

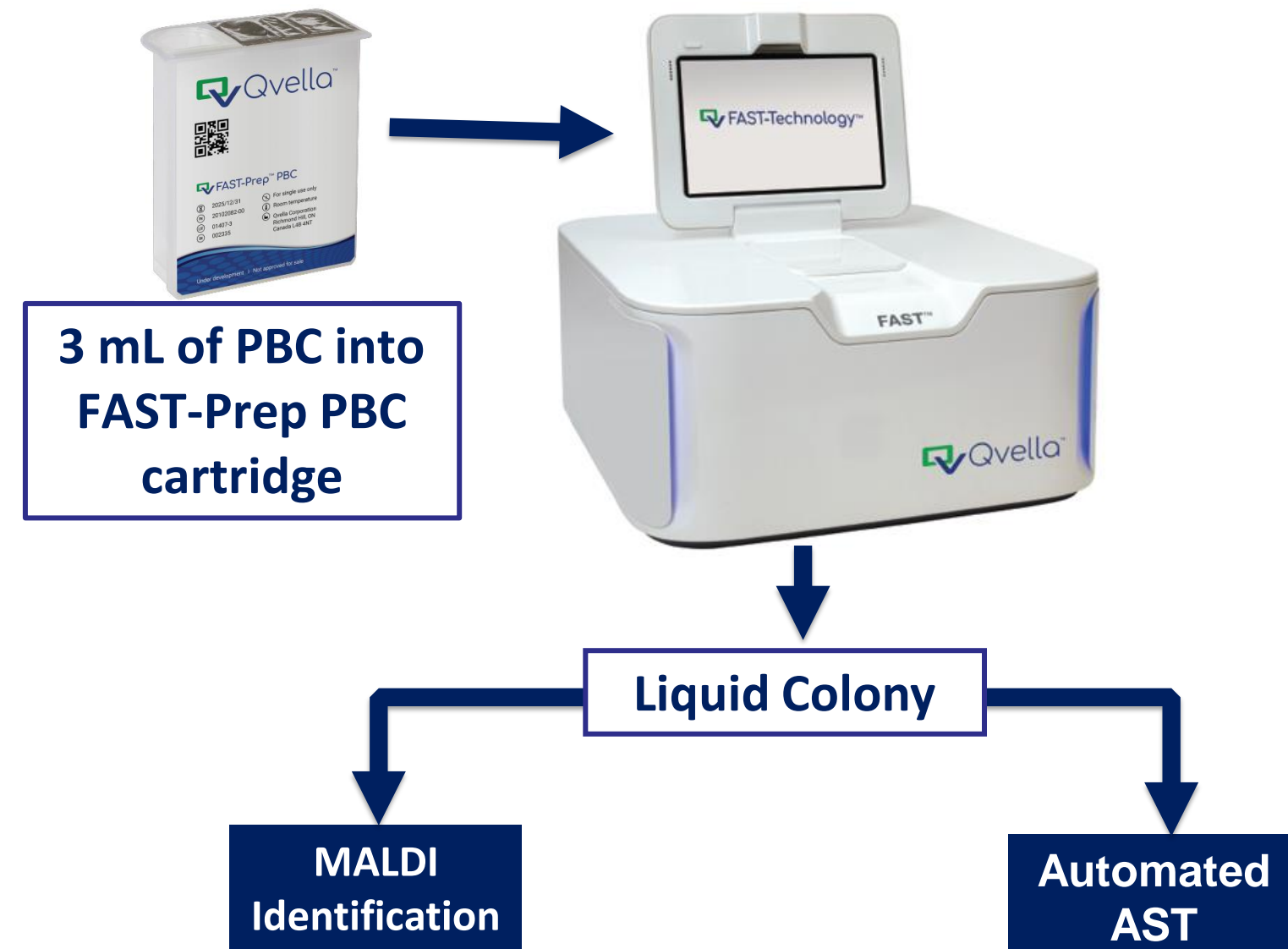
BACKGROUND

Conventional Clinical Microbiology requires sub-culturing of a positive blood culture (PBC) to isolate pure colonies for microbial identification (ID) and antimicrobial sensitivity testing (AST). Qvella has developed an automated FAST-Prep™ System that delivers a Liquid Colony™ cell suspension containing isolated and concentrated viable microorganisms from a PBC in ~30 minutes. The Liquid Colony may be used directly for conventional ID and AST methods.

OBJECTIVES

- Demonstrate comparability of biomass achieved in a Liquid Colony to an aliquot from a PBC
- Demonstrate comparability between a Liquid Colony and solid colony with VITEK® MS and VITEK® 2 AST

FAST-Prep WORKFLOW



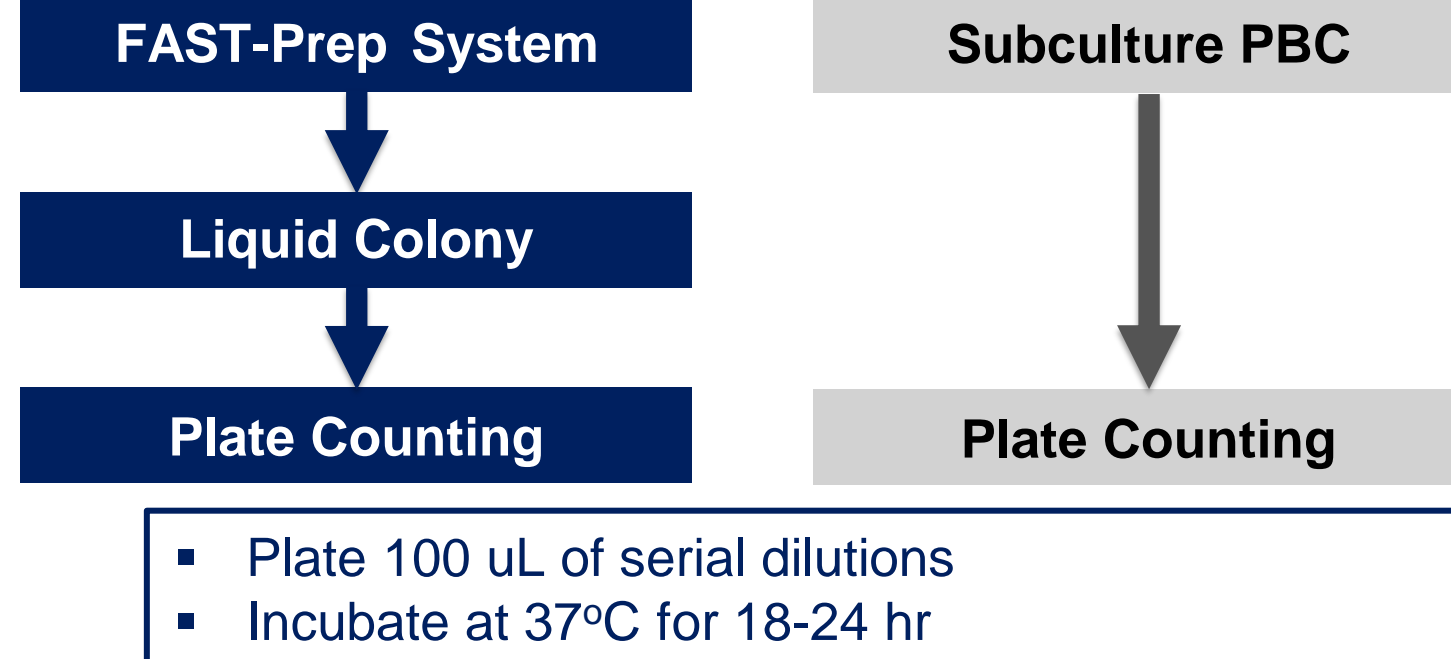
Gram Stain and subculture performed on all PBC

METHOD

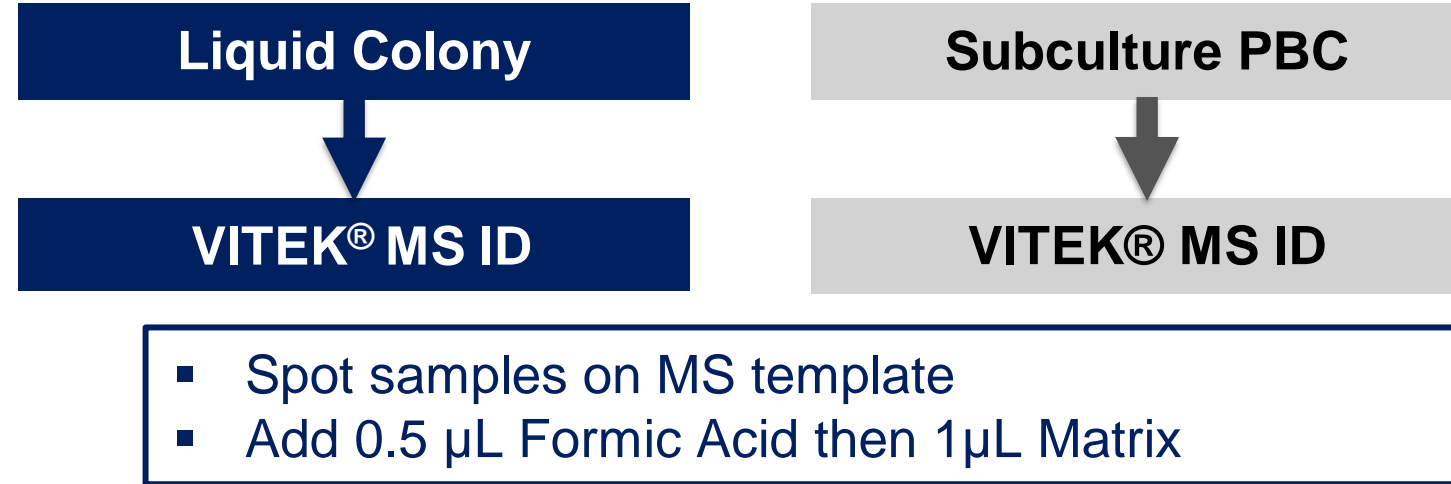
Contrived PBC Preparation and Processing

- BD Vacutainer® SPS tube containing whole human blood was spiked with <10 CFU/mL bacteria
- SPS tube inoculated into BacT/ALERT® FA Plus bottle
- Incubate bottle in BacT/ALERT® VIRTUO® System
- Auto-unload at positivity and process within 4 hr

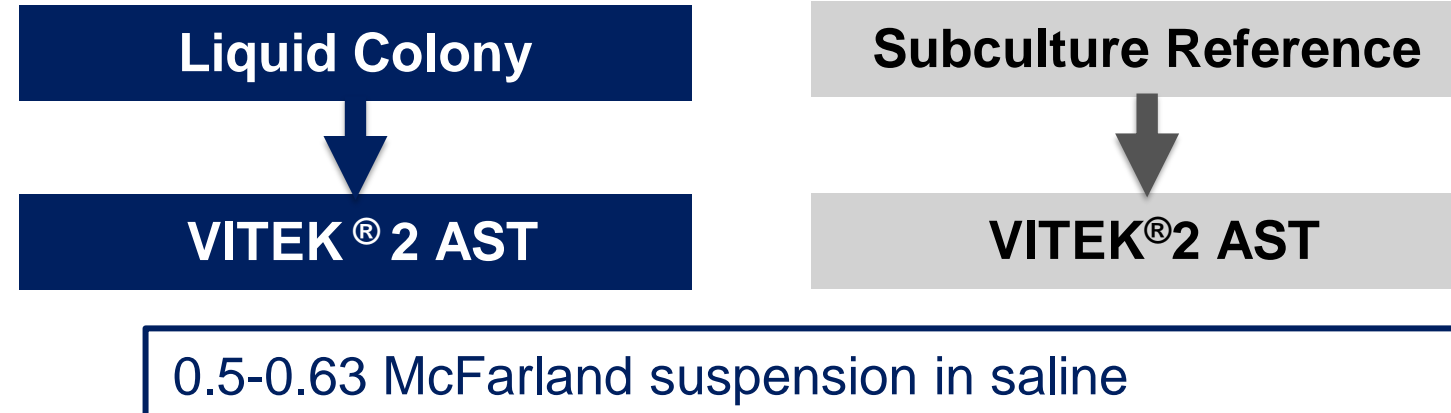
Biomass Comparison



ID by VITEK® MS



AST by VITEK® 2



Data Analysis

All Liquid Colony results were compared to solid colony reference method

RESULTS

Table 1. Microbial species tested in the study

Gram-positive bacteria		Gram-negative bacteria	
<i>Enterococcus faecalis</i>	<i>Streptococcus pyogenes</i>	<i>Acinetobacter baumannii</i>	<i>Serratia marcescens</i>
<i>Enterococcus faecium</i>	<i>Staphylococcus capitis</i>	<i>Enterobacter cloacae</i> Complex	<i>Proteus mirabilis</i>
<i>Staphylococcus aureus</i>	<i>Staphylococcus hominis</i>	<i>Enterobacter aerogenes</i>	<i>Citrobacter freundii</i>
<i>Staphylococcus epidermidis</i>	<i>Staphylococcus warneri</i>	<i>Escherichia coli</i>	<i>Stenotrophomonas maltophilia</i>
<i>Staphylococcus haemolyticus</i>	<i>Staphylococcus lugdunensis</i>	<i>Klebsiella oxytoca</i>	<i>Providencia stuartii</i>
<i>Streptococcus agalactiae</i>	<i>Staphylococcus pasteurii</i>	<i>Klebsiella pneumoniae</i>	<i>Proteus vulgaris</i>
<i>Streptococcus pneumoniae</i>	<i>Streptococcus mitis-oralis</i>	<i>Pseudomonas aeruginosa</i>	<i>Haemophilus influenzae</i>

Table 2. Liquid Colony biomass (CFU) compared to PBC aliquot

Total Biomass (Average CFU)	Species (n)	Strains (n)	PBC	Liquid Colony
Gram-positive bacteria	14	50	7.78 x 10 ⁸	4.86 x 10 ⁸
Gram-negative bacteria	14	42	2.44 x 10 ⁹	2.01 x 10 ⁹

3mL PBC Sample Input and 100µL Liquid Colony

Table 3. VITEK® MS ID performance: Liquid Colony compared to conventional subculture

VITEK® MS ID	Species (n)	Strains (n)	Runs (n)	% Correct ID	% No ID
Gram-positive bacteria	14	55	93	98.9	1.1*
Gram-negative bacteria	14	56	90	100	0.0
Total	28	111	183		

*One strain of *S. pneumoniae*

Table 4. VITEK® 2 AST performance: Liquid Colony compared to conventional subculture

	Species (n)	Strains (n)	Runs (n)	MIC Tests (n)	Category Tests (n)			EA	CA	mE	ME	
				Total #	Total #	S	I	R				
Gram-positive bacteria	13	43	62	950	1016	880	27	109	941	998	12	4
#									99.1	98.2	1.2	0.5
%												
Gram-negative bacteria	13	50	77	1126	1126	890	26	209	1117	1105	19	1
#									99.2	98.1	1.7	0.1
%												

EA; essential agreement, CA; category agreement, mE; minor error, ME; major error

CONCLUSIONS

- Study suggests comparable biomass from PBC aliquot and Liquid Colony
 - ≥95% correct to species ID for both Gram-positive and Gram-negative bacteria by VITEK® MS
 - ≥95% EA and CA with respect to the reference control AST for both bacteria
- FAST-Prep is under development and not approved for sale. The performance characteristics of this product have not been established