

# Using T2 Technology to Move the Needle on Sepsis

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# Learning Objectives

- Describe the principle of operation of the T2 Biosystems Platform
- List the yeast and bacterial targets on the current test menu
- Describe the optimal utilization of T2 technology in support of Diagnostic Stewardship

# The ERA of Rapid Diagnostics

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## Why Rapid Diagnostics?

- Need for accurate and early diagnosis (culture independent; direct specimen testing)
- Culture (Gold Standard): low sensitivity, increased TAT
- Initiate appropriate therapy to reduce morbidity and mortality
- Promote and Support Antimicrobial Stewardship: empiric, targeted or discontinuation of therapy
- Reduce unnecessary use of antibiotics/antifungals, poor outcomes, length of stay and/or readmission rates related to the initial hospitalization
- Support Sepsis Program

# Time to Appropriate Therapy is a Key Driver of Clinical Outcomes

- Extended time from presentation to appropriate therapy remains a **major** contributor to **poor patient outcomes** and proliferation of **antimicrobial resistance**
- Current standard of care requires up to 3 days to provide species ID and susceptibility results
- For **every hour delay in time to appropriate therapy** survival decreases by 7.6% during septic shock<sup>1</sup>
- As many as 80% of sepsis deaths could be **prevented** with rapid diagnosis and treatment<sup>1</sup>
- Prolonged use of **broad-spectrum antimicrobials** is a known risk factor associated with the development and spread of **antimicrobial-resistant organisms**

# Culture Independent Tests are Simple to Use

## Fully-automated T2Dx Instrument

- Rapid: results in 3 to 5 hours
- Simple: no sample preparation
- Ultra-sensitive: as low as 1 CFU/mL
- T2MR<sup>®</sup> technology is not inhibited by prior antimicrobial administration<sup>1</sup>



### T2Candida<sup>®</sup>

Sensitivity: 91%<sup>2</sup>  
Specificity: 99%<sup>2</sup>

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

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

### T2Bacteria<sup>®</sup>

Sensitivity: 90%<sup>3</sup>  
Specificity: 98%<sup>3</sup>

*E. faecium*  
*S. aureus*  
*K. pneumoniae*  
*A. baumannii*  
*P. aeruginosa*  
*E. coli*

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

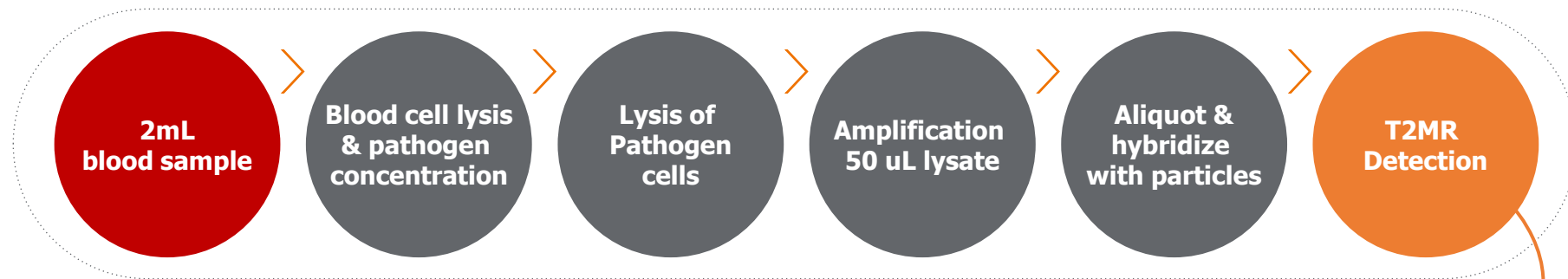
### T2Resistance<sup>®</sup>

FDA Breakthrough Device CE-  
mark/RUO 2019

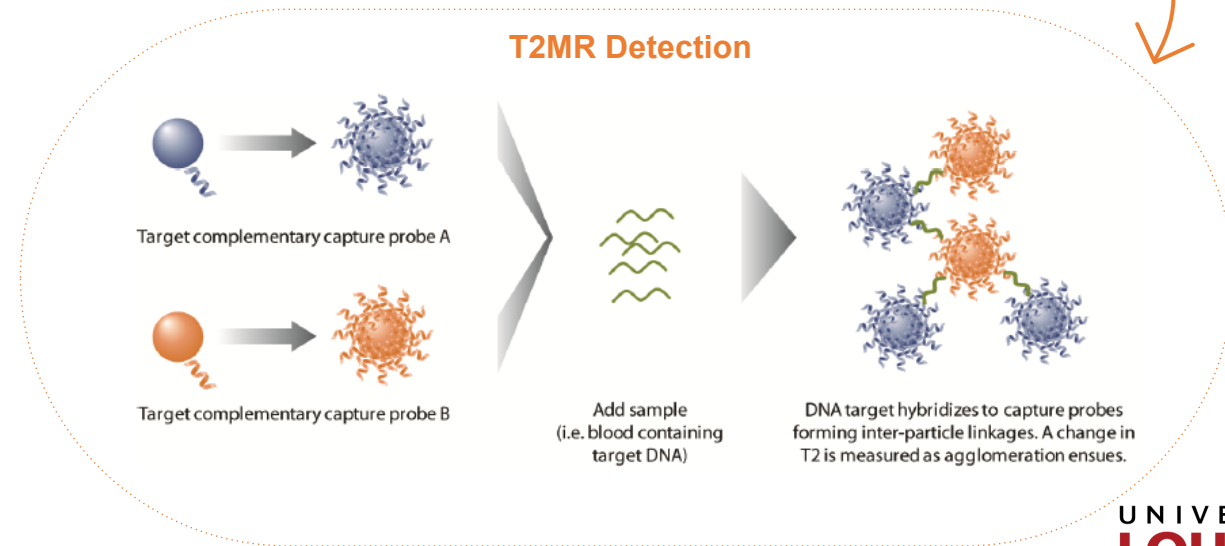
*mecA/C*  
*vanA/B*  
CTXM-14/15  
KPC  
OXA-48 Group  
NDM, VIM, IMP  
AmpC (CMY/DHA)

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

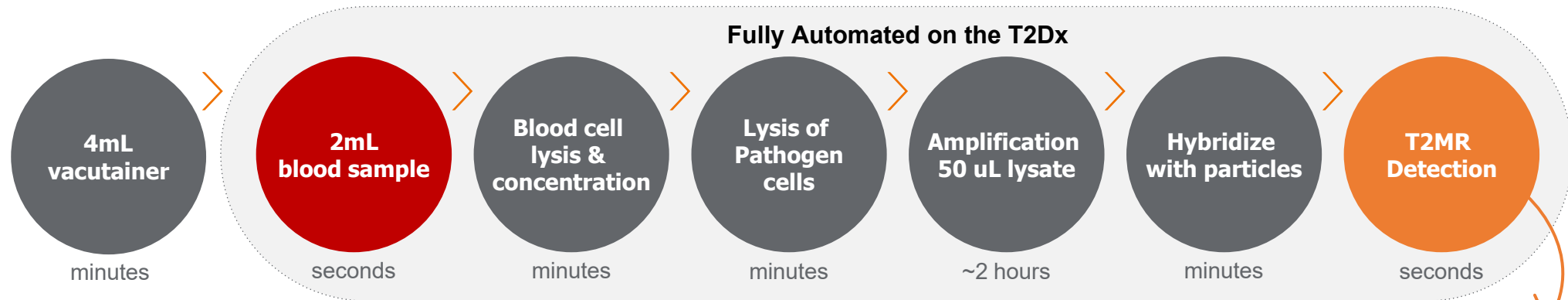
# T2MR Direct Detection for Superior Results



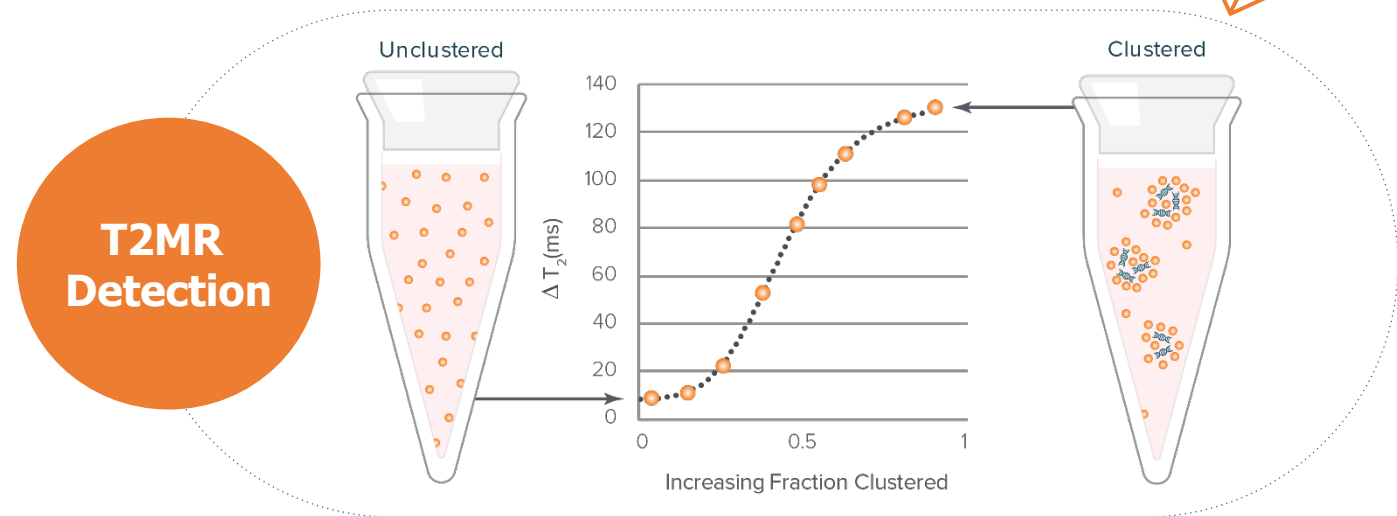
- T2 Magnetic Resonance (T2MR) enables measurement direct from patient sample enabling higher sensitivity
- Unparalleled 1 CFU/ml sensitivity in complex matrixes
- No background interference of T2MR signals eliminates sample preparation and extraction of targets



# T2Dx Instrument Workflow



Measuring the magnetic properties of the entire water population and not just the target provides breakthrough sensitivity in complex clinical samples



# Workflow



- Proprietary methodology enabling inhibition-free DNA amplification in complex clinical matrices. Utilizes miniaturized magnetic resonance technology which measures how water molecules react in presence of magnetic field.
- No background interference (e.g. human DNA, antibiotics, etc.) simplifies process and eliminates extraction & purification of targets
- T2 Magnetic Resonance (T2MR) enables measurement direct from patient sample enables higher sensitivity.



# T2SEPSIS SOLUTION™

## SAMPLE COLLECTION PRACTICE FOR OPTIMAL PERFORMANCE

### SAMPLE COLLECTION

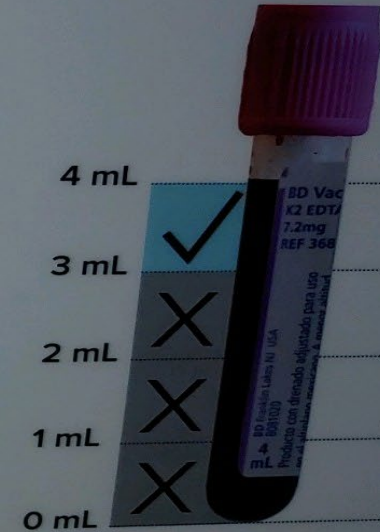
- Decontaminate the top of a 4 mL K<sub>2</sub>EDTA purple/lavender-top Vacutainer and allow to dry.
- Draw blood sample into the decontaminated 4 mL Vacutainer using the same aseptic technique and anatomical location as the blood culture draw.

**NOTE: SAMPLE WILL BE REJECTED IF VOLUME IS NOT AT LEAST 3 ML**

- Invert the filled vacutainer 8-10 times following draw to properly mix the sample and K<sub>2</sub>EDTA.
- Send the sample to the laboratory for processing as soon as possible. The sample may be stored at 15-25°C for no longer than 12 hours before processing.

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- as blood culture
- 4 mL K<sub>2</sub>EDTA tube
- Minimum 3 mL fill
- 8-10 Full inversions to avoid micro-clots



Must be accompanied by a peripheral blood culture collected within one hour

# Invalid Results

## Understanding the Results Report

### Sample Check

- ✓ Volume of  $\geq 3$  mL in a 4 mL K<sub>2</sub>EDTA
- ✓ Stored properly
  - 15-25°C  $\leq$  12 hours
  - 2-8°C  $\leq$  24 hours
- ✓ Equilibrated to room temperature prior to Panel assembly
- ✓ Check for clots

### Procedure Check

- ✓ Only use 4 mL K<sub>2</sub>EDTA tubes (lavender top)
- ✓ Use aseptic draw technique for sample collection
- ✓ Invert sample tube 8-10x prior to Panel assembly
- ✓ Sample Inlet “clicks” when attached to Cartridge
- ✓ Blood fills both wells of Sample Inlet
- ✓ Reagent tray vortexed at 2560-3200 RPM and flicked
- ✓ Temperature between 20-25°C

### Interferent Check\*

- ✓ Calcium Hypochlorite (20 mg/mL)
- ✓ K<sub>2</sub>EDTA ( $\geq 3.0$  mg/mL)
- ✓ Feraheme ( $\geq 76.5$  mg/mL)
- ✓ MRI Contrast Agents
  - Magnevist ( $\geq 1.7$  mg/mL)
  - Ablavar ( $\geq 0.39$  mg/mL)
- ✓ Intralipid ( $\geq 160$  mg/dL)
  - Lipemia
  - TPN
  - Lipid Emulsion

\*The effect of interfering substances has only been evaluated for those listed in the labeling. Interference by substances other than those described in the Interference section could lead to erroneous results.

# Promote Optimal Utilization (Diagnostic Stewardship)

- **Testing restricted to high-risk patients:**
  - Intensive Care Units
  - Transplant Patients (BMT and Solid Organ)
  - Oncology
  - Emergency Room
  - Infectious Diseases
- **Training of phlebotomists, nursing, and clinicians**
  - T2 sample collection (3 – 4ml in separate tube); **peripheral only, no line draws**
  - Blood culture collected simultaneously (20 ml: aerobic/anaerobic)

# Ordering Criteria and Establishing Order Set

- **Testing restricted to High Risk Patients:**
  - Intensive Care Units: recommend T2Bacteria Panel
  - Transplant (BMT and Solid Organ): recommend T2Candida Panel
  - Oncology: recommend T2Candida Panel
  - Emergency Room: recommend T2Bacteria Panel
  - Infectious Diseases: T2Candida or T2Bacteria Panel
- **Training of phlebotomists and nursing personnel: specimen collection (T2 sample and Blood Culture): Critical!**

# Results

	T2 Assay n=5	Control n=5	p-value
<b>Primary outcome</b> Time to therapy, median (days)	0.3	2.5	0.06
<b>Secondary outcome</b>			
Length of stay, median (days)	11.1	12.9	1.00
30-day readmission, n (%)	0	1 (20%)	0.29
Inpatient mortality, n (%)	0	1 (20%)	0.29

 **UL** Hospital

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# Impact of Results on Patient Management

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## Oncology patient

- persistent spiking fevers
- received broad spectrum antibiotics; port in place
- all blood cultures negative; spiking fevers continued
- plan was to remove the port and hope the offending organism had been treated
- T2 positive for *C. albicans/tropicalis*
- port removed, Rx DC'd, placed on targeted antifungal therapy
- fever terminated; **patient discharged**

# Summary

- Met Criteria of Performance
- Available 24/7
- Endorsed by “key” providers and service
- Impact study (expanded) on patient care, management, and antimicrobial use planned (Partnership with Pharmacy, Microbiology Laboratory, and Providers)
- A definite “TEAM” Effort
- Currently, the “only game in town”

**THANK YOU!!!!**

**QUESTIONS/COMMENTS?**