T2Biosystems[®]

Patient Selection for Sepsis Testing

Targeting the right patients, pathogens, and therapy.

With sepsis, every hour counts — Early diagnosis and treatment are crucial for better patient outcomes, as many as 80% of sepsis deaths could be prevented with rapid diagnosis and treatment.¹

T2 Biosystems sepsis panels enhance the standard of care for sepsis by providing species identification directly from a whole blood sample in 3 to 5 hours, often before the second dose of antimicrobials has been administered.

Establishing Panel Use and Selection Criteria

Instituting strong patient selection ensures that patients most at risk for developing bloodstream infections receive the best care. There are several proven patient selection models, like the ones outlined below, that care teams using T2Bacteria[®], T2Resistance[®] and T2Candida[®] have integrated into their existing sepsis protocols.

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Patient Type	Patient Location	Ordering Provider	Protocol Approach	
SepsisOncologyTransplant	 Emergency Dept. ICU Surgery 	 Infectious Diseases Intensivist Hospitalist	Patients meeting criteria • Lactate / PCT • Empiric Rx started • Sepsis scoring	
Sepsis : At risk patients with high mortality if treatment not started immediately	ED/ICU : High-risk patients coming into the ED or crashing in the ICU	Use in cases where a small group is heavily involved in managing septic patients	Biomarkers & sepsis risk scoring systems may increase the PPV of the test → More likely to find	
Oncology/Transplant: Immunocompromised, repeated exposure to antibiotics, neutropenic	Surgery : At risk for bacterial/ fungal translocation	Provider oversees test orders and is responsible for results interpretation/ therapeutic decisions	the true positives	

Patient Indicators for Ordering

PHYSICAL CONDITION

- Suspicion of a BSI
- Sepsis or septic shock
- Started on empiric therapy
- qSOFA >2
- Elevated PCT
- Lactate >2
- 3+ days in the ICU

UNDERLYING CONDITION

- Surgery (intra-abdominal, Gl/hepatobiliary, or solid organ transplant)
- Immunocomprimised/elderly (LTAC)
- Febrile neutropenic
- HAP/VAP
- IV drug use
- Trauma/burn

DEVICE IMPLANTS

- Dialysis access
- Central Venous Catheter (CVC)/ PICC
- Prosthetic valves
- TPN

Patient Selection Criteria in Clinical Use

Evangelismos General Hospital | Athens, Greece

T2Bacteria is restricted to patients suspected of a bloodstream infection (BSI) who meet the following criteria:

- Blood cultures have been ordered AND one of the following is present:
 - » Septic shock with Lactate > 2mmol/L
 - » Significant increase in vasopressors needed, or new need for vasopressors
 - » Patient already receiving antibiotics

NOTE: T2Resistance Panel is ordered in patients with positive T2Bacteria results (exception for A. baumannii)

Bambino Gesu Children's Hospital | Rome, Italy

Clinical criteria for BSIs are based on local internal protocols. T2Bacteria and T2Candida Panels are ordered at the discretion of the treating physicians.

T2 Biosystems Sepsis Panels

T2Bacteria Panel SENSITIVITY 90% ^{2,3} SPECIFICITY 98% ^{2,3}		T2Resistance Panel*	T2Candida Panel SENSITIVITY 91% ^{5.6} SPECIFICITY 99% ^{5.6}	
		SENSITIVITY >99% ⁴ SPECIFICITY >99% ⁴		
•	Enterococcus faecium	• mecA/C	Candida albicans	
•	Staphylococcus aureus	• vanA/B	Candida tropicalis	
•	Klebsiella pneumoniae	• KPC	Candida parapsilosis	
•	Acinetobacter baumannii	AmpC (CMY/DHA)	• Candida krusei	
•	Pseudomonas aeruginosa	• OXA-48 Group	Candida glabrata	
•	Escherichia coli	NDM/VIM/IMP		
		• CTX-M 14/15		





T20x T2 Country

 $^{\ast}\text{T2Resistance}$ has not yet been reviewed by FDA for clearance

1. Sepsis Alliance. Sepsis Alliance annual sepsis awareness survey. 2020. Accessed 7/23. 2. Nguyen, M. H., et al. Annals of Internal Medicine, 2019, 3. T2Bacteria Instructions for Use 4. T2Resistance Instructions for Use 5. Mylonakis, E., et al. Clinical Infectious Diseases, 2015 6. T2Candida Instructions for Use

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