reflect the current views of senior management of T2 Biosystems, Inc. ("we", "us", "our", "T2", "T2 Biosystems" or the "Company") and include those about T2's goals, strategies, plans, objectives, prospects, milestones, future operations, business and industry, anticipated product benefits, future events and conditions and potential scenarios. Such statements and those that include the words "expect," "intend," "plan," "believe," "project," "forecast," "estimate," "may," "should," "anticipate" and similar statements of a future or forward-looking nature identify forward-looking statements for purposes of the federal securities laws or otherwise. Forward-looking statements address matters that involve risks and uncertainties. Each forward-looking statement is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statement, including, for example: (i) our status as an early commercial-stage company and expectation to incur losses in the future; (ii) our ability to obtain marketing authorization from the FDA or regulatory clearance for additional product candidates in the United States or abroad; (iii) the market acceptance of our technology; (iv) our ability to timely and successfully develop and commercialize existing and future product candidates; (v) our lengthy and variable sales cycle and lack of sales history; (vi) our ability to successfully manage growth; (vii) federal, state and foreign regulatory requirements; (viii) our uncertain future capital needs and ability to raise future capital; (ix) dependence on third parties; (x) recruiting, training and retaining key personnel; (xi) competitive factors; (xii) manufacturing and other product risks; (xii) risks related to intellectual property; and (xiii) other risk factors included in our annual report on form 10-K filed with the Securities and Exchange Commission (SEC) on March 14, 2019 and other documents we file with the SEC from time to time. Accordingly, there are or will be important factors that could cause our actual results to differ materially from those indicated in these statements. The statements made herein speak only as of the date of this presentation. We do not undertake, and specifically disclaim, any obligation to update any forward-looking statements contained in this presentation.

# Why Are We Here Today?

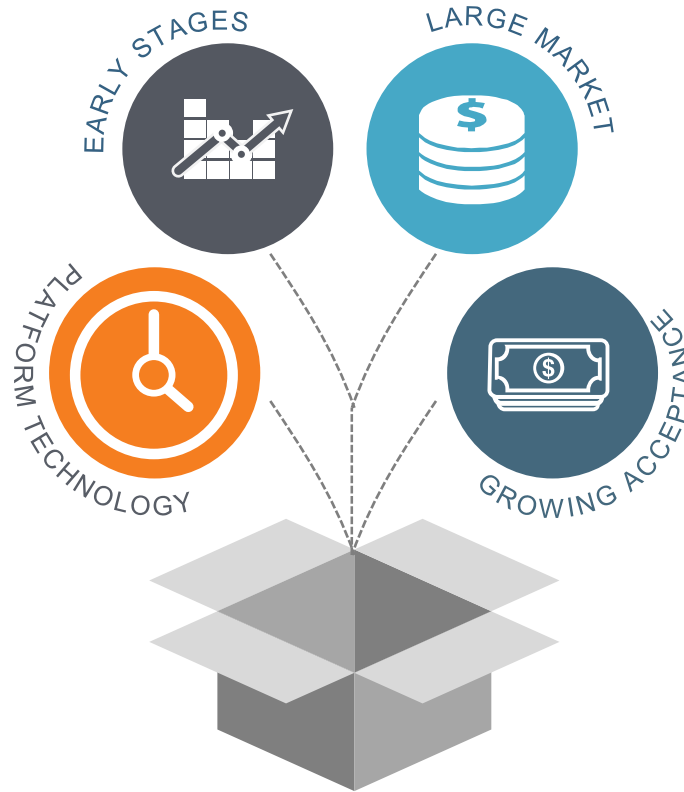
T2 has reached a tipping point for broad adoption of the T2Dx<sup>®</sup> technologies

## Early Stages

- Proven with T2Candida<sup>®</sup>
- Expanding with T2Bacteria<sup>®</sup>

## Platform Technology

- Market expansion to include detection of antimicrobial resistance, biothreats and Lyme disease



## Large Market

- Global unmet need

## Growing Market Acceptance

- 1st Dx to receive NTAP from **CMS**
- Up to \$69M **BARDA** contract
- T2Resistance **FDA** Breakthrough Designation
- Breakthrough Technology Contract with **Premier Inc**
- Growing patient success stories

# Growing Independent Support for T2MR Technology



The T2Bacteria Panel is the **first and only, in-vitro diagnostic test to ever receive approval** from the US Centers for Medicare & Medicaid Services (CMS) for New Technology Add-on Payment (NTAP). The payment of up to \$97.50 per case, is in addition to the current diagnosis-related group (MS-DRG) reimbursement.



BARDA contract providing **up to \$69 million** in funding for the development of four new products, further advancing our rich product pipeline and portfolio



Awarded “**Breakthrough Device**” designation from FDA for our T2Resistance Panel, which detects 13 resistance genes from both gram-positive and gram-negative pathogens without the wait for blood culture



Contracted Supplier

Secured a **Breakthrough Technology** contract with Premier Inc., a leading GPO that provides us access to over 4,000 US hospitals due to the impact of our products on improving patient care

*“The T2Bacteria Test Panel represents a substantial clinical improvement over existing technologies because it reduces the proportion of patients on inappropriate therapy, thus reducing the rate of subsequent diagnostic or therapeutic intervention as well as length of stay and mortality rates caused by sepsis causing bacterial infections.”*

-United States CMS FY 2020 inpatient prospective payments system final rule

# Advancing T2 Platform with up to \$69 Million BARDA Contract<sup>1</sup>

Largest contract for medical diagnostics ever funded by BARDA

Potentially funds  
expansion of  
product portfolio  
from development  
through FDA  
submission for 3  
panels, and...

Development of next-  
generation high-  
throughput T2Dx  
instrument

## Comprehensive Panel

- 99% of all bloodborne bacterial infections by means of  $\geq 36$  reported results
- Pan-Gram positive and pan-Gram negative results (detecting >250 species)
- All bloodborne antibiotic resistant threats identified by the CDC
- All from a single blood sample...

## T2Resistance Panel

- Breakthrough device designation by FDA
- 13 antibiotic resistance genes from gram positive/negative pathogens

## Biothreat Pathogens Panel

- First ever direct-from-blood panel for detection of biothreat pathogens
- *B. anthracis*, *F. tularensis*, *Burkholderia* spp., *Y. pestis*, *R. prowazekii*, and toxin genes

# Sepsis is a Deadly and Frustrating Global Problem

A recognized, but unsolved global crisis

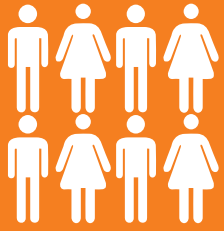


1 death every  
**5 seconds**  
(more or less)



# Sepsis is a Deadly and Frustrating Global Problem

A critical part of the solution is now available



Potentially  
**>40,000**  
preventable deaths in  
the U.S. with T2



# The Facts About Sepsis

Most expensive hospital-treated condition in the U.S.



Contributes to  
1 in 2-3 hospital  
deaths<sup>1</sup>



Representing  
\$27B in U.S.  
healthcare  
costs<sup>2,3</sup>



**Claims more  
lives than breast  
cancer, prostate  
cancer and  
AIDS, combined<sup>4</sup>**



1 in 5 surviving  
sepsis patients  
die within 2 years  
due to sepsis<sup>5</sup>



Kills ~250,000  
Americans  
annually and ~6  
million people  
worldwide<sup>6,7</sup>



Most prevalent  
and costly cause  
of hospital  
readmissions<sup>8</sup>

1. Liu, V., Escobar, G. J., Greene, J. D., et al. (2014). Hospital deaths in patients with sepsis from 2 independent cohorts. *Jama*, 312(1), 90-92.

2. Torio, C. M. and Moore, B. J. (2016). Statistical Brief# 204. Healthcare Cost and Utilization Project (HCUP). May.

3. McDermott, K. W., Elixhauser, A., Sun, R. (2017). Statistical Brief# 225. Healthcare Cost and Utilization Project (HCUP). June.

4. National Institute of General Medical Sciences. National Institutes of Health. Sepsis fact sheet. 2014.

5. Prescott, H. C., Osterholzer, J. J., Langa, K.M., et al. (2016). Late mortality after sepsis: propensity matched cohort study.

6. Centers for Disease Control and Prevention.

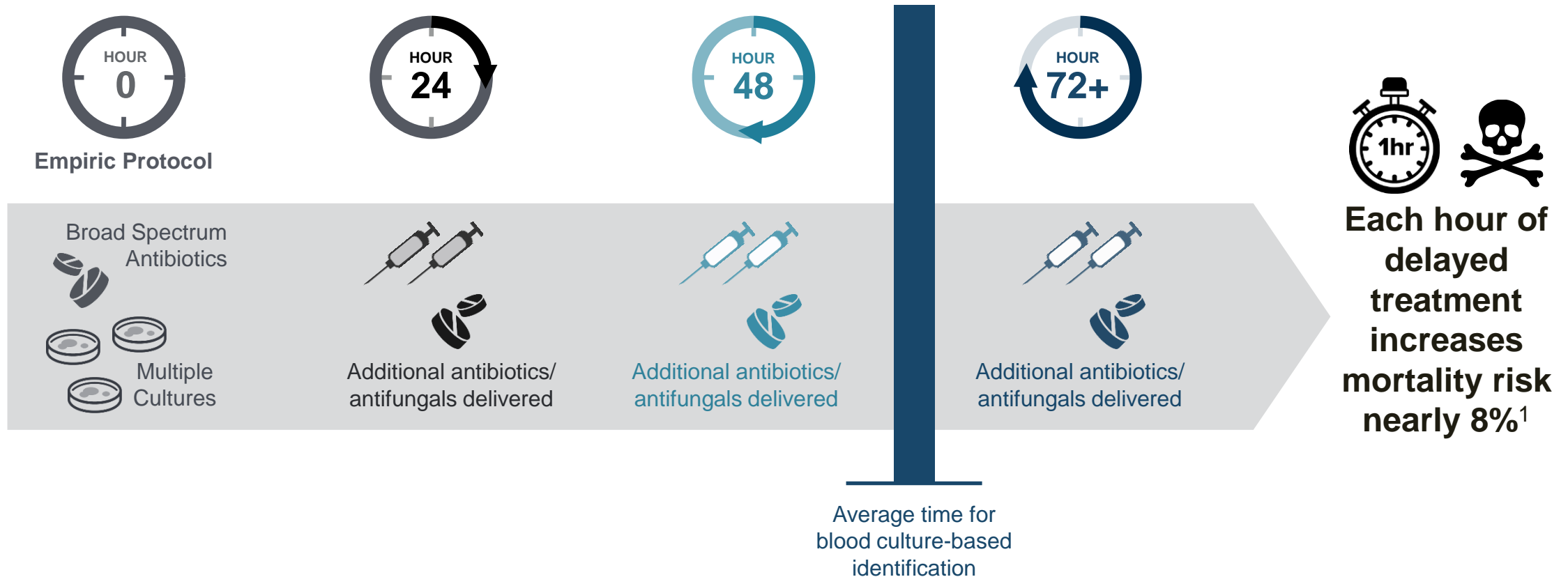
7. Gilbert, J. A. (2018). Sepsis care bundles: a work in progress. *The Lancet Respiratory Medicine*.

8. Mayr, F. B., Talisa, V. B., Balakumar, V., et al. (2017). Proportion and cost of unplanned 30-day readmissions after sepsis compared with other medical conditions. *JAMA*, 317(5), 530-531.



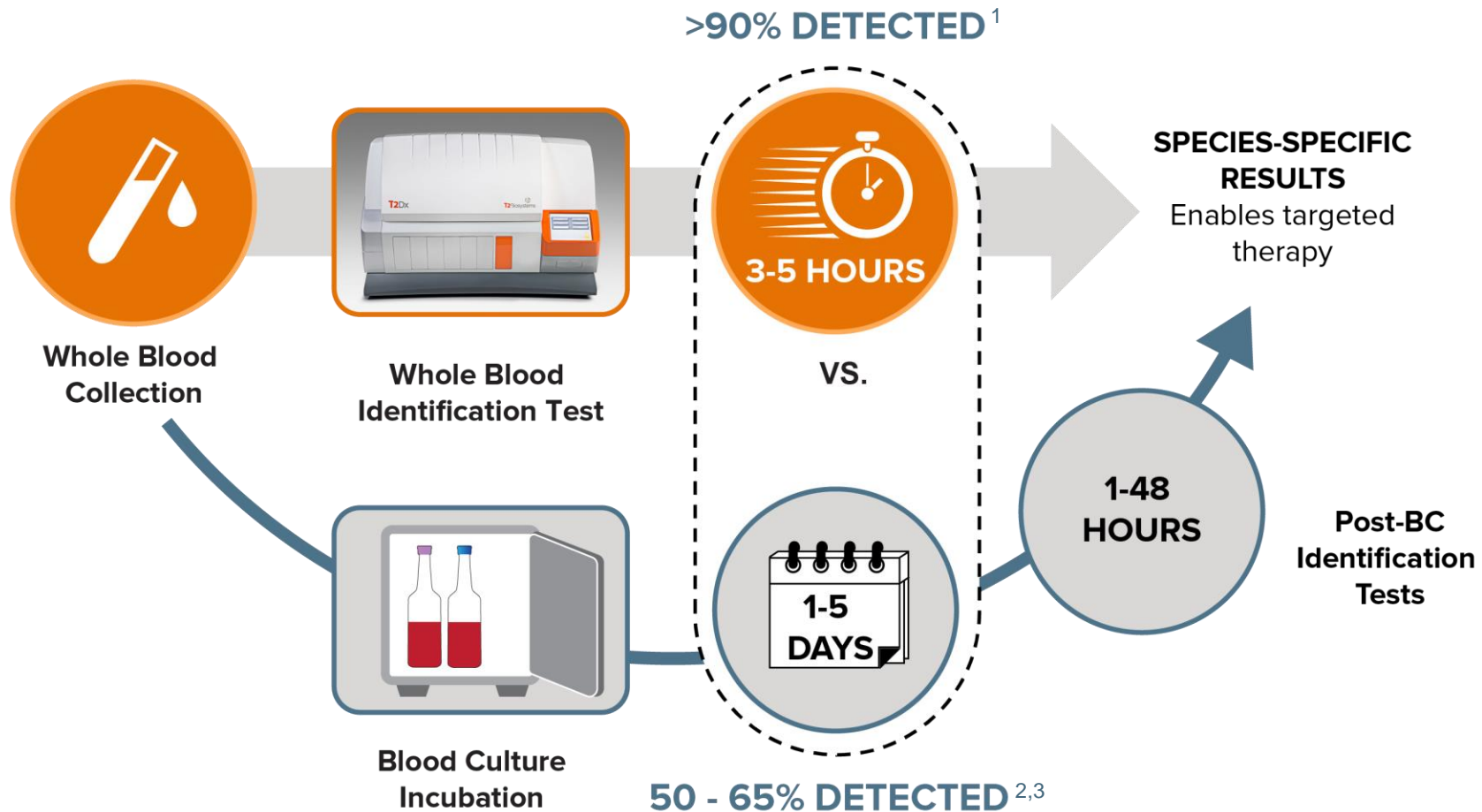
# Sepsis Poses an Hourly Challenge that Relies on Probability-Based Protocols

Patient journey: Current pathway and empiric “process”



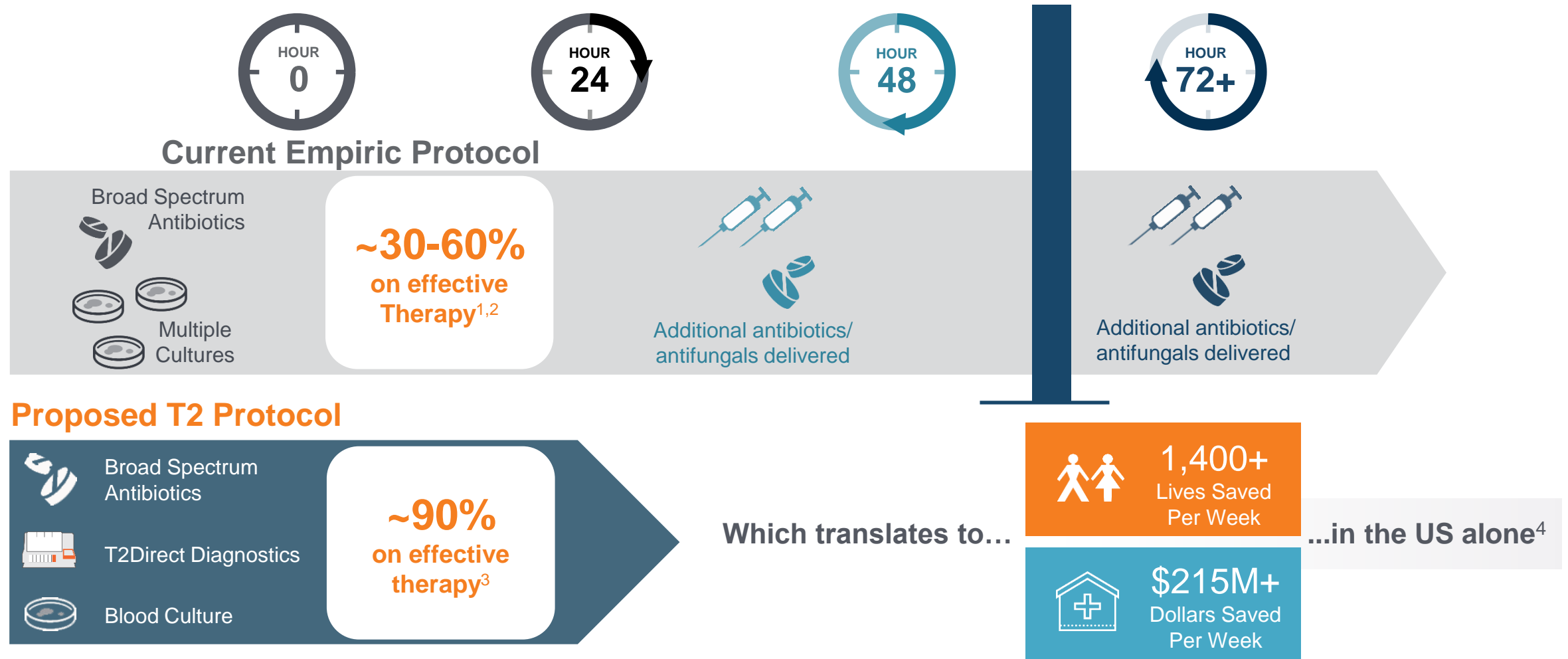
# T2MR: New Standard in Detecting Sepsis Causing Pathogens

T2Direct Diagnostics provide faster and more accurate detection



1. Mylonakis, E., Clancy, C. J., Ostrosky-Zeichner, L., et al. (2015). T2 magnetic resonance assay for the rapid diagnosis of candidemia in whole blood: a clinical trial. *Clinical Infectious Diseases*, ciu959.
2. Clancy, C. J., & Nguyen, M. H. (2013). Finding the "missing 50%" of invasive candidiasis: how nonculture diagnostics will improve understanding of disease spectrum and transform patient care. *Clinical infectious diseases*, 56(9), 1284-1292.
3. Cockerill III, F. R., Wilson, J. W., Vetter, E.A., et al. (2004). Optimal testing parameters for blood cultures. *Clinical Infectious Diseases*, 38(12), 1724-1730.

# A Simple Change, an Immense Impact



1. T2Bacteria Clinical Pivotal Trial Data.

2. Buehler, S. S., Madison, B., Snyder, S. R., et al. (2016). Effectiveness of practices to increase timeliness of providing targeted therapy for inpatients with bloodstream infections: a laboratory medicine best practices systematic review and meta-analysis. Clinical microbiology reviews, 29(1), 59-103.

3. Kumar, A., Ellis, P., Arabi, Y., et al. (2009). Initiation of inappropriate antimicrobial therapy results in a fivefold reduction of survival in human septic shock. CHEST Journal, 136(5), 1237-1248.

4. Represents the potential healthcare savings and lives saved using the T2Direct Diagnostic to test high risk patients based on assumed levels of total annual patients assuming all high-risk sepsis patients are tested with T2Direct Diagnostics and assuming (i) 90% of high risk patients receive appropriate therapy within hours of the presentation of symptoms, (ii) a 50% mortality rate reduction for patients who receive rapid appropriate therapy, and (iii) that each new detected patient saves \$22,800. This slide contains T2's estimates, which are not based on historical results and constitute forward-looking statements that are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statement.

# T2Bacteria Impacts Patient Care & Antimicrobial Stewardship Optimization

## Growing number of T2Bacteria success stories



- 1200-bed tertiary-care teaching hospital<sup>1</sup>
- Emergency Department, Infectious Diseases Unit, and ICU (n=140 samples)
- T2 Detected 20 Positive Cases Missed By Blood Culture, MALDI and BioFire.
- T2B+/BCx- results significantly more likely in patients receiving antibiotics,  $p < 0.001$
- 66.7% of Infected Patients Missed by BC and Detected By T2 Were Being Inappropriately Treated at Time of T2B Result



- 1423-bed not-for-profit community hospital<sup>2</sup>
- Patients with sepsis in the Emergency Department (n=25)
- Identified organisms 20 hours sooner than blood cultures
- Negative results provided 122 hours sooner than blood cultures and
- Numerous opportunities for stewardship intervention identified, including 36 opportunities for de-escalation of coverage for *S. aureus* and *P. aeruginosa*



- 2600-bed academic medical center<sup>3</sup>
- Hematologic Malignancy/ HSCT (n=94)
- T2Bacteria assay showed significantly faster time to species ID than a culture-dependent rapid diagnostic method
- T2Bacteria could have potentially influenced care and provided an opportunity to place (T2+/BC-) patients on effective therapy faster than with culture dependent methods.



- Subset of ED patients included in the Pivotal Trial (n=137)<sup>4</sup>
- Detection of more pathogens in 11 patients where blood cultures remained negative
- 70% (16/23) of patients with a positive T2 result could have experienced at least some clinical benefit from the T2Bacteria result
- T2Bacteria assay could have reduced time to effective therapy by an average of 28.0 hours

1. De Angelis G et al. T2Bacteria magnetic resonance assay for the rapid detection of ESKAPEc pathogens directly in whole blood. J Antimicrob Chemother. 2018 Mar 1;73(suppl\_4):iv20-iv26.  
2. Weisz E et al. MAD-ID 2018.  
3. Walsh T et al. ECCMID-EIM 2019.  
4. Voight C et al. ECCMID-EIM 2019.

# T2Candida Panel is Changing Treatment Protocols

Growing number of real-world T2Candida success stories



- Study demonstrated \$2.3M in annual hospital savings
- Reduced median ICU length of stay by 7 days; overall stay by 4 days
- Most negative patients had antifungals discontinued or de-escalated saving \$\$.<sup>1</sup>



- Median length of stay reduced by 7 days
- Unnecessary antifungal therapy was avoided in >50% of patients
- Average net antifungal savings of ~\$195 for every patient tested<sup>2</sup>



- Pharmacy savings of ~\$280 per patient
- T2Candida detected 56% more positive patients than blood culture<sup>3</sup>



- 100% of patients who tested positive received appropriate therapy in <9 hours
- Therapy was discontinued for all patients who tested negative<sup>4</sup>

1. Wilson, N.M., Kenney, R.M., Tibbetts, R.J., et. al. T2 Magnetic Resonance Improves the Timely Management of Candidemia. Poster Presentation IDWeek 2016.

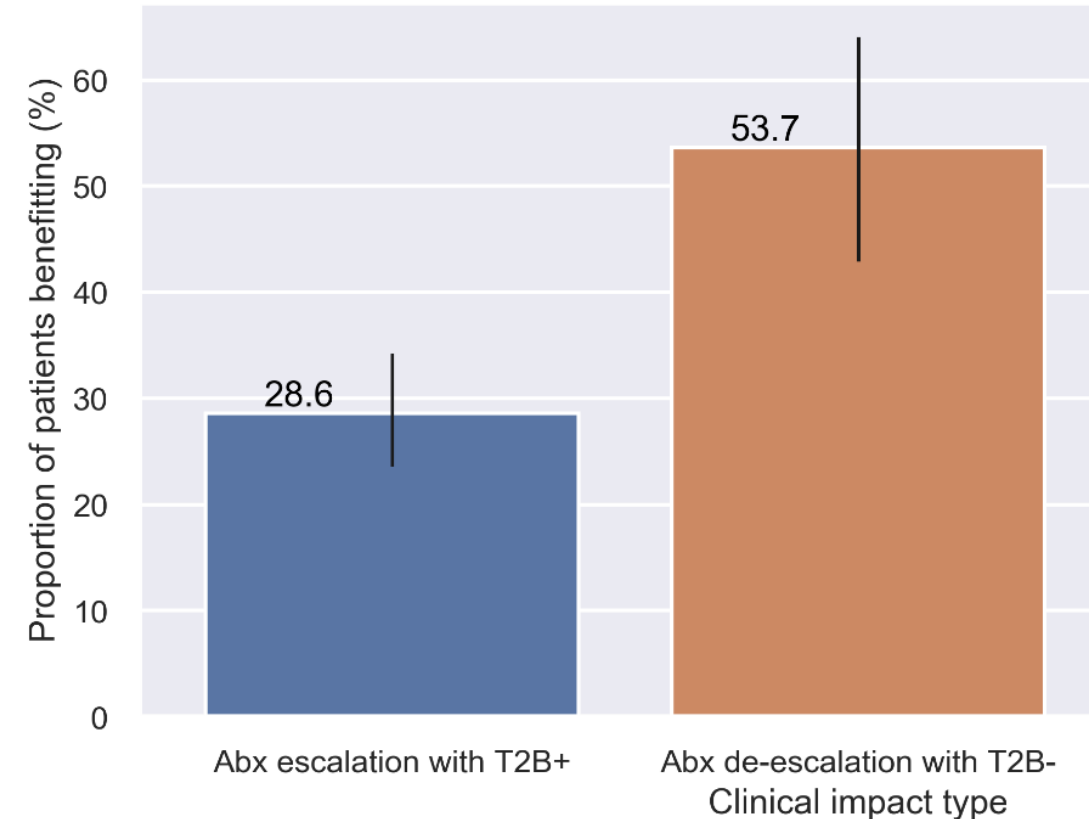
2. Estrada, S. J. Real World Value of T2Candida Lee Memorial Hospital. Slide Presentation ASM 2016.

3. Kateon, H., Edwards, J., Sawyer, A., et al. Utilization of T2Candida Panel for the rapid detection of *Candida* species in a large community hospital. Poster Presentation IDWeek 2016.

4. Patel, F. and Young, E. Antifungal Prescribing During Initial Implementation of Candidemia Early Detection and Species Identification Testing with T2Candida Panel. Poster Presentation IDWeek 2016.

# Emerging T2Bacteria Clinical Utility Data

- Cases from 7 ED & ICU studies aggregated here.
- 125/299 (42%) cases showed substantial clinical benefit of those evaluated under chart review
  - T2+: faster time to effective therapy
  - T2-: earlier antibiotic de-escalation
  - T2+: avoiding premature ED discharge/readmission
- 16% T2Bacteria positivity rate, range 13%-35% across all patients tested
- 2 cases of T2Bacteria helping avoid premature discharge and readmission in the ED
- A significant percentage of patients benefit from T2Bacteria results.



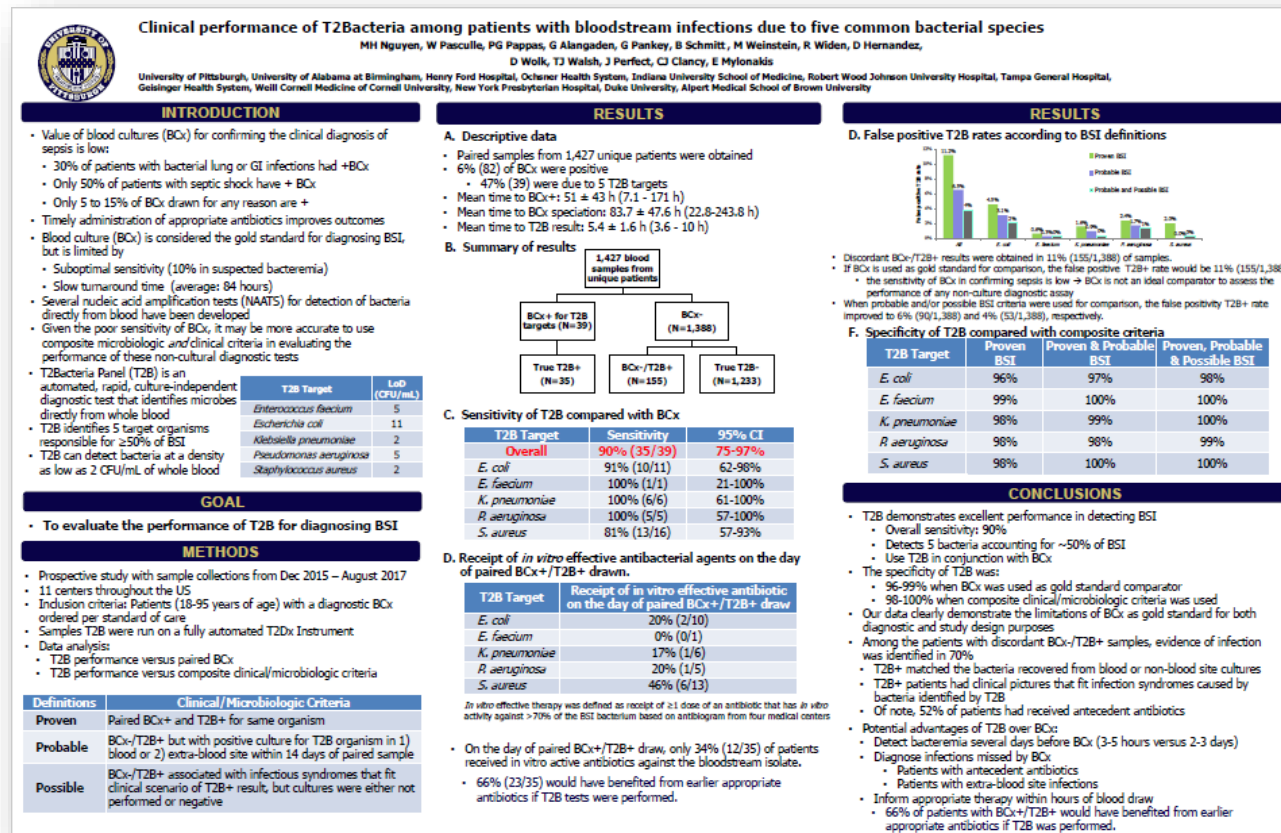


# T2Bacteria Pivotal Data Published in Annals of Internal Medicine

1,427 patient samples collected across 11 hospitals

## Comparisons to Blood Culture:

- Detected **69 patient** infections not detected by culture
- Provided results more than **2.5 days faster than culture** (5.4 hours)
- 68%** of patients with a BSI confirmed by T2 and blood culture could have benefitted from earlier rapid diagnostic result
- Noted advantage in detecting infected patients on antibiotics who were missed by blood culture





# Significant Burden of Bacterial Infection and Sepsis

Payors should support and incentivize revised protocols

**Add  
T2Bacteria  
&  
T2Candida**

**>90% of  
patients on the  
right targeted  
therapy within  
6 to 8 hours**



Representing \$27B in U.S. healthcare costs<sup>1,2</sup>

**~\$25,000 Cost Savings**

Per patient if on right therapy  
within 24 hours<sup>3</sup>

**Billions of Dollars**

In savings for hospitals, including  
decreased readmissions<sup>4</sup>

**50% Reduction**

In mortality for patients with rapid  
effective treatment<sup>5</sup>

**Patients Benefit**

From reduction in long-term  
side-effects

1. Torio, C. M. and Moore, B. J. (2016). Statistical Brief# 204. Healthcare Cost and Utilization Project (HCUP). May.

2. McDermott, K. W., Elixhauser, and A., and Sun, R. (2017). Statistical Brief# 225. Healthcare Cost and Utilization Project (HCUP). June.

3. Estimated economic impact based on customer experience with T2Candida Panel; Bilir, S. P., Ferrufino, C. P., Pfaller, M. A., and Munakata, J. (2015); and studies for target bacterial species.

4. See slide 11.

5. Leibovici, L., Shraga, I., Drucker, M., et al.(1998). The benefit of appropriate empirical antibiotic treatment in patients with bloodstream infection. Journal of internal medicine, 244(5), 379-386.

# New Technology Add-on Payment by CMS



- The T2Bacteria Panel is the first, and only, in-vitro diagnostic test to ever receive approval from the US Centers for Medicare & Medicaid Services (CMS) for New Technology Add-on Payment (NTAP)
- CMS is the single largest payer for health care in the US
- The payment is in addition to the current diagnosis-related group (MS-DRG) reimbursement

## CMS Found that T2Bacteria Met its Criteria For Additional Payment For Medical Advances

1

New

2

Cases are Inadequately  
Paid Under the Existing  
MS-DRG System

3

Substantial  
Clinical Improvement  
Over Existing  
Technologies

*“The T2Bacteria Test Panel represents a substantial clinical improvement over existing technologies because it reduces the proportion of patients on inappropriate therapy, thus reducing the rate of subsequent diagnostic or therapeutic intervention as well as length of stay and mortality rates caused by sepsis causing bacterial infections.”*

-United States CMS FY 2020 inpatient prospective payments system final rule

# Established Reimbursement Across Multiple Care Environments

Financially attractive in all settings

## Point-of-Care Testing

Emergency Room  
Outpatient Settings

- CPT 87640, 87798
- Coverage if not admitted; other outpatient settings
- ER is most common setting

	T2Bacteria
Reimbursement	\$220
Cost of Test	\$150

## In-Patient Hospital

Admitted from ER  
Admitted for Unrelated Procedure

- DRG 870, 871, 872; example DRG reimbursement: \$35,000<sup>1</sup>
- NTAP max reimbursement of \$97.50 (65% of list price of T2Bacteria), starting 10/1/19

	T2Bacteria	T2Candida
Cost of Test	\$150	\$200
Cost After NTAP	\$52.50	
Percent of DRG	0.15%	0.6%

0.75% of DRG

# Commercial Strategy

Global expansion of T2Direct Diagnostics driven by T2Bacteria Panel launch

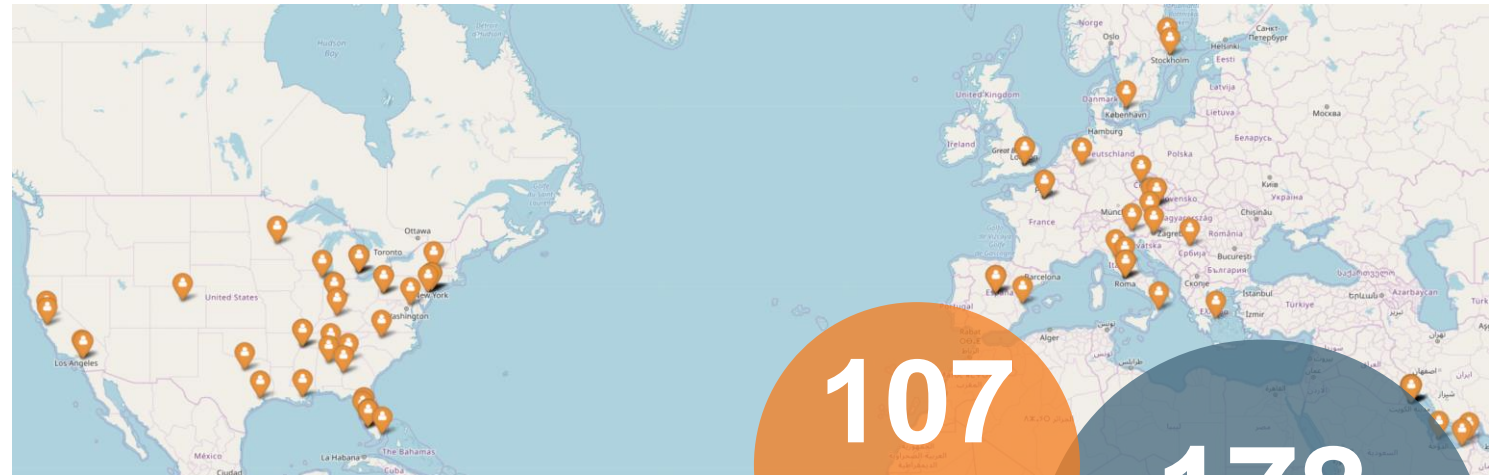
## Expanding on the existing T2Dx installed base



### United States

#### Direct Sales

- **Organization:** Growing to 15 sales reps and 6 medical affairs liaisons
- **Target:** Hospitals and Health Systems with the highest concentration of patients at risk for sepsis-related infections
- **Premier GPO agreement**
  - **Technology Breakthrough Product** designation
  - Simplifies sales & contracting process with **4,000+** Premier hospitals & health systems



### International

#### Distributor Sales in 35 Countries

- 14 distribution partners supported by small team of direct sales/marketing and field service personnel

107

Instruments placed  
or contracted  
to be placed

178

Hospitals with  
access to the  
T2Dx platform

# Adoption Drives Revenue and Rapid Pay Back

Doing well by doing good

## Typical High Risk Patients In Target Market

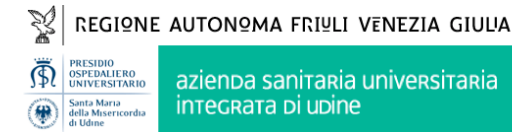
Patients Suspected of Sepsis	3,000
Patients Suspected of Fungal Infections	375

## Potential Hospital Utilization Scenario

	Patients Tested	Price per Test	Total Revenue
T2Bacteria	1,500	\$150	\$225,000
T2Candida	375	\$200	\$75,000
<b>Annual Recurring</b>	<b>1,875</b>		<b>\$300,000</b>
<b>T2Dx Instrument</b>		\$100,000 unit price	

In this example, patients suspected of sepsis are screened with the T2Bacteria Panel in the ER and throughout portions of the hospital as part of a sepsis protocol.

# Selected T2 Biosystems Customers





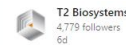
# Comprehensive Commercial Tactics

Global expansion of T2Direct Diagnostics driven by T2Bacteria Panel launch

## Medical Meetings & Conferences



## Digital Marketing



WEBINAR: "Sepsis Management: The Emergence of Rapid Diagnostics in the ED." Sepsis, the #1 cause of death in US hospitals, has a mortality that exceeds prostate cancer, breast cancer and AIDS combined. As many as 92% of s...



37 Likes - 3 Comments

### Targeted Social Media and Email Campaigns



... Rapidly diagnose and treat some of the most common and deadly pathogenic organisms. ... Differentiate how rapid diagnostics can be a "game changer" in the microbiology lab.



Download Prof. Sanguinetti's Presentation  
Schedule a Meeting on T2Bacteria

## Publications / Economic Models

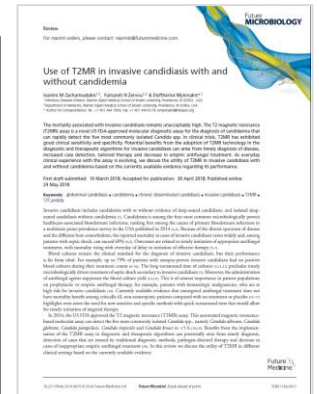
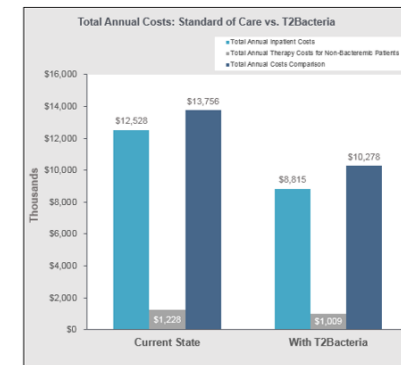
### Utilizing Same-Day Sepsis Pathogen ID for Faster Therapy, Enhanced Stewardship, Improved Outcomes

Cornelius J. (Neil) Clancy, M.D.

20 June 2018



### T2Direct Diagnostics™ Economic Model





# T2Resistance Panel

The first direct-from-blood detection of resistance markers

- Detection of **13 resistance genes** from both Gram-positive and Gram-negative pathogens from a single patient blood sample, without the wait for blood culture, in 3-5 hours
- Covers the most clinically important genes, including several listed on the **CDC's Urgent Threat list** for antibiotic resistance
- Utilizes **same T2Dx Instrument** as the T2Bacteria and T2Candida Panels
- Developed with the help of an award from CARB-X (funded by BARDA), the Wellcome Trust, and the National Institute of Allergy and Infectious Diseases (NIAID)
- Research use only (RUO) available as of 9/30/19
- Expected to receive CE Mark for commercial availability outside U.S. by the end of 2019

## FDA Breakthrough Designation

- Granted “Breakthrough Device” designation by the FDA
- Allows T2 Biosystems to work closely with the FDA during the premarket review phase to ensure patients can have access to the benefits of this innovation as soon as possible



Powered by **CARB-X**



# T2 Pipeline Highlights

Enabled by Highly Sensitive Detection

T2Candida auris	T2Resistance	T2Lyme	Comprehensive Panel	Biothreat Panel
<i>C. auris</i> <i>C. duobushaemulonii</i> <i>C. haemulonii</i>	<i>mecA/C</i> <i>vanA/B</i> CTXM-14/15 KPC OXA-48 Group NDM, VIM, IMP AmpC (CMY/DHA)	<i>B. burgdorferi</i> <i>B. afzelii</i> <i>B. garinii</i> <i>Borellia spp.</i>	99% of bloodborne bacterial infections  Pan-gram + / - results (detecting >250 species)  All bloodborne antibiotic resistant threats identified by CDC	<i>B. anthracis</i> <i>F. tularensis</i> <i>Burkholderia spp.</i> <i>Y. pestis</i> <i>R. prowazekii</i> Toxin genes
Research Use Only Available	Research Use Only Available CE Mark by YE 2019	Pivotal Study Ongoing	Development Commencing	Development Commencing

Next-Generation High Throughput Instrument

# Financial Summary<sup>1</sup>

June 30, 2019		
Revenue	2Q19	\$1.8M
	2Q18	\$3.9M
	FY18	\$10.5M
Product Revenue	2Q19	\$1.3M
	2Q18	\$1.2M
	FY18	\$4.8M
Product Growth	YoY	8%
Cash Burn	2Q19	\$8.9M
Cash <sup>4</sup>		\$28.6M
Common Shares Outstanding	2Q19	44.4M

>5% Investors – As of June 30, 2019 <sup>2,3</sup>	
Canon Life Sciences	13.6%
Goldman Sachs	9.6%
Senvest Management	6.4%

Post 2Q19 Results Updates
<ul style="list-style-type: none"> <li>Restructured CRG debt agreement               <ul style="list-style-type: none"> <li>Extends principal maturity and interest-only period by 1 year to 2022</li> <li>Reduces minimum revenue targets for 2019 – 2022 to levels below company's forecast</li> </ul> </li> </ul>

1. All amounts are rounded to the nearest hundred thousand.  
 2. Based on 44,535,572 shares outstanding as of June 30, 2019.  
 3. Source SEC filings as of July 25, 2019.  
 4. Includes \$180k restricted cash.

# Guidance

2019 Guidance	
<b>2019 total revenue</b>	<b>\$8.7 - \$9.6 million</b>
Product revenue	\$5.7 - \$6.1 million
<b>3Q 2019:</b>	
Product revenue	\$1.4 - \$1.5 million
<b>2019 T2Dx new contracts:</b>	<b>43 – 53</b>
<b>3Q/4Q 2019 T2Dx new contracts:</b>	<b>10 – 15</b>
<b>Quarterly operating expense:<sup>1</sup></b>	<b>\$10.5 - \$11.5 million<sup>2</sup></b>

Breakeven Model	
Total revenue	\$65 - \$75 million
Gross margin	~45 - 50%

1. Excluding cost of product revenue.

2. Including non-cash depreciation and stock based compensation of approximately \$3.0 million; contingent on closing a research collaboration

3. \* This slide contains T2's future goals and aspirations, which constitute forward-looking statements that are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. See "Forward-Looking Statements" on slide 2.

# Breakthroughs in Medical Diagnostics

First and only FDA-cleared diagnostic to detect pathogens directly from blood

FAST COMPANY



Early 20<sup>th</sup>  
century



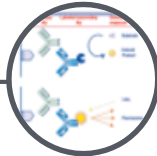
Blood  
Culture

1947



Cell  
Counting

1959



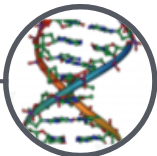
Immunoassay

1968



Automated  
Chemistry  
Analyzers

1985



PCR  
Technique

## Direct Sample Analysis Identify Pathogens Using Magnetic Resonance



# Building Positive Momentum for Business & Technology

BARDA, FDA Breakthrough Designation, NTAP, Debt Restructuring, Premier GPO

## *BARDA Key Takeaways*

- Provides added validation of T2Bacteria & T2Candida Panels and the T2Dx Platform
- Accelerates development of comprehensive panel & T2Resistance Panel
- Expands and funds pipeline including development of Biothreat panel
- Supports reduction of cash burn
- Drives growth in research revenue



## *Recent Updates*

- FDA Breakthrough Designation for T2Resistance
- CMS Add-On Reimbursement through New Technology Add-On Payment (NTAP)
  - Covers ~2/3 price of T2Bacteria Panel
- Premier Breakthrough Technology contract providing access to over 4,000 hospitals and health providers
- Restructured CRG debt
  - Extends principal maturity and interest-only period by 1 year to 2022
  - Reduces minimum revenue targets for 2019 – 2022 to levels below company's forecast

# Investment Highlights

A platform technology with multiple, billion-dollar franchise opportunities



## T2MR

Innovative  
technology - broad  
applications



## Market

\$2B+ Initial market  
potential



## Sepsis Causing Pathogen ID

Provide species-specific  
results, direct from whole  
blood, in 3 to 5 hours



## Reimbursement

Covered by existing  
reimbursement codes



## Robust Pipeline

A new generation of  
diagnostics



## Execution

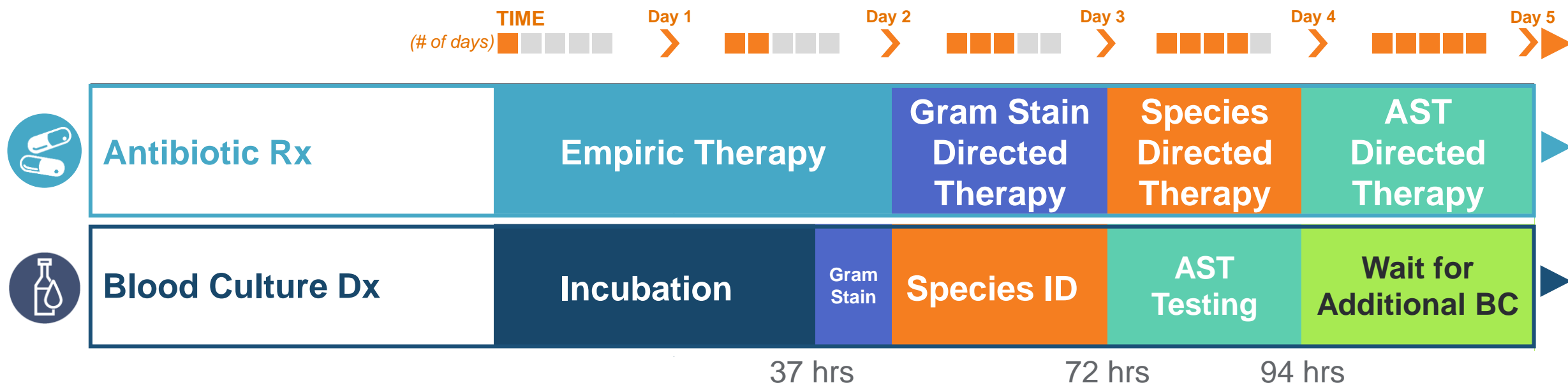
Patient access growing,  
key collaborations  
established



# Breakthrough Sepsis Pathogen Detection

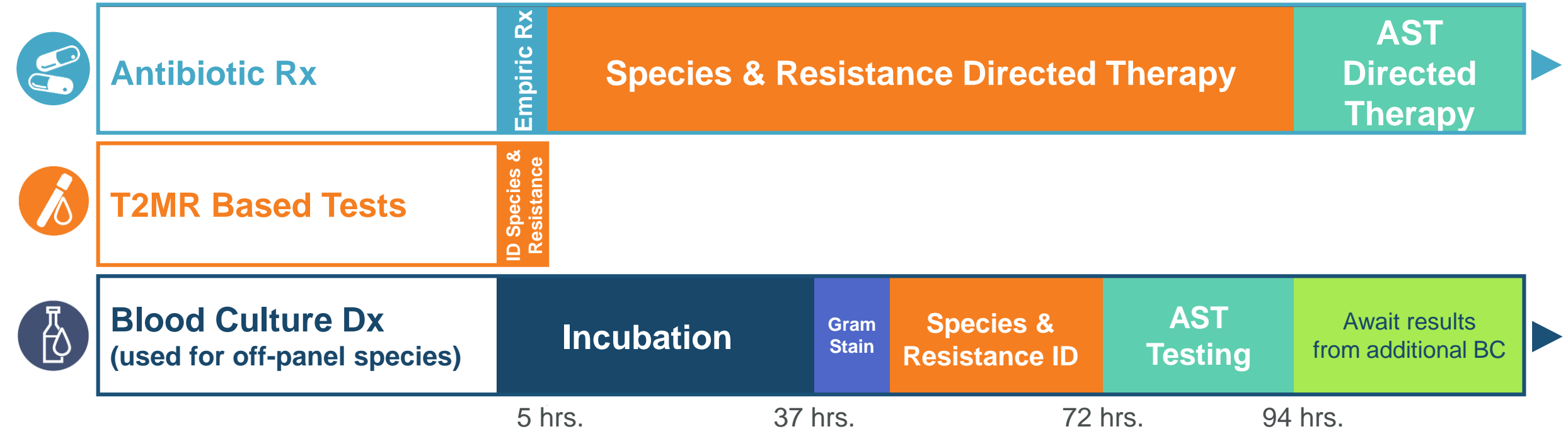
## Appendix

# Diagnostics Time to Result Influences Therapy



- Antibiotic administration rates range from 50% to 70% for patients with a blood culture draw <sup>(1-3)</sup>
- Only ~10% of patients suspected of sepsis yield a positive blood culture.
- Meta-analysis of 70 studies found empiric antibiotic therapy was inappropriate in 46.5% of patients<sup>4</sup>
- The proportion of patients on effective therapy after organism species ID has been shown to be >90%, demonstrating effectiveness of antibiogram-directed therapy based on species ID<sup>5</sup>
- Significant percentage of patients infected with resistant organisms die before AST results are available<sup>6</sup>

# T2MR & Blood Culture Results Influence Therapy



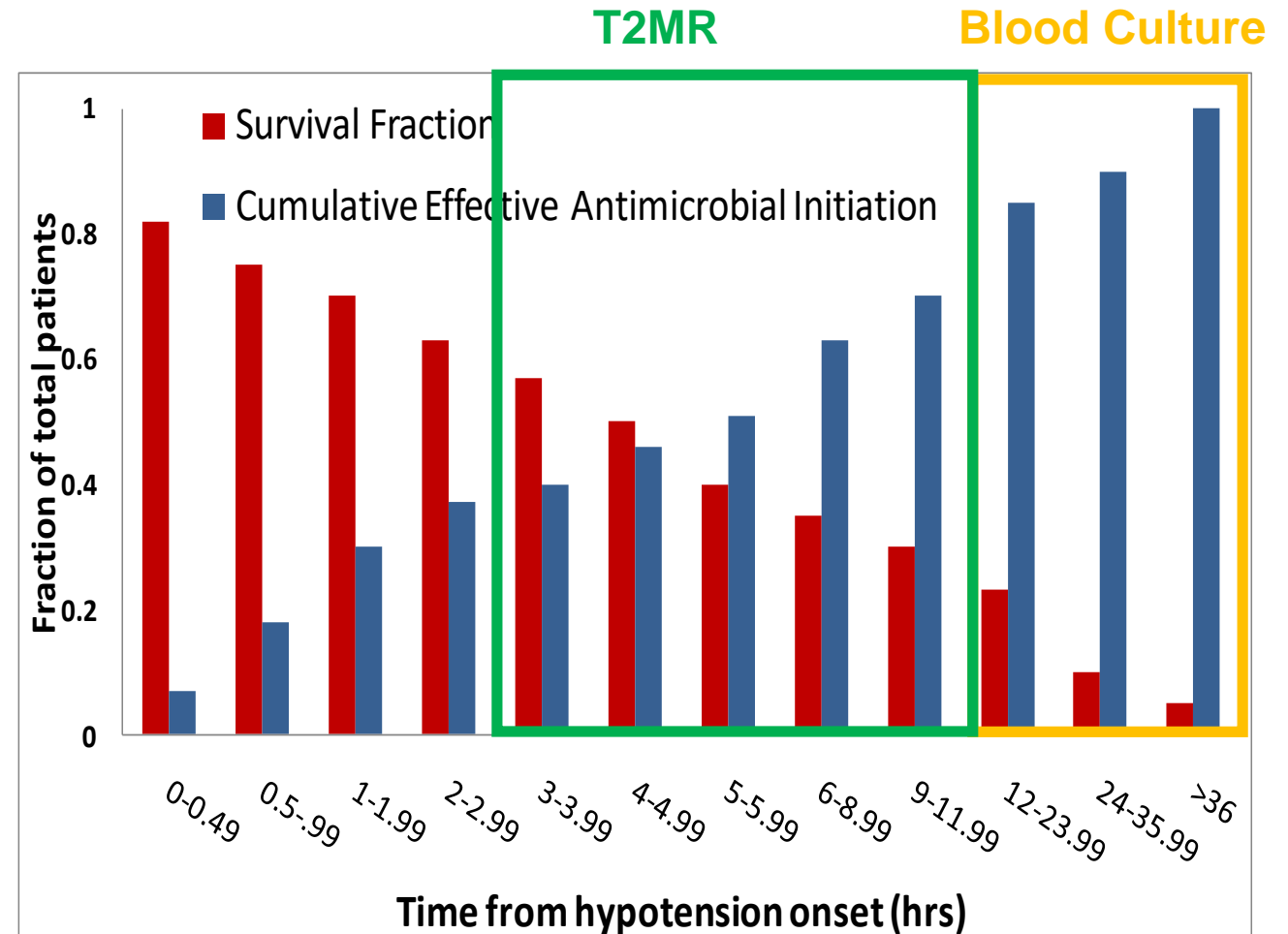
- T2MR Based tests enable more rapid targeted therapy based on species ID & resistance
- Across 3 studies, 94%-100% of patients are correctly treated after species ID, not after assessment of susceptibility testing, demonstrating effectiveness of antibiogram-directed therapy<sup>1-3</sup>
- Numerous studies indicate that this will reduce both LoS and mortality for infected patients

(1) Doern et al. *J Clin Micro* 1994; (2) Byl et al. *Clin Infect Dis* 1999; (3) Kerremans et al. *J Clin Microbiol* 2012  
CORPORATE PRESENTATION

Average Turn around times from Nguyen et al. *Annals Int Med* 2019

# Time to Appropriate Therapy Impacts Survival










- Key predictor of survival and length of stay (LoS) for patients with bacteremia is time to effective therapy
- As many as 80% of sepsis deaths could be prevented with rapid diagnosis and treatment
- For every hour delay in time to appropriate therapy:
  - Survival decreases by 7.6% during septic shock<sup>1</sup>
  - Relative odds of death increase by 4.0% during bacteremia<sup>2</sup>
- Reducing time to effective therapy has resulted in significant reductions in LoS, up to 8 days<sup>3-5</sup>
- Appropriate and rapid delivery of targeted antibiotics is critical for surviving sepsis<sup>6</sup>



Kumar A. et al., Crit Care Med 2006, 34:1286, N=2731










# “Pursuit of the Holy Grail”\*

## Rapid, Direct-from-Blood Pathogen & Resistance Results

	Development	CE-Marked	FDA Cleared	US Clinical Use
				
				
				
				
			X	
		X		
		X		
		X		
				

1. For decades, numerous companies & technologies have pursued the development of a platform for direct-from-blood pathogen & resistance results.
2. Several have stopped or shifted their development programs to post positive blood culture as a “direct” sample input.

# Progress towards Culture Independent Tests

	LoD (CFU/mL)*	Clinical Sensitivity	Clinical Specificity	Comments
	1-11	90% - per sample 90% - per result	90% - per sample 98% - per result	CE mark & FDA cleared <sup>1</sup>
	3-100	65%	86%	Manual test, CE mark only <sup>2</sup>
	1-100	44%	87%	Automated test, CE-mark only <sup>3</sup>
	10-50	85%	48%	Manual test, CE mark only <sup>4</sup>
	8-32	86% - per sample	86% - per sample	Withdrew FDA application, not on market <sup>5</sup>
	1,000,000	N/A	N/A	Focused on post-culture <sup>6</sup>
	1,000	N/A	N/A	Maintained focus on post-culture <sup>7</sup>
	N/A	N/A	N/A	Formal LoD data not disclosed <sup>8</sup>
	N/A – cfDNA	94% - per sample	40% - per sample	Send-out reference lab test <sup>9</sup>

1. Nguyen et al. Annals Int Med 2019; 2. Roche Septifast labeling; Stevenson et al Health Technol Assess 2016; 3. McKeating JCP 2018; 4. Molzyme Sepsitest product labeling; 5. Metzgar et al PLOS ONE 2016; 6. PhenoTest 510(k) summary; 7. BCID product labelling; 8. Qvella AMP 2017 presentation; 9. Blauwkamp et al. Nature Micro 2019.  
\*LoD based on ≥95% positivity rate for N≥20 replicates at a given titer level using CFU/mL assignment of cell solution spiked into blood.



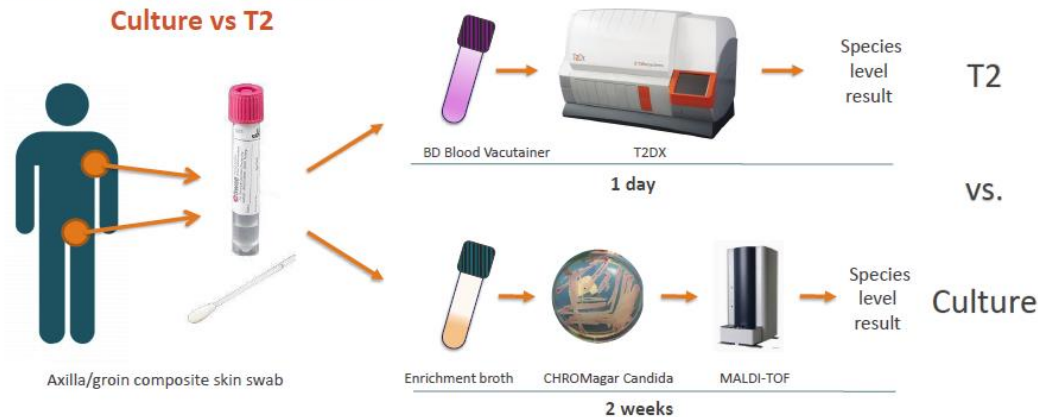
# Rapid Development of *C.auris* T2MR Panel

- ID of *Candida auris* has been hampered by the poor specificity, poor sensitivity and slow growth of organism
- Resulting in delays in therapy for infected patients and delays in infection controls for colonized patients accelerating the spread of *Candida auris*



## *C. auris* diagnostic comparison:

### Culture vs T2



The New York Times

DEADLY GERMS, LOST CURES

## How a Chicago Woman Fell Victim to *Candida Auris*, a Drug-Resistant Fungus

The mysterious infection has appeared at hospitals around the world, but few institutions or families have discussed their experience.



Stephanie Spoor, center, with her husband, Gregory, left, during a bedside wedding ceremony of her son, Zack, to his new wife, Carley (right), at Northwestern Memorial Hospital in Chicago. Ms. Spoor died just a few days later. Spoor family photo

- CDC approached T2 Biosystems with problem of prolonged culture for *C. auris*
- T2Candida auris Panel RUO (5 hr TAT) vs. Patient swab cultures (14 days TAT)
- T2Dx's installed at CDC Mycology laboratory for validation of use on patient skin swab samples<sup>1-3</sup>
- 100% inclusivity of Clades I-IV,  $\leq 5$  CFU/mL LoD;  $\geq 89\%$  Sensitivity & 98% Specificity; 98% PPV, 89% NPV

1. Manning et al. "Automated Detection of *Candida auris* Direct from Whole Blood and Swab Specimens by T2MR" ID Week 2017  
 2. Sexton et al "Evaluation of a new T2 Magnetic Resonance assay for rapid detection of emergent fungal pathogen *Candida auris* on clinical skin swab samples." Mycoses 2018  
 3. Sexton et al. "Evaluation of T2 Magnetic Resonance *Candida auris* Panel as a Rapid Diagnostic for this Emerging Multidrug Resistant Yeast in Clinical Skin-Swab Samples." ASM 2018.



# T2Lyme Clinical Performance

N= 21 Subjects	Tissue Culture		
Diagnostic Test	PPA	NPA	OPA
T2Lyme (blood)	78%	100%	90%
Tissue PCR	67%	100%	86%
Seroconversion	67%	67%	67%
2-Tier (Serology/WB)	56%	92%	76%
Blood PCR	0%	100%	57%
T2Lyme and 2-tier IgM	100%	92%	95%

- True positive subjects were established by culturing *Borrelia* from an EM tissue sample.
- T2Lyme PPA was 78%, while CDC recommended 2-tier diagnosis PPA was 56%
- T2Lyme had higher accuracy (OPA) than all other methods; combination of T2Lyme & 2-tier IgM provided best overall clinical accuracy
- Blood PCR (PPA, 0%) failed to return any positive results
- NPA of T2Lyme was 100%, indicating greater specificity over serology results
  - We've tested >550 negative samples with no false-positive results

# Comprehensive T2MR Panel for Bloodstream Infections

Result type	N	Results
Pan-level	3	Gram positive bacteria, Gram negative bacteria, Fungi
Genus level	11	<i>Acinetobacter spp.</i> , <i>Candida spp.</i> , <i>Citrobacter spp.</i> , <i>Enterobacter spp.</i> , <i>Enterobacteraceae</i> , <i>Enterococcus spp.</i> , <i>Listeria spp.</i> , <i>Mycobacterium spp.</i> , <i>Staphylococcus spp.</i> , <i>Coag negative Staphylococcus spp.</i> , <i>Streptococcus spp.</i>
Gram pos. species	6	<i>E. faecium</i> , <i>E. faecalis</i> , <i>S. aureus</i> , <i>S. pneumoniae</i> , <i>S. pyogenes</i> , <i>S. viridans</i>
Gram neg. species	6	<i>A. baumannii</i> , <i>E. coli</i> , <i>Enterobacter cloacae</i> complex, <i>H. influenzae</i> , <i>K. pneumoniae</i> , <i>P. aeruginosa</i>
Fungal Species	7	<i>C. albicans</i> , <i>C. tropicalis</i> , <i>C. dublinensis</i> , <i>C. parapsilosis/C. metapsilosis/C. orthopsilosis</i> , <i>C. krusei</i> , <i>C. glabrata</i> , <i>C. auris</i>
Resistance genes	13	<i>mecA/C</i> , <i>mefA/E</i> , <i>vanA/B</i> , <i>ermA/B</i> , KPC, NDM, VIM, IMP, OXA, SHV, AmpC (CMY, DHA), CTX-M 14/15, TEM

- T2MR Feasibility data in hand to support T2MR panel of ≥40 reported results
- Achieves inclusivity of ≥ 99% of infections caused by blood-borne bacterial and fungal pathogens
- “Pan-level” channels detect >250 pathogen species; ≤10 CFU/mL detection demonstrated for pan gram+/-
- Resistance markers provide coverage for all blood-borne CDC antibiotic resistance threats
- New T2MR detection technology developed to shorten turn-around time and reduce cost
- T2MR is proven for direct-from-whole-blood; new data shows feasibility for positive culture detection