Evaluating the Analytical Sensitivity of Qvella's FAST™ ID System for Early Detection and Identification of Blood Stream Infection in Whole Blood

Khine AA, Parmar V, Talebpour A, Maaskant R, Alavie T
Qvella Corporation, Richmond Hill, Ontario, Canada

Background

Early administration of appropriate antimicrobial therapy improves the outcomes of sepsis. Broad spectrum antibiotics are administered empirically as early as possible despite the risk of antimicrobial overuse and emergence of antimicrobial resistant pathogens. Qvella's FAST™ ID System provides isolation, concentration and lysis of pathogens directly from whole blood in less than one hour. Early detection and identification of blood stream infection by FAST™ ID System and FAST™ ID Panel would allow antibiotic selection narrowed to target the specific species or groups of pathogens.

Objective

To evaluate the analytical sensitivity of Qvella™ FAST™ ID System

FAST™ ID System 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 inhibitory factors
- Lysate ready for fast multiplexed real-time RT-PCR

Method

FAST™ ID Process Steps

Sample Pre-treatment → **Electrical e-lysis™** → **Fast Multiplexed Real-time RT-PCR**

- Whole blood samples from healthy volunteers were collected in vacutainers
- Whole blood of 5 mL was spiked with 6 respective pathogen species at a concentration of 1 to 10 CFU/mL
- Spiking number of pathogen was confirmed by agar plating and post-growth colony counting
- Spiked blood was subjected to FAST™ ID Process and the spiked pathogen was identified by real-time RT-PCR

FAST™ ID Panel

Gram-positive Bacteria	Gram-negative Bacteria	Fungi
Staphylococcus	*Enterobacteriaceae sub-family*	*C. albicans/C. dubliniensis*
S.aureus	*E. coli*	*C. glabrata/ C .krusei*
S. lugdunensis	*K. pneumoniae*	*Candida sub-genus*
Streptococcus	*Proteus*	*C. gattii/C. neoformans*
S. pneumoniae	*P. aeruginosa*	
Enterococcus	*A. baumannii*	

Results

FAST™ ID Process Performance; Lowest limit of detection (LoD)

S. aureus	Total	Detected	% Detected
6-10 CFU/mL	5	5	100
2-5 CFU/mL	10	15	100
1 CFU/mL	5	4	80

E. faecium	Total	Detected	% Detected
6-10 CFU/mL	4	4	100
2-5 CFU/mL	14	14	100
1 CFU/mL	2	2	100

P. aeruginosa	Total	Detected	% Detected
6-10 CFU/mL	3	3	100
2-5 CFU/mL	11	11	100
1 CFU/mL	6	6	100

K. pneumoniae	Total	Detected	% Detected
6-10 CFU/mL	2	2	100
2-5 CFU/mL	7	7	100
1 CFU/mL	11	11	100

C. albicans	Total	Detected	% Detected
6-10 CFU/mL	2	2	100
2-5 CFU/mL	13	13	100
1 CFU/mL	5	5	100

C. glabrata	Total	Detected	% Detected
6-10 CFU/mL	1	1	100
2-5 CFU/mL	17	17	100
1 CFU/mL	2	2	100

Conclusion

- FAST™ ID provides rapid identification of pathogens in whole blood in less than one hour
- Microbial cells in whole blood, with concentrations of ~1 CFU/mL can be detected
- Allows clinicians to expedite and tailor initial antimicrobial therapy
- Potentially improves clinical outcomes and may reduce the use of unnecessary antibiotics

Visit Qvella Corporation at Booth # 112