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Category and Description:	Package Insert, BD Phoenix™ PMIC/ID-600 Panel	Rev from: N/A      Rev to: 01
		Job Number: 451-18

Catalog Number: 449057

Blank (Sheet) Size: Length: 8.5" Width: 14.0"

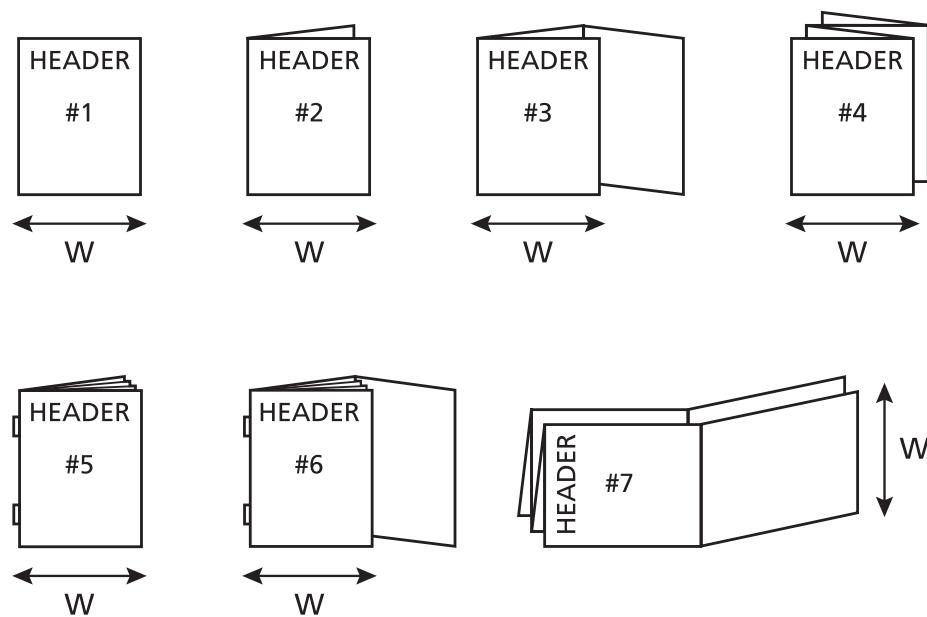
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**INTENDED USE**

The **BD Phoenix™ PMIC/ID** panel is used for the rapid identification and susceptibility testing of most aerobic and facultative anaerobic gram-positive bacteria of human origin with selected antimicrobial agents (for a complete listing of taxa, refer to the **BD Phoenix System User's Manual**). This panel is only for use with the **BD Phoenix Automated Microbiology System** Instrument.

**PRINCIPLES OF THE PROCEDURE**

Refer to the **BD Phoenix System User's Manual**.

**PANELS**

**Identification:** Refer to the **BD Phoenix System User's Manual**.

**Susceptibility:** The PMIC/ID panel contains the antimicrobial agents and concentrations in doubling dilutions found in Table 1.

**STORAGE**

Store at 15–25 °C. Do not use panel if the pouch is punctured or opened. Do not use the panel if desiccant is missing or if the desiccant pouch is torn.

Panels must be used within 2 h of being removed from the pouch.

**Precautions:**

For *in vitro* Diagnostic Use.

**WARNINGS**

Observe established precautions against microbiological hazards throughout all procedures. "Standard Precautions"<sup>1,2</sup> and institutional guidelines should be followed in handling all items contaminated with specimens and microorganisms. Prior to discarding, sterilize specimen containers and other inoculated materials by autoclaving.

**QUALITY CONTROL**

**Identification:** See expected results below.

Test Organism	Expected Result
<i>Staphylococcus aureus</i> ATCC® 29213	<i>Staphylococcus aureus</i>
<i>Enterococcus faecalis</i> ATCC 29212	<i>Enterococcus faecalis</i>

**Susceptibility:** See expected results in Table 1.

NOTE: QC may be reported as less than or equal to the lowest, or greater than the highest concentration of the antimicrobial.

**LIMITATIONS OF THE PROCEDURE**

The clinical relevance of a specific antimicrobial and organism combination is determined by the activity of that antimicrobial against the organism and whether the antimicrobial is indicated for treatment of a disease state associated with that organism. The **BD Phoenix** System provides results for combinations, whether they are clinically relevant or not relevant. Overall, the results obtained using the **BD Phoenix** System compare favorably with the CLSI broth microdilution reference methodology; however, Table 2 contains clinically relevant combinations that did not meet the strict standards of BD during clinical trials and will either not be reported or an alternate method is recommended for confirmation of the result. Similarly, Table 3 contains combinations which are not clinically relevant and are either not reported or an alternate method is recommended for confirmation of the result.

**PERFORMANCE CHARACTERISTICS**

Refer to the **BD Phoenix System User's Manual**.

**REFERENCES**

- Clinical and Laboratory Standards Institute. 2014. Approved guideline M29-A4. Protection of laboratory workers from occupationally acquired infections, 4th ed., CLSI, Wayne, Pa.
- U.S. Department of Labor, Occupational Safety and Health Administration, 29 CFR Part 1910.1030. 1991. Occupational exposure to bloodborne pathogens. Federal Register 56:64175-64182.
- Clinical and Laboratory Standards Institute. 2015. Approved standard M07-A10. Methods for dilution antimicrobial susceptibility tests for bacteria that grow aerobically, 10th ed., CLSI, Wayne, Pa.

Technical Information: In the United States contact BD Technical Service and Support at 1.800.638.8663 or [www.bd.com](http://www.bd.com).

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MADE IN USA  
L011294(01)  
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Table 1

REF 449057

		( µg/mL )	<i>S. aureus</i> ATCC® 29213	<i>E. faecalis</i> ATCC 29212	<i>E. faecalis</i> ATCC 51299	<i>S. aureus</i> ATCC 25923	<i>S. aureus</i> ATCC BAA-976	<i>S. aureus</i> ATCC BAA-977
Amikacin	AN	4 - 16	1 - 8					
Amoxicillin-Clavulanate	AMC	2/1 - 8/4	≤0.25/0.125 - 0.5/0.25	≤0.25/0.125 - 1/0.5				
Ampicillin	AM	2 - 16	0.5 - >1	0.5 - 2				
Cefoxitin	FOX	2 - 16	≤1 - 4					
Ciprofloxacin	CIP	1 - 4	≤0.125 - 0.5	0.5 - 4				
Clindamycin	CC	0.25 - 1	≤0.125 - 0.25	4 - >8				
Daptomycin	DAP	1 - 4	0.25 - 1	1 - 8				
Erythromycin	E	0.25 - 4	0.25 - 1					
Fosfomycin	FF	8 - 32	≤8	32 - 128				
Fusidic Acid	FA	1 - 8	≤0.5 - 1	1 - 4				
Gentamicin	GM	1 - 4	≤0.5 - 1					
Gentamicin-Synergy	GMS	500		≤500	>500			
Inducible macrolide resistance test (iMLSb)*	ECC	YES	NEG			NEG	POS	
Levofloxacin	LVX	1 - 8	≤0.25 - 0.5	≤0.25 - 2				
Linezolid	LZD	2 - 8	1 - 4	1 - 4				
Beta-Lactamase (Nitrocefin-based)	NCF	YES	POS			NEG		
Moxifloxacin	MXF	0.25 - 1	≤0.125	≤0.125 - 0.5				
Nitrofurantoin	FM	32 - 128	≤16 - 32	≤16				
Oxacillin	OX	0.25 - 4	0.125 - 0.5	>4				
Penicillin	P	0.125 - 0.5	0.25 - >1	1 - 4				
Rifampin	RA	0.25 - 1	≤0.25					
Streptomycin-Synergy	STS	1000		≤1000	>1000			
Teicoplanin	TEC	1 - 8	≤0.5 - 1	≤0.5				
Tetracycline	TE	0.5 - 2	≤0.5 - 1	8 - >16				
Trimethoprim-Sulfamethoxazole	SXT	2/38 - 8/152	≤0.5/9.5	≤0.5/9.5				
Vancomycin	VA	1 - 16	≤0.5 - 2	1 - 4				

\* Either *S. aureus* ATCC 29213 or *S. aureus* ATCC BAA-976 may be used as the CLSI QC negative control.

Table 2

Organism / Микроорганизъм / Organizam / Organismus / Organisme / Организъм / Mikroorganizmus / Microrganismo / Organism / Mikroorganizmas / Drobnostrój / Microorganism / Микроорганизъм / Organizmus / Microorganismo / Mikroorganism / Organizma / Мікроорганізм	Not Reported / Неочертени / Nije zabilježeno / Nenahlášeno / Ikke rapporteret / Esitamata / Non rendu / Nicht berichtet / Δεν αναφέρθηκε / Nincs eredmény / Non riportato / Берілгенег / Nepranešta / Ikke rapportert / Nie zgłoszono / Não reportado / Nu sunt raportate / Не указано / Nisu prijavljeni / Neuvážza sa / No informado / Ej rapporterad / Raporlanmadı / Не включава се до звіту	Alternate Method / Алтернативен метод / Drugačija metoda / Alternativní metoda / Alternativ metode / Alternatiivne metood / Autre méthode / Alternative Methode / Εναλλακτική μέθοδος / Alternativ módszer / Método alternativo / Балама ёдис / Alternatyvus metodos / Metoda zamienna / Método alternativo / Metoda alternativa / Балама ёдис / Alternatyvus metodos / Metoda zamienna / Método alternativo / Metoda alternativa / Альтернативный метод / Druga metoda / Alternativna metoda / Alternativ metod / Alternatif Yöntem / Альтернативний метод

Table 3

Organism / Микроорганизъм / Organizam / Organismus / Organisme / Организъм / Mikroorganizmus / Microrganimo / Organism / Mikroorganizmas / Drobnostrój / Microorganism / Микроорганизъм / Organizmus / Microorganismo / Mikroorganism / Organizma / Мікроорганізм	Not Reported / Неочертени / Nije zabilježeno / Nenahlášeno / Ikke rapporteret / Esitamata / Non rendu / Nicht berichtet / Δεν αναφέρθηκε / Nincs eredmény / Non riportato / Берілгенег / Nepranešta / Ikke rapportert / Nie zgłoszono / Não reportado / Nu sunt raportate / Не указано / Nisu prijavljeni / Neuvážza sa / No informado / Ej rapporterad / Raporlanmadı / Не включава се до звіту	Alternate Method / Алтернативен метод / Drugačija metoda / Alternativní metoda / Alternativ metode / Alternatiivne metood / Autre méthode / Alternative Methode / Εναλλακτική μέθοδος / Alternativ módszer / Método alternativo / Балама ёдис / Alternatyvus metodos / Metoda zamienna / Método alternativo / Metoda alternativa / Балама ёдис / Alternatyvus metodos / Metoda zamienna / Método alternativo / Metoda alternativa / Альтернативный метод / Druga metoda / Alternativna metoda / Alternativ metod / Alternatif Yöntem / Альтернативний метод
Coagulase Negative <i>Staphylococcus</i> other than <i>S. epidermidis</i>	Ampicillin, Penicillin	
<i>Staphylococcus epidermidis</i>	Ampicillin	
<i>Enterococcus</i> other than <i>E. faecalis</i> or <i>E. faecium</i>	Ciprofloxacin, Levofloxacin	
All <i>Enterococcus</i> species	Rifampin	
<i>Enterococcus faecalis</i>		Erythromycin