

The Only FDA-Cleared Direct-From-Blood **PRE BLOOD** Culture Rapid ID Diagnostic Testing of Sepsis-Causing Pathogens

Fully-automated T2Dx® Instrument

- **Rapid: results in 3 to 5 hours**
- **Simple: no sample preparation**
- **Ultra Sensitive: 1 CFU/mL**
- **T2MR® Technology is not inhibited by prior antimicrobial administration¹**



T2Candida®

Sensitivity: 91%²
Specificity: 99%²

C. albicans
C. tropicalis
C. parapsilosis
C. krusei
C. glabrata

**FDA-Cleared
CE-marked**
1-3 CFU/mL LoD

T2Bacteria®

Sensitivity: 95%³
Specificity: 98%³

E. faecium
S. aureus
K. pneumoniae
A. baumannii
P. aeruginosa
E. Coli

85%-91% of bacterial sepsis cases presenting in the ED at HCMC were caused by pathogens covered by the T2Bacteria Panel

**FDA-Cleared
CE-marked**
2-11 CFU/mL LoD

T2Resistance®

**FDA Breakthrough Device
CE-mark/RUO 2019**

mecA/C
vanA/B
CTXM-14/15
KPC
OXA-48 Group
NDM, VIM, IMP
AmpC (CMY/DHA)

U.S. Clinical Trial
(patient enrollment complete)
CE-marked
3-11 CFU/mL LoD

1. T2Candida and T2Bacteria Instructions for Use, refer to Performance Characteristics: Interfering Substances
2. Mylonakis, E., Clancy, C.J., Ostrosky-Zeichner, L., et al. (2015). Clinical Infectious Diseases
3. Nguyen H, et al. Performance of the T2Bacteria Panel for Diagnosing Bloodstream Infections: A Diagnostic Accuracy Study. Ann Intern Med. 2019.

How Is T2 Different Than Other Rapid Moleculars?

Key Points of Differentiation

- T2MR DX is the only FDA cleared whole blood direct diagnostics tool for pathogen ID, **no blood culture required**
- Which Provides a much faster time to result – T2MR DX provides speciated result within 5 hrs of presentation to ED w/greater than 95% specificity (Candida)
- 95.8% Sensitivity (Bacteria Panel), 98% Specificity & excellent LOD
- T2MR DX pathogen detection is NOT inhibited by antimicrobials in bloodstream
- T2 Bacteria detects 90% ESKAPE Pathogens
- T2MR is not subject to DNAemia

Who to Test?

T2 BACTERIA DIAGNOSTICS – PATIENT SELECTION CRITERIA

- T2Bacteria
 - Emergency Department
 - Patient is suspected of sepsis
 - Sepsis order code
 - SEP1 bundle
 - Admitted
 - In-patient
 - Sepsis, or
 - Septic shock, and/or
 - ICU stay, or
 - Lactate &/or PCT positive, or
 - Adding or escalating therapy
- T2Candida
 - **Considering antifungal therapy for Sepsis, or**
 - Septic shock, and/or
 - 3+ days in ICU, or
 - T2Bacteria Panel negative

Biggest Impact and Highest Incidence Rate

Initial Assessment/DRGs 870, 871:

- Suspect bloodstream infection and lactate, procalcitonin ≥ 0.5
- Suspected sepsis admitted to ICU (recommend ordering procalcitonin)
- Septic shock

And/OR confirmed

Critical illness with one or more of the following underlying conditions and a

Lactate pos./procalcitonin ≥ 0.5 :

- Complicated UTI
- Post-op; GI/hepatobiliary surgery
- IV drug user
- Febrile neutropenia/heme-onc malignancy/SOT
- Cellulitis
- HAP/VAP
- Immunocompromised/elderly (LTAC)
- Implanted device (dialysis access, CVC/PICC, prosthetic valve, prosthetic joint)

T2Dx Impact: Real World Case Studies

Reducing the cost of sepsis management



- Statistically-powered study demonstrating \$2.3MM in annual hospital savings
- Reduced median ICU length of stay per patient by 7 days (p=0.009)
- Reduction in total length of stay by 4 days/patient (p=0.164)
- 75% of negative patients had antifungals discontinued or deescalated¹



- Average length of stay per patient reduced by 7 days
- Unnecessary antifungal therapy was avoided in 41% of patients
- Unnecessary antifungal therapy was discontinued after 1 dose in another 15% of patients
- Average net antifungal savings of approximately ~\$200 for every patient tested²



- Reduction in duration of therapy and time to de-escalation in negative patients resulted in pharmacy savings of ~\$500 per patient
- T2Candida detected 56% more positive patients than blood culture³



- 83% of patients who tested positive received appropriate therapy within 6 hours of the blood draw and 100% in under 9 hours
- 0 patients who tested positive had been on antifungals prior to testing
- Therapy was discontinued for 100% of the patients who tested negative⁴

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

T2Dx: Detection of Significantly More True Infections as Blood Culture

T2Bacteria Panel	T2 Panel Positive	Blood Culture Positive
Paired +	35	39
Add'l Proven/Probable +	63	0
Total +	98/102 (96%)	39/102 (38%)

T2Candida Panel	T2 Panel Positive	Blood Culture Positive
Paired +	31	33
Add'l Proven/Probable +	22	0
Total +	53/55 (96%)	33/55 (60%)

* Paired blood culture

T2 enables, early targeted therapy by providing:

- Detection of significantly more true infections as blood culture
- No interference by antimicrobial therapy
- Accurate, actionable results in 3-5 hours
 - **Up to 10x faster than blood-culture dependent testing¹**
 - **3x more than Blood Cultures alone**

1. Worden L. Analysis of lab workflow details the need for next generation diagnostics. Beckers Hospital Review. October 12, 2017. Downloaded from: <https://www.beckershospitalreview.com/quality/analysis-of-lab-workflow-details-the-need-for-next-generation-diagnostics.html>

2. T2Bacteria Pivotal Study data presented by Leber Podium Presentation IDWeek 2017

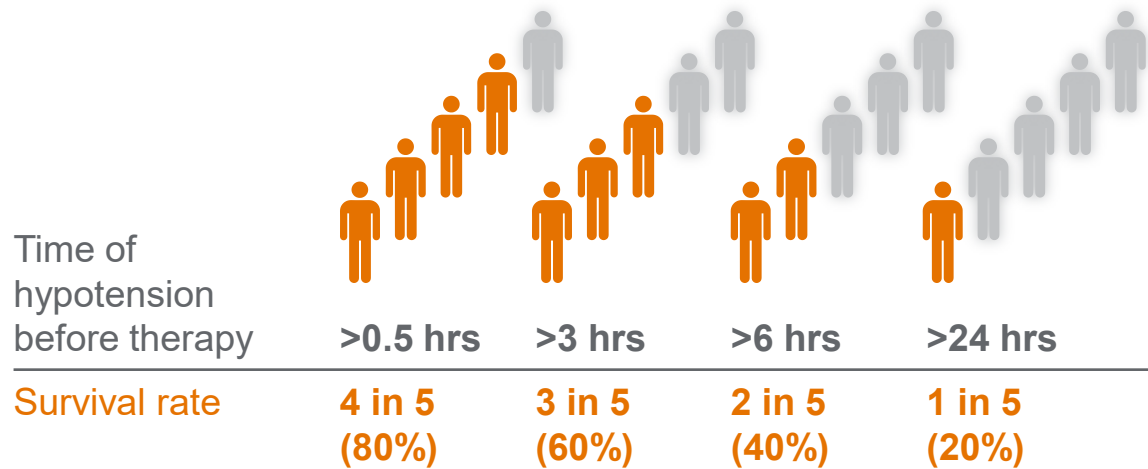
3. Pfaller et al. Future Microbiology 2015; Pappas, et al. Data Presented at ICAAC 2015

T2Dx: Potential to Improve Outcomes

For each hour of delay to administration of effective antibiotics after the onset of hypotension, there is a 7.6% increase in mortality.

Kumar et al. Crit Care Med, 2006.

Earlier targeted therapy increases chances for survival



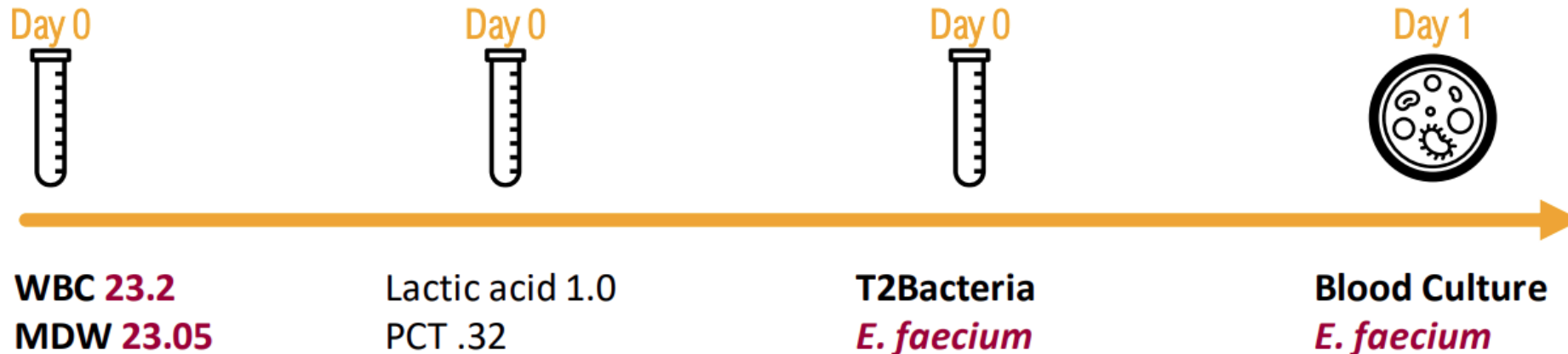
- Faster species ID of major sepsis-causing pathogens allows early, targeted therapy
- Faster rule out of deadly pathogens allows targeting of alternative empiric coverage
- 75% of negative test results have facilitated de-escalation of broad spectrum antifungals¹
- Length of stay reduction proven to be 7 days, inclusive of ICU duration²
- Significantly reduced exposure to antimicrobial drugs to reduce toxicity adverse events and resistance

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.

70 Y/O M, SHORTNESS OF BREATH

- Vitals: T: **99.8**; BP: **152/86**; P: 70
 - Findings: hypothermia, hypertension, patient admitted
 - No sepsis indicators, no action taken for sepsis screening.



20h*

Saved to Targeted Tx