

Revisions

SO 0191-5

Rev from	Rev to	ECO #
0107	2011/01	5632-10

Notes:

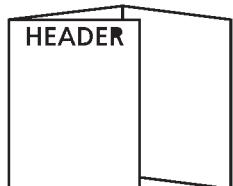
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Number of Pages: 2 Number of Sheets: 1
Page Size: Length 8.5" Width 14.0" Final Folded Size: No Fold.
3. Style (see illustrations below): # 1



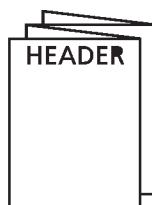
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#2



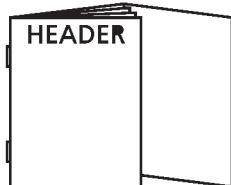
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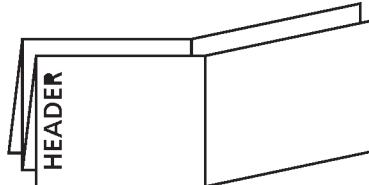
#4



#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		
Checked By	Date	Category and Description	Sheet: 1 of 3
Part Number: L009726		Package Insert, Phoenix NMIC/ID-70	Scale: N/A

A

INTENDED USE

The **Phoenix™** NMIC/ID panel is used for the rapid identification and 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.

PANELS

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

Susceptibility: The NMIC/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"^{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

Identification: See expected results below.

Test Organism	Expected Result
<i>Escherichia coli</i> ATCC 25922	<i>Escherichia coli</i>
<i>Pseudomonas aeruginosa</i> ATCC 27853	<i>Pseudomonas aeruginosa</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 **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;³ 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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INDICATIONS
La galerie NMIC/ID **Phoenix** sert aux tests d'identification rapide et de sensibilité de la plupart des bactéries aérobie et anaérobies facultatives à Gram négatif d'origine humaine avec des antibiotiques sélectionnés (pour la liste complète des taxons, se reporter au manuel d'utilisation du système **Phoenix**). Cette galerie s'utilise uniquement avec l'instrument du système de microbiologie automatisée **Phoenix**.

PRINCIPES DE LA MÉTHODE

Se reporter au manuel d'utilisation du système **Phoenix**.

GALERIES

Identification: Se reporter au manuel d'utilisation du système **Phoenix**.

Sensibilité: La galerie NMIC/ID contient les antibiotiques et les concentrations dans la série de dilutions doublées figurant au tableau 1.

CONSERVATION

Conserver à 15–25°C. Ne pas utiliser la galerie si la pochette est percée ou ouverte. Ne pas utiliser la galerie si elle ne contient pas de déshydratant ou si la pochette de ce dernier est déchirée.

Les galeries doivent être utilisées dans les 2 h après avoir été sorties de la pochette.

Précautions:
pour le diagnostic *in vitro*.

AVERTISSEMENTS

Observer à tout moment les précautions en vigueur en matière de protection contre les dangers microbiologiques. Les "précautions universelles", 1,2 ainsi que les directives des institutions concernées devront être suivies lors de la manipulation de tous les éléments contaminés par des échantillons et des microorganismes. Avant de les jeter, stériliser à l'autoclave tous les récipients ayant contenu des échantillons et tout autre matériel inoculé.

CONTROLE DE QUALITE

Identification: Voir les résultats escomptés ci-dessous.

Organisme de référence	Résultats escomptés
<i>Escherichia coli</i> ATCC 25922	<i>Escherichia coli</i>
<i>Pseudomonas aeruginosa</i> ATCC 27853	<i>Pseudomonas aeruginosa</i>

Sensibilité: Voir les résultats escomptés dans le tableau 1.

NOTA : le CQ peut être noté comme inférieur ou égal à la concentration d'antibiotiques la plus basse ou supérieure à la concentration d'antibiotiques la plus élevée.

LIMITATIONS DE LA MÉTHODE

La valeur clinique d'une combinaison spécifique d'organisme et d'antibiotique est déterminée par l'action de cet antibiotique sur l'organisme et si cet antibiotique est prescrit pour le traitement d'une maladie associée à cet organisme. Le système **Phoenix** fournit des résultats pour toutes les combinaisons avec ou sans signification clinique. En général, les résultats obtenus avec le système **Phoenix** se comparent de façon favorable avec la méthode de référence de microdilution en bouillon du CLSI (anciennement NCCLS).³ Cependant, le tableau 2 contient les combinaisons ayant une signification clinique qui n'ont pas satisfait aux normes strictes de BD lors des essais cliniques. Elles ne seront pas rapportées ou bien une autre méthode sera recommandée pour la confirmation des résultats. De la même façon, le tableau 3 contient les combinaisons ayant une signification clinique qui sont pas rapportées ou bien une autre méthode est recommandée pour la confirmation des résultats.

CARACTÉRISTIQUES DE PERFORMANCE

Se reporter au manuel d'utilisation du système **Phoenix**.

BIBLIOGRAPHIE : voir la rubrique "References" du texte anglais.

LITERATURNACHWEIS: S. "References" im englischen Text.

INDICATIONS
Die **Phoenix** NMIC/ID Panel ist zum Schnellnachweis und zur Empfindlichkeitstestung der meiststen aeroben und fakultativ anaeroben gramnegativen Humanbakterien (eine vollständige Liste der Taxa finden Sie im **Phoenix**-Benutzerhandbuch) eingesetzt. Die Panel darf nur mit dem automatisierten **Phoenix**-Mikrobiologiesystem verwendet werden.

VERFAHRENSPRINZIP

Bitte lesen Sie im **Phoenix**-Benutzerhandbuch nach.

PANNELE

Identification: Consultare il Manuale d'uso del sistema **Phoenix**.

Sensibilità: Il pannello NMIC/ID contiene gli antibiotici e le concentrazioni in diluizioni in doppie presenti nel Quadro 1.

CONSERVATION

Conservare a 15–25 °C. Non usare la galerie se la busta è rotta o aperta. Non usare la galerie se non contiene il desiccatore o se la busta dell'essiccatore è rotta.

Le galeries doivent être utilisées dans les 2 h après avoir été sorties de la pochette.

PRÉCAUTIONS

pour le diagnostic *in vitro*.

AVERTISSEMENT

Observer à tout moment les précautions en vigueur en matière de protection contre les dangers microbiologiques. Les "précautions universelles", 1,2 ainsi que les directives des institutions concernées devront être suivies lors de la manipulation de tous les éléments contaminés par des échantillons et des microorganismes.

CONTROLE DI QUALITA

Identification: Vedere qui sotto i risultati attesi.

Organismo di prova	Risultato atteso
<i>Escherichia coli</i> ATCC 25922	<i>Escherichia coli</i>
<i>Pseudomonas aeruginosa</i> ATCC 27853	<i>Pseudomonas aeruginosa</i>

Sensibilità: Vedere alla tabella 1 i risultati attesi.

NOTA : Per il controllo di qualità è possibile riportare un valore inferiore o uguale alla concentrazione più bassa di antibiotico, oppure superiore alla concentrazione più elevata.

LIMITAZIONI DELLA PROCEDURA

L'importanza clinica di una combinazione specifica di antibiotico e organismo dipende dall'azione che tale antibiotico esercita contro l'organismo e da quanto l'antibiotico sia indicato o meno per il trattamento di una condizione patologica associata a tale organismo. Il sistema **Phoenix** fornisce risultati sia per le combinazioni significative dal punto di vista clinico, che per le combinazioni non significative.

Le combinazioni significative dal punto di vista clinico, elencate nella tabella 2, non hanno soddisfatto i rigorosi standard della BD durante la sperimentazione clinica e pertanto i risultati o non sono riportati o se ne raccomanda la conferma con un metodo alternativo.

Le combinazioni non significative dal punto di vista clinico sono elencate nella tabella 3: anche questi risultati non sono riportati o se ne raccomanda la conferma con un metodo alternativo. La relevancia clinica di una combinazione specifica di un agente antimicrobiano e un organismo se determina per la actividad de dicho agente antimicrobiano contra el organismo y la indicación del agente antimicrobiano en el tratamiento de estados de enfermedad asociados a dicho organismo. El Sistema **Phoenix** proporciona los resultados de combinaciones tanto relevantes como no relevantes desde el punto de vista clínico. En conjunto, los resultados obtenidos con el Sistema **Phoenix** son favorables en comparación con la metodología de referencia del CLSI (antes NCCLS) de microdilución en caldo,³ sin embargo, la Tabla 2 contiene combinaciones, relevantes desde el punto de vista clínico, que no cumplen las estrictas normas de BD durante los ensayos clínicos y no serán registradas, o se recomendará un método alternativo para la confirmación del resultado de la prueba.

De manera similar, la Tabla 3 contiene combinaciones que no son relevantes desde el punto de vista clínico, y que tampoco se registran o se recomienda utilizar un método alternativo para la confirmación del resultado.

CARATTERISTICHE DELLE PRESTAZIONI

Consultare il Manuale d'uso del sistema **Phoenix**.

BIBLIOGRAFIA: vedere "References" nel testo inglese.

INDICATIONS
Il pannello **Phoenix** NMIC/ID è usato per la identificazione rapida e il test di sensibilità della maggioranza dei batteri Gram negativi aerobi e anaerobi facoltativi di origine umana con alcuni antibiotici selezionati (per un elenco completo dei taxoni, consultare il Manuale d'uso del sistema **Phoenix**). Questo pannello va usato solo con lo strumento del sistema per microbiologia automatizzata **Phoenix**.

PRINCIPI DELL'USO

Consultare il Manuale d'uso del sistema **Phoenix**.

PANELE

Identification: Consultare il Manuale d'uso del sistema **Phoenix**.

Sensibilità: Il pannello NMIC/ID contiene gli antibiotici e le concentrazioni in diluizioni in doppie indicate nel Quadro 1.

CONSERVAZIONE

Conservare a 15–25 °C. Non usare la galera se la busta è rotta o aperta. Non usare la galera se non contiene il desiccatore o se la busta del desiccatore è rotta.

I pannelli vanno usati entro 2 h dall'estrazione del sacchetto.

PRECAUZIONI

per uso diagnostico *in vitro*.

AVVERTENZE

Observer a tutto momento le precauzioni in vigore in materia di protezione contro i pericoli microbiologici. Le "precauzioni universali", 1,2 così come le direttive delle istituzioni riguardanti la manipolazione di tutti gli elementi contaminati da campioni e da microrganismi.

CONTROLO DI QUALITÀ

Identification: Vedere qui sotto i risultati attesi.

Organismo di prova	Risultato atteso
<i>Escherichia coli</i> ATCC 25922	<i>Escherichia coli</i>
<i>Pseudomonas aeruginosa</i> ATCC 27853	<i>Pseudomonas aeruginosa</i>

Sensibilità: Consultare i risultati attesi nella Tabella 1.

NOTA: Il CC può essere registrato come inferiore o uguale a quella minima del agente antimicrobiano, o come superiore a quella massima del stesso.

LIMITAZIONI DEL PROCEDIMENTO

O significado clínico de uma combinação específica de anti-microbiano e microrganismo é determinado pelo facto de anti-microbiano estar ou não indicado no tratamento de um estado patológico associado a esse microrganismo. O Sistema **Phoenix** fornece resultados para combinações, quer estas sejam clinicamente significativas ou não. No global, os resultados obtidos mediante a utilização do Sistema **Phoenix** compararam-se favoravelmente com a metodologia de referência de diluição em caldo de carne do CLSI (anteriormente NCCLS)³; todavia, no Quadro 2 apresentam-se combinações clinicamente significativas que não cumpriram os padrões estritos de BD durante os ensaios clínicos e que não serão participadas ou para as quais se recomenda a utilização de um método alternativo para confirmação do resultado. Analogamente, no Quadro 3 apresentam-se combinações que não são clinicamente significativas e que não serão participadas ou para as quais se recomenda a utilização de um método alternativo para confirmação do resultado.

CARATTERISTICHE DI DESEMPEÑO

Consultar o Manual do Utilizador do Sistema **Phoenix**.

BIBLIOGRAFIA: Ver "References" en el texto en inglés.

INDICATIONS
El panel NMIC/ID de **Phoenix** se utiliza para la identificación rápida y las pruebas de sensibilidad a agentes antimicrobianos seleccionados de la mayoría de las bacterias gram-negativas aerobias y anaerobias facultativas de origen humano a agentes anti-microbianos seleccionados (para ver la lista completa de los taxones, consultar el Manual del usuario del sistema **Phoenix**). Este panel solamente está indicado para utilizarse con el instrumento del sistema para microbiología automatizada **Phoenix**.

PRINCIPIOS DEL PROCEDIMIENTO

Consultar el Manual del usuario del sistema **Phoenix**.

PANELES

Identification: Consultar el Manuale d'uso del sistema **Phoenix**.

Sensibilidad: El panel NMIC/ID contiene los antibióticos y las concentraciones en diluciones dobles indicadas en el Cuadro 1.

		(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
Amoxicillin/Clavulanate	AMC	4/2 - 16/8	2/1 - 8/4		4/2 - 16/8	
Ampicillin	AM	4 - 16	2 - 8			
Ampicillin/Sulbactam	SAM	4/2 - 16/8	2/1 - 8/4		8/4 - 32/16	
Aztreonam	ATM	2 - 16	≤ 0.5	2 - 16		
Cefazolin	CZ	4 - 16	1 - 4			
Cefepime	FEP	2 - 16	≤ 0.5	1 - 8		
Cefotaxime	CTX	2 - 32	≤ 0.5	16 - 64		
Cefoxitin	FOX	1 - 16	2 - 8			
Ceftazidime	CAZ	2 - 16	≤ 0.5	1 - 4		
Cefuroxime	CXM	4 - 16	2 - 8			
Ciprofloxacin	CIP	0.5 - 2	≤ 0.125	0.25 - 1		
Ertapenem	ETP	0.5 - 4	≤ 0.25			
Gentamicin	GM	2 - 8	≤ 0.5 - 1	≤ 0.5 - 2		
Levofloxacin	LVX	1 - 4	≤ 0.25	0.5 - 4		
Meropenem	MEM	1 - 8	≤ 0.25	≤ 0.25 - 1		
Moxifloxacin	MXF	1 - 4	≤ 0.125	1 - 8		
Piperacillin	PIP	4 - 64	1 - 4			
Piperacillin/Tazobactam	TZP	4/4 - 64/4	1/4 - 4/4	1/4 - 8/4	≤ 0.5/4 - 2/4	
Tetracycline	TE	1 - 8	≤ 0.5 - 2	8 - >16		
Tobramycin	NN	2 - 8	0.25 - 1	0.25 - 1		
Trimethoprim/Sulfamethoxazole	SXT	0.5/9.5 - 2/38	≤ 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 / Organismus / Organisme / Οργανισμός / Mikroorganizmus / Organismo / Mikroorganizmai / Droboustrój / Microrganismo / Organizmus	Not Reported / Nenahlášeno / Ikke rapportert / Hinnang puudub / Non rapporté / Nicht berichtet / αναφέρθηκε / Nem jelenik meg / Non referato / Nepateikiami / Não podano / Não apresentado / Nie je známy / No registrado / Ej rapporterad	Alternate Method / Alternativní postup / Alternativ metode / Alternatiivne metod / Autre méthode / Alternative Methode / Εναλλακτική μέθοδος / Alternativ módszer / Método alternativo / Alternatyvus metodos / Inna metoda / Método alternativo / Alternatívna metóda / Alternativ metod
<i>Morganella morganii</i>	Piperacillin	
<i>Proteus mirabilis</i>		Aztreonam, Cefazolin
<i>Pseudomonas aeruginosa</i>		Piperacillin
<i>Yersinia enterocolitica</i>	Ertapenem	

Table 3

Organism / Organismus / Organisme / Οργανισμός / Mikroorganizmus / Organismo / Mikroorganizmai / Droboustrój / Microrganismo / Organizmus	Not Reported / Nenahlášeno / Ikke rapportert / Hinnang puudub / Non rapporté / Nicht berichtet / αναφέρθηκε / Nem jelenik meg / Non referato / Nepateikiami / Não podano / Não apresentado / Nie je známy / No registrado / Ej rapporterad	Alternate Method / Alternativní postup / Alternativ metode / Alternatiivne metod / Autre méthode / Alternative Methode / Εναλλακτική μέθοδος / Alternativ módszer / Método alternativo / Alternatyvus metodos / Inna metoda / Método alternativo / Alternatívna metóda / Alternativ metod
<i>Serratia marcescens</i>		Tetracycline