

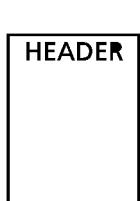
## Revisions

SO 0191-5

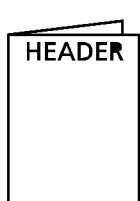
Rev from	Rev to	ECO #
2009/12	2011/01	5657-11

### Notes:

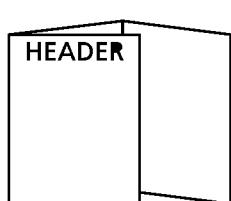
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3. Style (see illustrations below): # 1



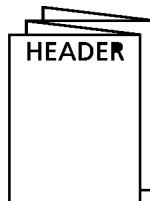
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#2



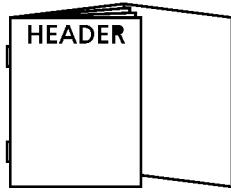
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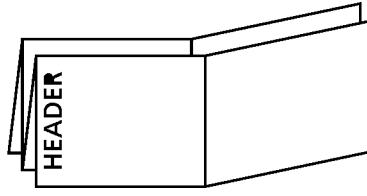
#4



#5



#6



#7

4. See Specification Control Number N/A for Material Information
5. Ink Colors: Printed two sides  Yes  No  
No. of Colors: 1 PMS# Standard Black
6. Graphics are approved by Becton, Dickinson and Company. Supplier has the responsibility for using the most current approved revision level

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Proofer	Date			
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Part Number:  L010043	Category and Description  Package Insert, Phoenix UNMIC-85	Sheet: 1 of 3  Scale: N/A		A



Phoenix™

UNMIC-85

English

Phoenix  
UNMIC-85**INTENDED USE**

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

**PRINCIPLES OF THE PROCEDURE**Refer to the **Phoenix** System User's Manual.**PANEL**

**Susceptibility:** The UNMIC 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" 1,2 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****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 **Phoenix** System provides results for combinations, whether they are clinically relevant or not relevant. Overall, the results obtained using the **Phoenix** System compare favorably with the CLSI (formerly NCCLS) broth microdilution reference methodology;<sup>3</sup> 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 **Phoenix** System User's Manual.**REFERENCES**

- Clinical and Laboratory Standards Institute. 2005. Approved guideline M29-A3. Protection of laboratory workers from occupationally acquired infections, 3rd 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. 2009. Approved standard M7-A8. Methods for dilution antimicrobial susceptibility tests for bacteria that grow aerobically, 8th ed., CLSI, Wayne, Pa.

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		( µg/mL )	<i>E. coli</i> ATCC™ 25922	<i>P. aeruginosa</i> ATCC 27853	<i>E. coli</i> ATCC 35218	<i>K. pneumoniae</i> ATCC 700603
Antimicrobic / Антимикробен агент / Zaštita od mikroba / Antimikrobiální činidlo / Antimikrobe / Antimicrob / Antibiotico / Mikrobička čárosť záťaž / Antimikrobiálne väťasť / Antimikrobiell agens / Antibiotyk / Antimicrobiano / Antibiotic / Антибиотик / Antimikrobik / Antimikrobiálna látka / Antimicrobiano / Antimikrobikum						
Amikacin	AN	4 - 16	≤ 0.5 - 4	1 - 4		
Amoxicillin/Clavulanate (f)	AXC	2/2 - 8/2	2/2 - 8/2		4/2 - 16/2	
Ampicillin	AM	2 - 8	2 - 8			
Aztreonam	ATM	1 - 16	≤ 0.5	2 - 16		
Cefazolin	CZ	1 - 4	1 - 4			
Cefepime	FEP	1 - 8	≤ 0.5	1 - 8		
Cefoxitin	FOX	4 - 16	2 - 8			
Ceftazidime	CAZ	1 - 8	≤ 0.5	1 - 4		
Ceftriaxone	CRO	1 - 4	≤ 0.5	8 - 64		
Cefuroxime	CXM	2 - 8	2 - 8			
Ciprofloxacin	CIP	0.125 - 1	≤ 0.125	0.25 - 1		
Ertapenem	ETP	0.25 - 1	≤ 0.25			
Fosfomycin	FF	16 - 64	≤ 16	≤ 16		
Gentamicin	GM	1 - 4	≤ 0.5 - 1	≤ 0.5 - 2		
Meropenem	MEM	0.5 - 8	≤ 0.25	≤ 0.25 - 1		
Nitrofurantoin	FM	16 - 64	≤ 8 - 16			
Norfloxacin	NOR	0.5 - 2	≤ 0.25	1 - 4		
Piperacillin	PIP	4 - 16	1 - 4			
Piperacillin/Tazobactam	TZP	4/4 - 16/4	1/4 - 4/4	1/4 - 8/4	≤ 0.5/4 - 2/4	
Temocillin	TEM	4 - 32	≥ 8	>32		
Trimethoprim	TMP	1 - 4	≤ 0.5 - 2	>16		
Trimethoprim/Sulfamethoxazole	SXT	1/19 - 4/76	≤ 0.5/9.5	8/152 - >16/304		
ESBL	ESBL	-	NEG		POS	
Cefotaxime/Clavulanate (ESBL)	CCX	<9	N/A		N/A	
Ceftazidime/Clavulanate (ESBL)	CCZ	<9	N/A		N/A	
Cefpodoxime-proxetil (ESBL)	CPD	<9	N/A		N/A	
Ceftazidime (ESBL)	CAZ	<9	N/A		N/A	
Ceftriaxone/Clavulanate (ESBL)	CCR	<9	N/A		N/A	

Table 2

Organism / Микроорганизъм / Organizam / Organismus / Organisme / Mikroorganism / Οργανισμός / Mikroorganizmus / Microrganismo / Организм / Mikroorganizmas / Drobnoústrój / Microorganism / Микроорганизм / Organizmus / Microorganismo / Organizma	Not Reported / Неочетено / Nije zabilježeno / Nenahlášeno / Ikke rapportert / Esitamata / Non rendu / Nicht berichtet / Δεν очарефчено / Nincs eredmény / Non riportato / Нетижеся бяяндалган јок / Nepranešta / Ikke rapportert / Nie zgłoszono / Não reportado / Nu sunt raportate / Не указано / Nisu prijavljeni / Neuvádzsa sa / No informado / Ej rapporterad / Raporlanmadı	Alternate Method / Алтернативен метод / Drugačija metoda / Alternativní metoda / Alternativ metod / Alternativne metod / Autre méthode / Alternative Methode / Εναλλακτική μέθοδος / Alternatív módszer / Metodo alternativo / Балама едис / Alternatyvus metodus / Metoda zamienna / Metodă alternativă / Альтернативный метод / Druga metoda / Alternativna metôda / Método alternativo / Alternativ metod / Alternatif Yöntem
All <i>Providencia</i> species	Temocillin	
<i>Hafnia alvei</i>	Temocillin	
<i>Morganella morgani</i>	Piperacillin, Temocillin	
<i>Proteus mirabilis</i>		Aztreonam, Cefazolin
<i>Pseudomonas aeruginosa</i>		Piperacillin
<i>Yersinia enterocolitica</i>	Ertapenem	

Table 3

Organism / Микроорганизъм / Organizam / Organismus / Organisme / Mikroorganism / Οργανισμός / Mikroorganizmus / Microrganimo / Организм / Mikroorganizmas / Drobnoústrój / Microorganism / Микроорганизм / Organizmus / Microorganismo / Organizma	Not Reported / Неочетено / Nije zabilježeno / Nenahlášeno / Ikke rapportert / Esitamata / Non rendu / Nicht berichtet / Δεν очарефчено / Nincs eredmény / Non riportato / Нетижеся бяяндалган јок / Nepranešta / Ikke rapportert / Nie zgłoszono / Não reportado / Nu sunt raportate / Не указано / Nisu prijavljeni / Neuvádzsa sa / No informado / Ej rapporterad / Raporlanmadı	Alternate Method / Алтернативен метод / Drugačija metoda / Alternativní metoda / Alternativ metod / Alternativne metod / Autre méthode / Alternative Methode / Εναλλακτική μέθοδος / Alternatív módszer / Metodo alternativo / Балама едис / Alternatyvus metodus / Metoda zamienna / Metodă alternativă / Альтернативный метод / Druga metoda / Alternativna metôda / Método alternativo / Alternativ metod / Alternatif Yöntem
All <i>Serratia</i> species		Fosfomycin
<i>Ralstonia</i> species	Cefepime	
<i>Burkholderia</i> species	Cefepime	
<i>Yersinia frederiksenii</i>	Cefepime, Ceftriaxone	