

## ABACUS GenomEra MRSA/SA Blood Culture evaluation results

Updated 19.9.2011

SITE 1 (BD BACTEC), n = 470 All positive cultures analyzed		Routine methods		
		MRSA +	SA + (mecA -)	Negative
GenomEra MRSA/SA Blood Culture Assay	MRSA +	-	-	1*
	SA + (mecA -)	-	57	-
	Negative	-	-	410

MRSA

Sensitivity: N/A  
Specificity: 467/468 = 99.8%

SA

Sensitivity: 57/57 = 100%  
Specificity: 411/411 = 100%

Unresolved rate\*\*  
2/470 = 0.43%

PCR-inhibition rate  
4/470 = 0.85%\*\*\*

\* False-positive result due to *Serratia marcescens* and \*\*\*two borderline results due to *S. marcescens* and *Streptococcus pyogenes*. The extracellular DNA nucleases of *S. marcescens* and *S. pyogenes* are able cleave the oligonucleotide probes during PCR and cause interference in the assay.

\*\*\* Resolved by re-analysis

SITE 2 (bioMérieux BacT/ALERT), n =102 Pre-selection performed using Gram stain		Routine methods		
		MRSA +	SA + (mecA -)	Negative
GenomEra MRSA/SA Blood Culture Assay	MRSA +	9	-	-
	SA + (mecA -)	-	42	-
	Negative	-	-	51

MRSA

Sensitivity: 9/9 = 100%  
Specificity: 93/93 = 100%

SA

Sensitivity: 42/42 = 100%  
Specificity: 60/60 = 100%

Unresolved rate  
0%

PCR-inhibition rate  
0%

SITE 3 (bioMérieux BacT/ALERT), n = 84 Pre-selection performed using Gram stain		Routine methods		
		MRSA +	SA + (mecA -)	Negative
GenomEra MRSA/SA Blood Culture Assay	MRSA +	2	-	-
	SA + (mecA -)	-	28	-
	Negative	-	-	54

MRSA

Sensitivity: 2/2 = 100%  
Specificity: 82/82 = 100%

SA

Sensitivity: 28/28 = 100%  
Specificity: 56/56 = 100%

Unresolved rate  
0%

PCR-inhibition rate  
0%

TOTAL, n = 656		Routine methods		
		MRSA +	SA + (mecA -)	Negative
GenomEra MRSA/SA Blood Culture Assay	MRSA +	11	-	1
	SA + (mecA -)	-	127	-
	Negative	-	-	515

MRSA

Sensitivity: 11/11 = 100%  
Specificity: 642/643 = 99.8%

SA

Sensitivity: 127/127 = 100%  
Specificity: 527/527 = 100%

Unresolved rate  
2/656 = 0.3%

PCR-inhibition rate  
4/656 = 0.6%  
(resolved by re-analysis)

**Samples:**

- 656 routine cultures of whole blood. In addition, two MRSA-positive EQA control samples for blood culture (Labquality, Finland)
- Cultures were performed according to the manufacturer's instructions in the respective culture automates until positive signal

**Culture media:**

- bioMérieux BacT/ALERT (n = 186)
  - BacT/ALERT FA FAN Aerobic, n = 102
  - BacT/ALERT SN Standard Anaerobic, n = 72
  - BacT/ALERT PF Pediatric FAN, n = 12
- BD BACTEC (n = 470)
  - Plus Aerobic/F, n = 244
  - Plus Anaerobic/F, n = 197
  - Peds Plus/F, n = 29

**Bacterial identification methods:**

- Positive cultures were Gram stained before (BacT/ALERT) or after (BD BACTEC) analysis by the GenomEra MRSA/SA Blood Culture assay
- Species identification was performed using routine biochemical techniques (e.g. tube coagulase test, SASelect chromogenic agar (Bio-Rad), Api20E, Api20NE or StaphID32 (Biomérieux))
- Susceptibility testing of individual bacterial isolates was performed after pure culturing and included disc diffusion tests and E-tests on Mueller-Hinton agar

**GenomEra test sequence:**

- One drop of positive blood culture sample (average drop volume 22 µL, range from 15 to 32 µL) was diluted to assay buffer. The diluted sample was used directly in the GenomEra MRSA/SA Blood Culture assay (35 µL/test chip)
- The thermal cycling and homogeneous detection were performed in the GenomEra CDX™ instrument with results reported in 50 min

**Results:**

- All SA and MRSA strains (127 and 11, respectively) were correctly identified by the GenomEra test, resulting in a clinical sensitivity of 100%
- One false positive MRSA-result was obtained due to the presence of *S. marcescens*, resulting in a specificity of 99.8% (642/643)

**Conclusions:**

- Starting from positive blood culture samples, detection of SA and MRSA was achieved within 60 min, including sample preparation
- Using the routine methodology, sample identification data was available at the soonest 16 hours later.