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Prospective, non-interventional, multi-centre clinical study of the T2Resistance system for detection resistance genes in bacterial bloodstream infections: an interim analysis

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Background: The incidence of blood stream infections (BSIs) caused by multi-drug resistant organisms (MDROs) is growing at an unprecedented pace. BSIs caused by MDROs are associated with high attributable mortality and increased healthcare costs. Rapid and reliable direct-from-blood pathogen identification remains an unmet healthcare need that may guide early-targeted therapy. The T2Resistance Panel provides direct-from-blood identification of resistance genes in both Gram-positive and Gram-negative pathogens within 3 to 5 hours of sample collection: *bla*KPC, *bla*OXA, *bla*NDM, *bla*VIM, *bla*IMP, *bla*CTXM-14, *bla*CTXM-15, *bla*CMY, *bla*DHA, *van*A/B and *mec*A/C. The main objective of this study is to evaluate the diagnostic accuracy of T2Resistance in patients with BSIs in comParison to standard methods of blood culture diagnosis and to determine if T2Resistance results would impact treatment decisions in the enrolled patient population.

Materials/methods: This is a prospective, non-interventional, multicenter clinical study conducted in whole blood samples (4mL) that were collected in K2 or K3EDTA tubes and analyzed using the T2Resistance and T2Bacteria panels and compared to standard pathogen phenotypic, and genotypic detection methods including direct from positive blood culture species identification via matrix-assisted laser desorption/ionization time-of flight mass spectrometry – MALDI-TOF.

Results: Among the 13 cases enrolled to date and of the 7 blood cultures that were positive, five cases demonstrated 100% concordance between the T2Resistance system and conventional methods. Results from the other two cases are pending blood culture results. The median time (range) to identification of resistance genes via T2Resistance was 3.7 h (3.5 – 8.8 h) versus 98 h (16 - 233 h) by conventional microbiological methods shown to be significant ($p<0.001$). The resistance genes identified by the T2Resistance system were NDM, VIM, CTX, KPC, AmpC, and MecA/C.

Conclusions: An interim analysis of the data from a prospective, multicenter clinical study of the T2Resistance system for detection of resistance genes in bacterial blood stream infections demonstrates a high concordance with the results of conventional microbiological methods but with results available in real time to physicians within 4 to 9 hours from the time of processing blood cultures.

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