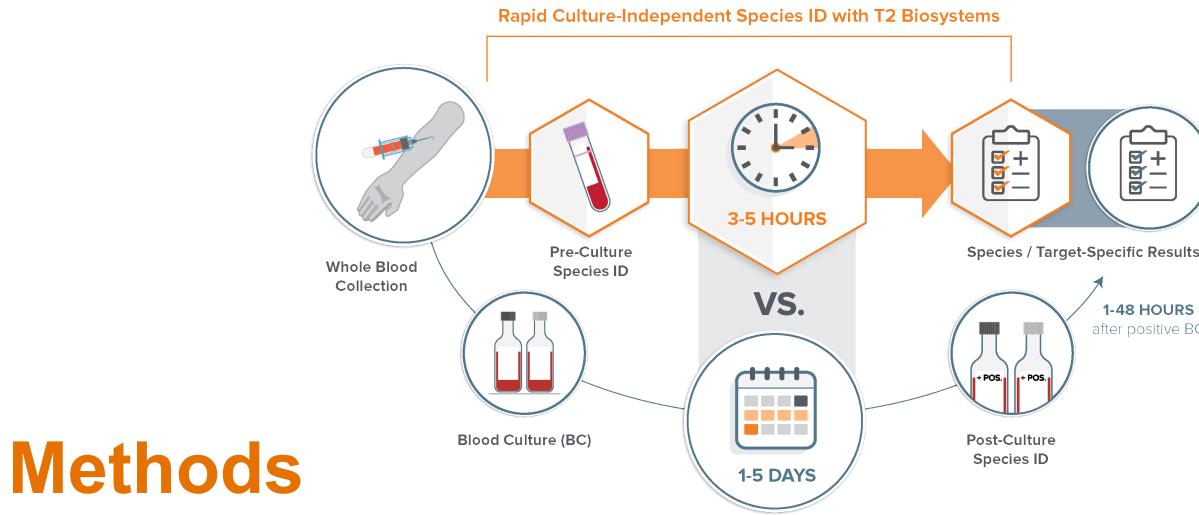
The T2Candida Panel Identifies 3.55 Times More On-Panel Candida Species **Compared to Conventional Blood Culture**

Oscar E. Guzman, PharmD, BCPS, BCCCP, FCCM¹; Brian C. Bohn, PharmD, BCIDP² ¹T2 Biosystems, Lexington, MA, USA, ² Paratek Pharmaceuticals, Boston, MA

Background

- The T2Candida[®] Panel is an FDA-cleared and CE-marked culture-independent in *vitro* diagnostic test that identifies common species that cause fungal sepsis utilizing T2 Magnetic Resonance Technology (T2MR).
- This FDA-cleared panel detects Candida albicans, Candida tropicalis, Candida parapsilosis, Candida krusei, and Candida glabrata directly from whole blood within 3-5 hours.
- The T2Candida Panel has been demonstrated to be highly sensitive with a sensitivity of 91.1% and a limit of detection (LoD) of 1-3 CFU/mL.¹
- The T2Dx Instrument detects intact pathogen cells² \rightarrow both active and nonproliferating/stationary cells
- The purpose of this study is to quantify the rate at which T2Candida detects onpanel species compared to blood culture in studies evaluating T2Candida.



Results



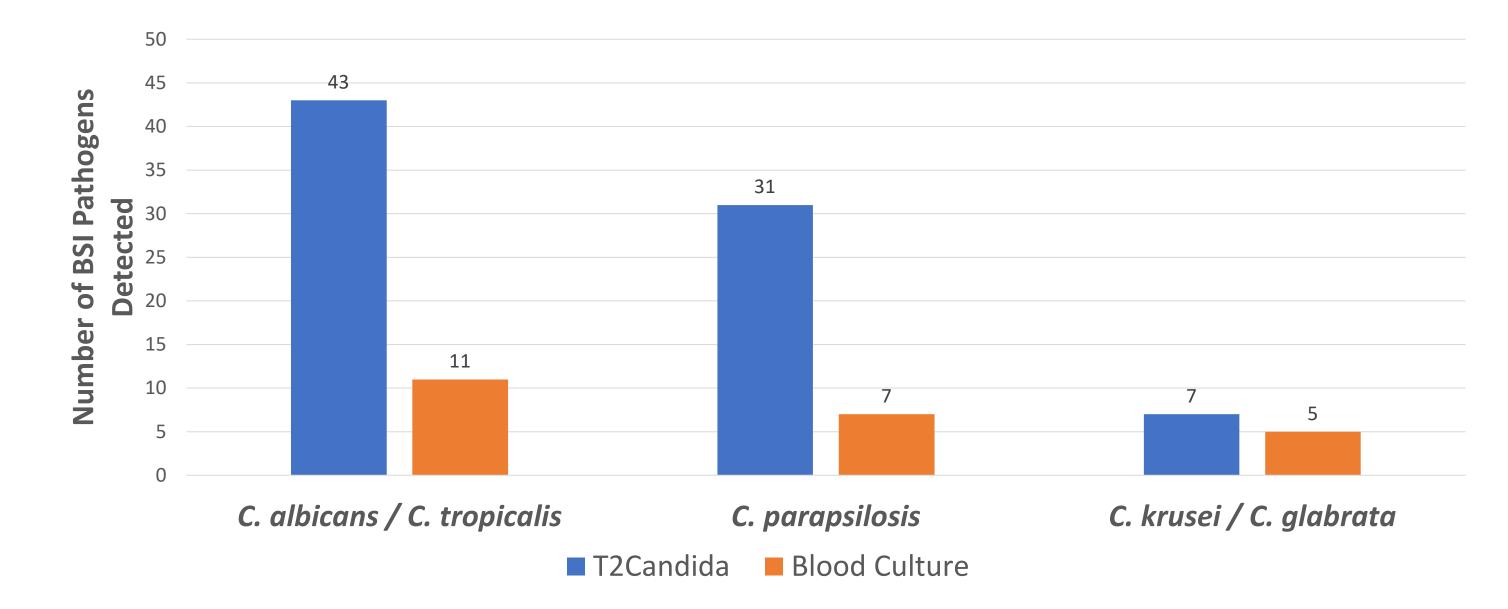


Table 3: Ratio of Additional Pathogens Detection with the T2Candida Panel Compared to Conventional Blood Culture (1,3-6,10)

INCLUSION:

Publications, presentations, and abstracts evaluating the T2C and ida Panel were systematically screened and included if the study reported organism level detection data for both the T2Candida panel and conventional blood cultures.

EXCLUSION:

Studies were excluded if organism level data were not available for both on and off-panel organisms. Data relating to bacterial species and the T2Bacteria Panel were excluded from analyses.

OUTCOMES:

The primary outcome is the ratio of on-panel organisms identified overall by the T2Candida Panel compared to conventional blood cultures.

Results

Table 1: Included Studies

Species	No. BSIs Pathogens Identified	T2C+/ BC+ Ratio		
C. albicans / C. tropicalis	43	3.9		
C. parapsilosis	31	4.4		
C. krusei / C. glabrata	7	1.4		
Total	81	3.5		

 Table 4: Clinical Adjudication of T2Candida Positive – Blood Culture
Negative Cases^(3,5,6,10)

Author	No. of T2C+/ BC- cases	Adjudication*
Cendejas-Bueno, E ³	5	5/5 = Pathogen identified in other cultures
Lucignano, B ⁵	6	6/6 = Probable or Possible IC
Seitz, T ⁶	8	8/8 = True infections
O'Donnell, M ¹⁰	7	$2/7 = Probable or Possible IC^{\pm}$

* Adjudication process and definitions varied by study, ±Eighty percent of false-positive cases were attributed to C. parapsilosis, a skin commensal

• Across 9 studies, a total of n=3,165 T2Candida Panels were prospectively collected and tested.

Author	Year	Location	T2C Tested	Patient Population
Mylonakis, E ¹	2015	USA	1501	Blood Culture Ordered
Cendejas-Bueno, E ³	2021	Spain	97	Medical-surgical PICU
Cruz, H ⁴	2023	Portugal	34	ICU
Lucignano, B ⁵	2022	Italy	106	Pediatric Sepsis
Seitz, T ⁶	2022	Austria	85	ICU
Birk, N ⁷	2023	USA	870	ICU
Zacharioudakis, IM ⁸	2023	USA	216	ICU
Krifors, A ⁹	2022	Sweden	101	Surgical ICU
O'Donnell, M ¹⁰	2023	USA	155	Medical ICU

Table 2: Time to Pathogen Detection and Ratio of T2Candida Panel vs **Blood Culture Pathogen Detection**



- A total of n=1,656 were tested in the USA and n=1,509 were tested outside of the US.
- The T2Candida Panel identified 3.5 times more on-panel organisms than conventional blood cultures.
- For prospective interventional clinical studies (n=4) describing complete or partial clinical adjudication of T2C+/BC- cases, 21/26 (81%) were deemed true, probable or possible infections.^(3,5,6,10)

Conclusion

- The highly sensitive T2Candida Panel identified 3.5 more on-panel organisms, directly from whole blood within 4.8 hours, compared to conventional blood cultures at 92.3 h across 9 clinical studies.
- T2Candida Panel has the potential to improve care by allowing clinicians to optimize antifungal therapy through added identification of BSI-causing pathogens that otherwise were missed by conventional blood culture.
- Future studies are needed to evaluate the impact of these added detections compared to conventional blood cultures.

REFERENCES:

1. Mylonakis E, Clancy CJ, Ostrosky-Zeichner L, et al. T2 magnetic resonance assay for the rapid diagnosis of

	30	4.2	/	~ 120	113.0	J. I
Cendejas-Bueno, E ³	7	NA	2	NA	NA	3.5
Cruz, H ⁴	5	5.7	2	70.3	64.6	2.5
Lucignano, B ⁵	10	3.7	4	125.5	121.8	2.5
Seitz, T ⁶	9	5	1	85.6	80.6	9
Birk, N ⁷	79	NA	22	NA	NA	3.6
Zacharioudakis, IM ⁸	5	NA	3	NA	NA	1.7
Krifors, A ⁹	9	NA	2	NA	NA	4.5
O'Donnell, M ¹⁰	14	5.6	7	60	54.4	2
Total	174		50		3.5	
Time (mean)	4.8 h		92.3		87.5	

* Prospectively collected samples ONLY

- candidemia in whole blood: A clinical trial (DIRECT1). *Clin Infect Dis* 2015;60:892–899.
- 2. T2Bacteria and T2Candida Instructions for Use. T2Biosystems, Lexington, MA, 2023.
- 3. Cendejas-Bueno E, Falces-Romero I, Laplaza-González M, et al. Candidemia Diagnosis With T2 Nuclear Magnetic Resonance in a PICU: A New Approach. *Pediatr Crit Care Med* 2021;22(2):e109-e114.
- 4. Cruz N. Impact of the T2MR technology on early detection of bacteremia and fungemia in critically ill patients. T2Biosystems In-booth presentation ECCMID 2023, Copenhagen, DE. April 2023.
- 5. Lucignano B, Cento V, Agosta M, et al. Effective Rapid Diagnosis of Bacterial and Fungal Bloodstream Infections by T2 Magnetic Resonance Technology in the Pediatric Population. J Clin Microbiol 2022; 60(10):e0029222.
- 6. Seitz T, Holbik J, Hind J, et al. Rapid Detection of Bacterial and Fungal Pathogens Using the T2MR versus Blood Culture in Patients with Severe COVID-19. *Microbiol Spectr* 2022; 10(3):e00140-22.
- 7. Birk NK, Soman S, Kapur N, et al. 607. Candidemia: Role of T2Candida® compared to Bact/Alert Virtuo blood culture system in a real-world setting. Open Forum Infect Dis 2023;10(Suppl 2):ofad500.673.
- 8. Zacharioudakis IM, Zervou FN, Marsh K, et al. Utility of incorporation of beta-D-glucan and T2Candida testing for diagnosis and treatment of candidemia. *Diagn Microbiol Infect Dis* 2024;108(2):116107.
- 9. Krifors A, Ullberg M, Castegren M, et al. Combining T2Bacteria and T2Candida Panels for Diagnosing Intra-Abdominal Infections: A Prospective Multicenter Study. J Fungi (Basel) 2022;8(8):832.

10.0'Donnell M, Shields RK, Marini RV, et al. Stewardship-Guided T2Candida Testing Shortens Time to Antifungal Treatment and Reduces Antifungal Usage Among Medical Intensive Care Unit Patients With Septic Shock. Open Forum Infect Dis 2023;10(11):ofad538.