

# Preliminary Evaluation of the Development version of FilmArray® BJI panel: a fast way for the detection of bacteria and fungi in bone and joint infections

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## Background

- Bone and joint infections (BJIs) → require adapted medical management and accurate microbiological diagnosis
- Can be polymicrobial or caused by fastidious bacteria

### Culture-based diagnosis

- Gold-standard for microbiological diagnosis
- Antibiotics before surgery → distort culture results: increase the difficulty of culture-based diagnosis
- Up to 15 days until final results

### Molecular approaches

- Antibiotics before surgery → detection of DNA even of dead microorganisms
- 1 to a few hours until final results

→ **Objective : better and faster diagnosis of BJIs**

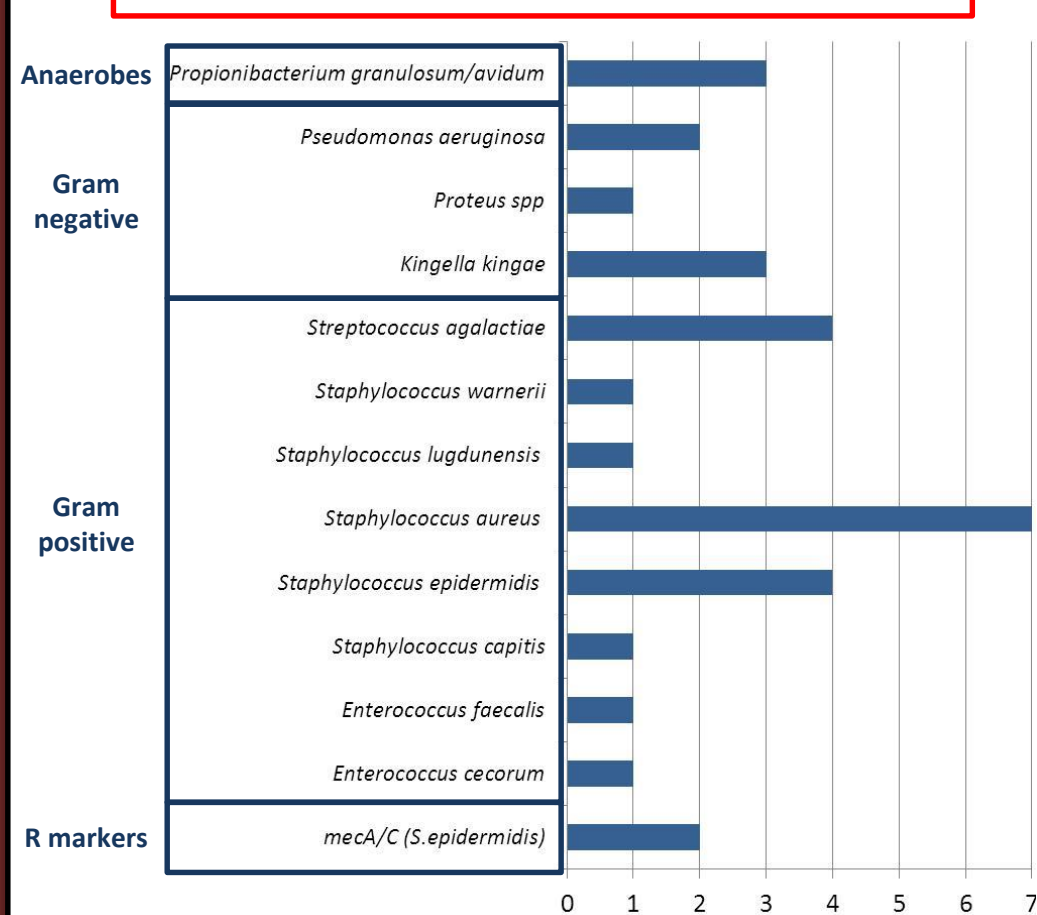
## Materials and methods

- 112 patients** with suspected BJI (September 2016 to January 2017)
- 116 synovial fluids** collected and tested
- Development version of FilmArray® (FA) BJI panel: detects **gram-positive (GP)** and **gram-negative (GN) bacteria, yeasts, and antibiotic resistance markers (R markers)**
  - two internal controls
  - 200µL of each specimen
- Results available in **one hour** and compared to the culture-based results obtained in routine clinical microbiology lab testing

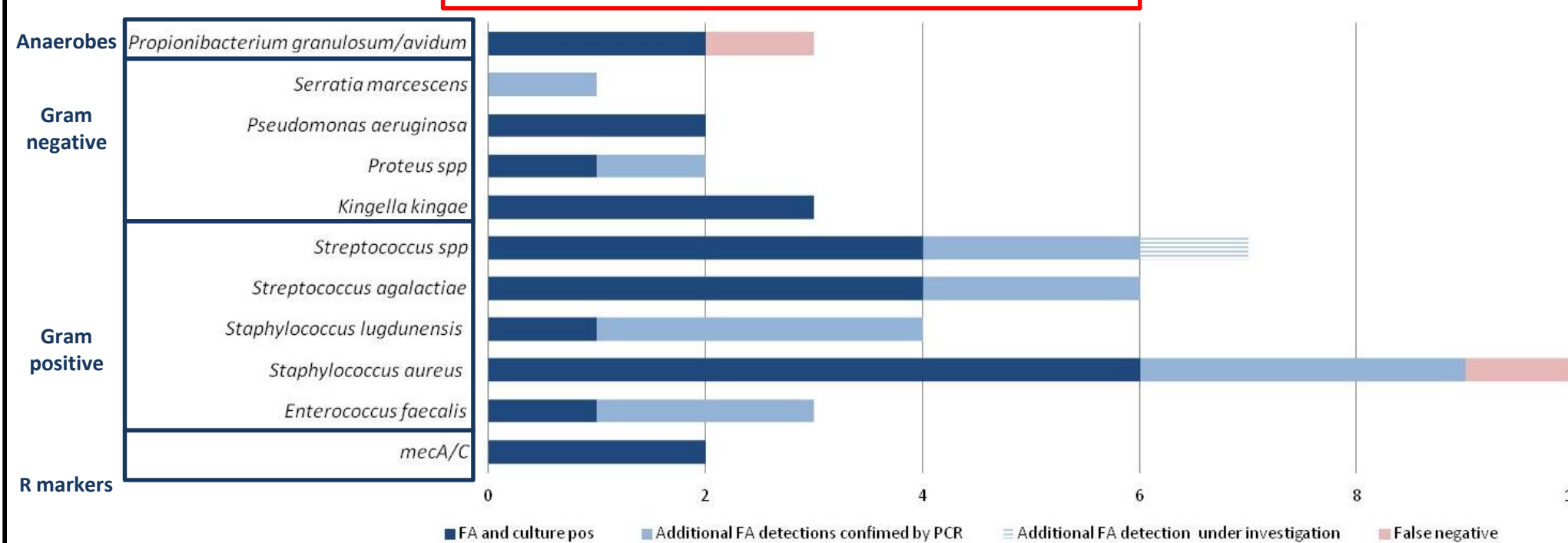
GP	GN	R markers	Yeasts
<i>S. aureus</i>	<i>E. coli</i>	vanA/B	<i>Candida</i> spp
<i>S. lugdunensis</i>	<i>K. pneumoniae</i>	CTX-M	<i>C. albicans</i>
<i>Streptococcus</i> spp	<i>Enterobacter</i> spp	mecA/C	
<i>S. pyogenes</i>	<i>Proteus</i> spp	KPC	
<i>S. agalactiae</i>	<i>M. morgannii</i>	NDM	
<i>S. pneumoniae</i>	<i>Citrobacter</i> spp	OXA-48	
<i>E. faecalis</i>	<i>S. marcescens</i>	IMP	
<i>E. faecium</i>	<i>Salmonella</i> spp	VIM	
<i>F. magna</i>	<i>P. aeruginosa</i>		
<i>P. granulosum/avidum</i>	<i>K. kingae</i>		
<i>C. perfringens</i>	<i>N. gonorrhoeae</i>		
<i>Anaerococcus</i> spp / <i>Peptoniphilus</i> spp	<i>H. influenzae</i>		
<i>P. micra/P. anaerobius</i>	<i>B. fragilis</i>		

## Results

### Microorganisms obtained in culture



### Microorganisms obtained in FA BJI panel



FA detections were compared to culture results:

- 26 FA positive** detections were concordant with culture
- 15 additional positive** detections by FA were investigated:
  - 14 were **confirmed** by a **comparator assay PCR**, 1 is still under investigation
  - 12 were **detected** in **previous or concomitant osteo-articular samples** of the same patient (9 cases corresponded to patients who **received antibiotics before the moment of sampling**)

One of the 2 false negative results observed was in fact a true-negative result (*Propionibacterium* obtained in culture was concluded to be a contaminant) and concerning the second false negative, FA was positive for *S. aureus* on the second synovial fluid sample from the same patient therefore the patient would have been detected positive by FilmArray.

### FA versus culture

Target	TP	FN	Sensitivity	TN	FP	Specificity
<i>Staphylococcus aureus</i>	6	1	85.7	106	3	97.2
<i>Staphylococcus lugdunensis</i>	1	0	100	112	3	97.4
<i>Streptococcus</i> spp	4	0	100	109	3	97.3
<i>Streptococcus agalactiae</i>	4	0	100	110	2	98.2
<i>Enterococcus faecalis</i>	1	0	100	113	2	98.3
<i>Proteus</i> spp	1	0	100	114	1	99.1
<i>Serratia marcescens</i>	0	0	NA	115	1	99.1
<i>Pseudomonas aeruginosa</i>	2	0	100	114	0	100
<i>Kingella kingae</i>	3	0	100	113	0	100
<i>Propionibacterium granulosum/avidum</i>	2	1	66.7	113	0	100
<i>mecA/C</i>	2	0	100	114	0	100

### FA versus clinical diagnosis (considering previous or concomitant osteo-articular sample of the same patient)

Target	TP	FN	Sensitivity	TN	FP	Specificity
<i>Staphylococcus aureus</i>	9	1	90	106	0	97.2
<i>Staphylococcus lugdunensis</i>	4	0	100	112	0	97.4
<i>Streptococcus</i> spp	6	0	100	109	1	99
<i>Streptococcus agalactiae</i>	6	0	100	110	0	98.2
<i>Enterococcus faecalis</i>	3	0	100	113	0	98.3
<i>Proteus</i> spp	1	0	100	114	1	99.1
<i>Serratia marcescens</i>	0	0	NA	115	1	99.1
<i>Pseudomonas aeruginosa</i>	2	0	100	114	0	100
<i>Kingella kingae</i>	3	0	100	113	0	100
<i>Propionibacterium granulosum/avidum</i>	2	0	100	114	0	100
<i>mecA/C</i>	2	0	100	114	0	100

TP: true-positive; FN: false-negative; TN: true-negative; FP: false-positive

The **other microorganisms present in the FA BJI panel** were not detected neither in culture nor in FA in the study (no false-positive in FA so **specificity** of these assays was 100%).

## Conclusion

These preliminary results showed **overall good correlation between FilmArray and culture**. Additional FA detections were either **confirmed** by a comparator PCR followed by sequencing (14/15) or corresponded to organisms detected in previous or concomitant biopsy samples from the same patients (12/15). *The data presented are a preliminary analysis of the R&D Pilot FilmArray Bone & Joint Infection Panel data and are subject to change upon re-analysis with future versions of the software. The FilmArray BJI panel has not been evaluated by the FDA or other regulatory agencies for In Vitro Diagnostic use.*