Evaluation of a New Rapid Multiplexed Molecular System for the Direct Detection of Bacterial Pathogens in Blood

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Background

A primary goal of sepsis treatment is administration of appropriate antimicrobial therapy as early as possible. Broad spectrum antibiotics are prescribed prior to the clinical microbiology identification of the pathogen by conventional blood culture. Tailored antimicrobial therapy may be adopted only after pathogen identification. A key element to improve the immediate treatment of sepsis is rapid identification of bloodstream pathogens. Qvella's Field Activated Sample Treatment (FAST™) and e-lysis™ provide isolation, concentration and lysis of microbial cells enabling detection and identification of pathogens directly from whole blood in less than one hour.

Objective

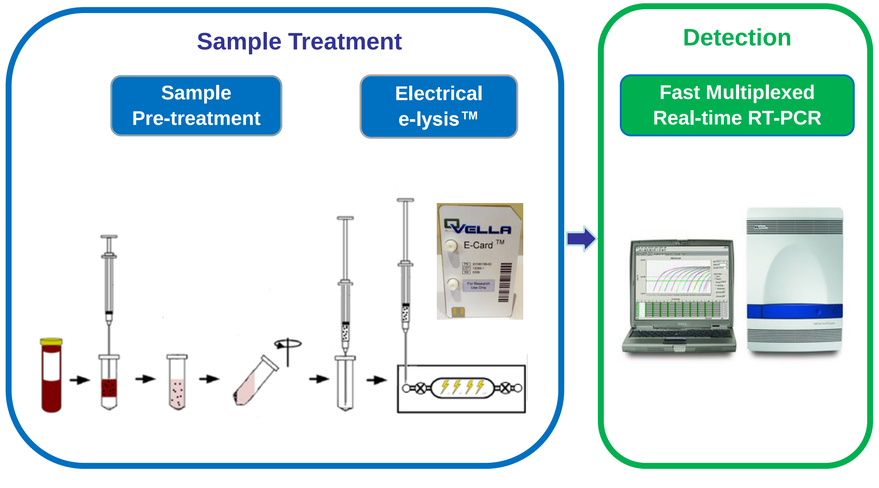
To conduct a study comparing the results of pathogen detection directly from whole blood using the Qvella™ FAST™ ID Prototype System to conventional pathogen identification by blood culture.

FAST™ ID and e-lysis™ Overview

- Isolation and concentration of microbial cells from whole blood
- Release and preservation of rRNA content by e-lysis™
- Improves accessibility of nucleic acid target region for reverse transcription
- Inactivates nucleases and reduces PCR inhibitor factors
- Lysate ready for rapid multiplexed real-time RT-PCR

Method

FAST™ ID Process Steps



Study Design

- Study site: Mount Sinai Hospital, Toronto, Ontario
- Study period: February to November 2015
- Patient criteria: ≥18 years, admitted to emergency department with suspected sepsis
- Sample collection:
  - 2 sets of blood culture bottles for routine clinical microbiology culture and identification by MALDI-TOF
  - 1 'test" blood culture bottle for FAST™ ID
- FAST™ ID workflow:
  - 800 microliters from "test" bottle was drawn and processed by FAST™ ID system
  - Subsequently, the "test" bottle was incubated up to 6 days or until positive for determining sensitivity and specificity of FAST™ ID for detection of bacteremia
  - Pathogen identification results from FAST™ ID were compared with identification from MALDI-TOF

Results

Table 1. FAST™ ID vs. Culture Results

	Culture +	Culture -	Total
FAST ID +	28	1	29
FAST ID -	1	559	560
Total	29	560	589

Table 2. FAST™ ID Concordance

	#	FAST™ ID Results	#
FAST™ ID + Culture +	28		
Concordant ID results	26	*S.aureus*	3
		Streptococcus	3
		S.pneumoniae	1
		Enterococcus	1
		Enterobacteriaceae	17
		Enterobacteriaceae / P. aeruginosa (polymicrobial)	1
Discordant ID results	2	CoNS cross-reactivity to *S. aureus*	2

Table 3. FAST™ ID Data Analysis

Sensitivity	Specificity	ID Concordance
28/29	559/560	26/28
96.5%	99.8%	92.8%

Conclusions

- FAST™ ID provides rapid identification of pathogens in whole blood
- Allows clinicians to expedite and tailor initial antimicrobial therapy
- Potentially improves clinical outcomes and may reduce the use of unnecessary antibiotics