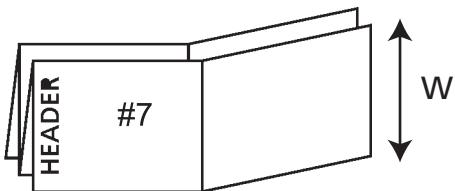
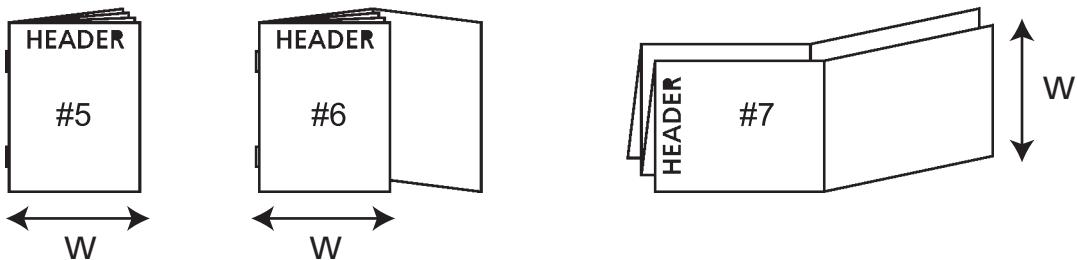
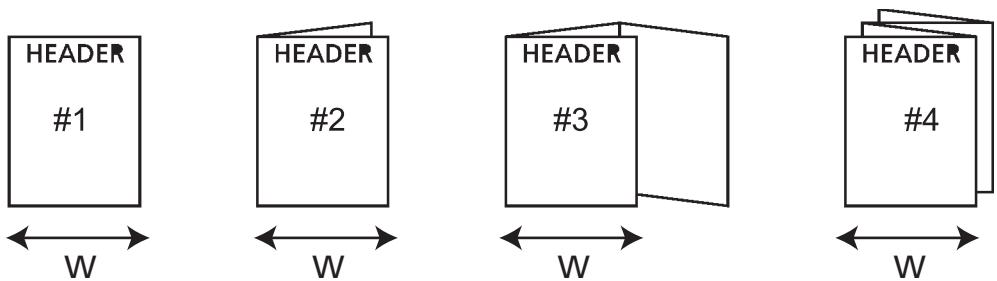


Rev from	Rev to	JOB #
01	02	9057-17

Notes:

1. BD Catalog Number: 449012
2. Blank (Sheet) Size: Length: 8.5" Width: 14.0"
3. Number of Pages: 2 Number of Sheets: 1
4. Page Size: Length: 8.5" Width: 14.0" Final Folded Size: No Fold
5. Ink Colors: No. of Colors: 1 PMS#: Standard Black
6. Printed two sides: Yes No
7. Style (see illustrations below): # 1



8. Vendor Printed Online/In House Printed Web
9. See specification control no. N/A for material information.
10. Graphics are approved by Becton, Dickinson and Company. Supplier has the responsibility for using the most current approved revision level.

Label Design	REVISED BY By Tori Pagani at 1:12 pm, Apr 11, 2017	COMPANY CONFIDENTIAL. THIS DOCUMENT IS THE PROPERTY OF BECTON, DICKINSON AND COMPANY AND IS NOT TO BE USED OUTSIDE THE COMPANY WITHOUT WRITTEN PERMISSION.	 Becton, Dickinson and Company 7 Loveton Circle Sparks, MD 21152 USA
Proofer	PROOFING APPROVED BY By Natalie Morio at 8:57 am, Apr 24, 2017		
Checked By	THIRD EYE BY By Terrence Means at 1:49 pm, Apr 27, 2017		
Part Number:	L010939	Category and Description	Sheet: 1 of 3
		Packaging Insert, BD Phoenix™ NMIC/ID-418 Panel	Scale: N/A

A

INTENDED USE

The **BD 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 **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 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 antimicrobic.

LIMITATIONS OF THE PROCEDURE

The clinical relevance of a specific antimicrobic and organism combination is determined by the activity of that antimicrobic against the organism and whether the antimicrobic 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 methodology³; 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. 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.

Technical Information: In the United States contact BD Technical Service and Support at 1.800.638.8663 or www.bd.com.

ATCC is a trademark of the American Type Culture Collection.

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INDICATIONS

La galerie NMIC/ID **BD 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 **BD Phoenix**). Cette galerie s'utilise uniquement avec l'instrument du système de microbiologie automatisé **BD Phoenix**.

PRINCIPES DE LA MÉTHODE

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

GALERIES

Identification: Se reporter au manuel d'utilisation du système **BD 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 des 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 à tester	Résultats escomptés
<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 antimicrobic.

LIMITATIONS OF THE PROCEDURE

The clinical relevance of a specific antimicrobic and organism combination is determined by the activity of that antimicrobic against the organism and whether the antimicrobic 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 methodology³; 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. 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.

Technical Information: In the United States contact BD Technical Service and Support at 1.800.638.8663 or www.bd.com.

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INDICATIONS

La galerie NMIC/ID **BD 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 **BD Phoenix**). Cette galerie s'utilise uniquement avec l'instrument du système de microbiologie automatisé **BD Phoenix**.

VERFAHRENSPRINZIP

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

PANNELS

Nachweis: Bitte lesen Sie im **BD Phoenix**-Benutzerhandbuch nach.

Empfindlichkeit: Das NMIC/ID-Panel enthält die in Tabelle 1 aufgeführten Antibiotika in den nebenstehend in geometrischen Verdünnungsserien angegebenen Konzentrationen.

AUFBEWAHRUNG

Bei 15–25 °C lagern. Panel nicht verwenden, wenn der Verpackungsbeutel beschädigt oder offen ist. Verwenden Sie das Panel nicht, wenn kein Trockenmittel beigelegt oder wenn der Trockenmittelbeutel beschädigt ist.

Ihre Panels müssen innerhalb von 2 h Std. nach der Entnahme aus dem Beutel verwendet werden.

Sicherheitshinweise:

Zur *In-Vitro*-Diagnostik.

WANRUNG

Der Umgang mit mikrobiologischem Material sollte bei allen Verfahren unter Einhaltung der üblichen Vorsichtsmaßnahmen erfolgen. Bei der Handhabung von mit Probenmaterial oder Mikroorganismen kontaminierten Materialien allgemeine Vorsichtsmaßnahmen und örtliche Laborrichtlinien^{1,2} beachten. Probenbehältnisse und andere inkulpierte Materialien sind vor der Entsorgung im Autoklaven zu sterilisieren.

QUALITÄTSKONTROLLE

Nachweis: Erwartete Ergebnisse sind unten aufgeführt.

Test-Organismus	Erwartetes Ergebnis
<i>Escherichia coli</i> ATCC 25922	<i>Escherichia coli</i>
<i>Pseudomonas aeruginosa</i> ATCC 27853	<i>Pseudomonas aeruginosa</i>

Empfindlichkeit: Siehe erwartete Ergebnisse in Tabelle 1.

HINWEIS: Qualitätskontrollergebnisse können im Vergleich zur niedrigsten Antibiotikakonzentration als geringer oder gleich berichtet werden, bzw. als höher im Vergleich zur höchsten Antibiotikakonzentration.

LIMITES 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 **BD Phoenix** fournit des résultats pour toutes les combinaisons avec ou sans signification clinique. En général, les résultats obtenus avec le système **BD Phoenix** se comparent de façon favorable avec la méthode de référence de microdilution en bouillon du CLSI.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 n'ayant pas de signification clinique et qui, soit ne sont pas rapportées ou bien une autre méthode est recommandée pour la confirmation des résultats.

CARACTÉRISTIQUES DE PERFORMANCE

Consultez le Manuel d'utilisation du système **BD Phoenix**.

BIBLIOGRAPHIE:

voir la rubrique « References » du texte anglais. Service et assistance technique : contacter votre représentant local de BD ou consulter le site www.bd.com.

LEISTUNGSMERKMAL

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

LITERATURNACHWEIS:

S. «References» im englischen Text.

Technischer Kundendienst: setzen Sie sich mit Ihrer zuständigen BD-Vertretung in Verbindung oder besuchen Sie www.bd.com.

USO PREVISTO

Il pannello NMIC/ID di **BD Phoenix** è usato per l'identificazione rapida e le prove di sensibilità a agenti antimicrobici selezionati delle batterie Gram negativi aerobi e anaerobi facoltativi di origine umana ad una serie di antibiotici (per un elenco completo delle unità tassonomiche consultare il Manuale d'uso del sistema **BD Phoenix**). Questo pannello va usato solo con lo strumento del sistema per microbiologia automatizzato **BD Phoenix**.

PRINCIPI DELLA PROCEDURA

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

PANNELLI

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

Sensibilità: Il pannello NMIC/ID contiene gli antibiotici e le concentrazioni in diluizioni al raddoppio elencati nella tabella 1.

CONSERVAZIONE

Conservare a 15–25 °C. Non usare il pannello se il sacchetto è perforato o aperto. Non usare il pannello se manca l'essiccatore o se la busta dell'essiccatore è lacrata.

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

ALMACENAMIENTO

Almacenar a 15–25 °C. No utilice el panel si la bolsa está perforada o abierta. No utilice el panel si falta el desecante o si está rota la bolsa del desecante.

Los paneles se deben utilizar en el plazo de 2 h después de retirarlos de la bolsa.

PRECAUCIONES:

Para uso em Diagnóstico *in-vitro*.

ADVERTÊNCIAS

Cumprir as precauções estabelecidas contra riscos microbiológicos emitidos os procedimentos. Deverão seguir-se "Precauções Universais"^{1,2} e as normas institucionais na manipulação de todos os artigos contaminados com amostras e microrganismos. Antes de eliminar, esterilizar por autoclave os recipientes das amostras e outro material inoculado.

CONTROLO DE QUALIDADE

Identificação: Consulte os resultados esperados abaixo.

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 **BD Phoenix** fornisce risultati sui per le combinazioni significative dal punto di vista clinico, che per quelle non significative. Nel complesso, i risultati ottenuti con il sistema **BD Phoenix** concordano con il metodo di riferimento CLSI di microdiluizione in brodo.³ Tuttavia, 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.

CARATTERISTICHE DELLE PRESTAZIONI

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

BIBLIOGRAFIA:

vedere "References" nel testo inglese.

Assistenza e supporto tecnico: rivolgersi al rappresentante locale BD o visitare il sito www.bd.com.

CARACTERÍSTICAS DE RENDIMIENTO

Consulte el Manual del usuario del sistema **BD Phoenix**.

BIBLIOGRAFIA:

Ver "References" en el texto en inglés.

Servicio técnico: ponerse en contacto con el representante local de BD o visite www.bd.com.

CHARACTERÍSTICAS DE DESEMPEÑO

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

REFERÊNCIAS:

Consulte "References" no texto em inglês.

Assistência Técnica e Suporte: contacte o representante local da BD ou visite www.bd.com.

Table 1

		($\mu\text{g/mL}$)	<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 / Защита от микробы / Antimikrobiálni činidlo / Antimikrobe / Antimikroob / Antimicroben / Antibiotikum / Антимикробный / Antibiotico / Микробика юрсы зат / Antimikrobinis vaistas / Antimikrobiell agens / Antibiotyk / Antimicrobiano / Antibiotic / Антибиотик / Antimikrobik / Antimikrobiálna látka / Antimikrobikum / Протимикробный агент						
Amikacin	AN	4 - 16	≤ 0.5 - 4	1 - 4		
Amoxicillin/Clavulanate (f)	AXC	2/2 - 32/2	2/2 - 8/2		4/2 - 16/2	
Ampicillin	AM	2 - 8	2 - 8			
Aztreonam	ATM	1 - 16	≤ 0.25	2 - 8		
Cefotaxime	CTX	0.5 - 4	≤ 0.5	8 - 32		
Ceftazidime	CAZ	0.5 - 8	≤ 0.5	1 - 4		
Cefuroxime	CXM	2 - 8	2 - 8			
Cephalexin	CN	4 - 16	4 - 16			
Ciprofloxacin	CIP	0.125 - 1	≤ 0.125	0.25 - 1		
Ertapenem	ETP	0.25 - 1	≤ 0.0625	2 - 8		
Gentamicin	GM	1 - 4	≤ 0.5 - 1	≤ 0.5 - 2		
Imipenem	IPM	0.25 - 8	≤ 0.0625 - 0.25	1 - 4		
Mecillinam	MEC	2 - 8	≤ 0.5			
Meropenem	MEM	0.125 - 8	≤ 0.125	0.25 - 1		
Nitrofurantoin	FM	32 - 128	≤ 8 - 16			
Piperacillin/Tazobactam	TZP	4/4 - 16/4	1/4 - 4/4	1/4 - 8/4	≤ 0.5/4 - 2/4	
Tigecycline	TGC	0.5 - 2	≤ 0.25			
Tobramycin	NN	1 - 4	0.25 - 1	0.25 - 1		
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	
Cepodoxime-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 / Организм / Mikroorganizmus / Microrganismo / Организм / Mikroorganizmas / Drobnoústrój / Microorganism / Микроорганизм / Organizmus / Microorganismo / Mikroorganism / Organizma / Mikroorganizm	Not Reported / Неочетени / Nije zabilježeno / Nenahlášeno / Ikke rapporteret / Esitamata / Non rendu / Nicht berichtet / Δεν съчленяват / Nincs eredmény / Non riportato / Берілген / Nepranešta / Ikke rapportert / Nie zgłoszono / Não reportado / Nu sunt raportate / Не указано / Nisu prijavljeni / Neuvedza sa / No informado / Ej rapporterad / Raporlanmadı / Не включается до звіту	Alternate Method / Алтернативен метод / Drugačija metoda / Alternativni metoda / Alternativ metode / Alternativne metod / Autre méthode / Alternative Methode / Evaľактик мéтодос / Alternativ módszer / Metodo alternativo / Балама адис / Alternatyvus metodás / Metoda zamieniona / Método alternativo / Metodă alternativă / Альтернативный метод / Druga metoda / Alternatívna metóda / Alternativ metod / Alternatif Yöntem / Альтернативний метод
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Table 3

Organism / Микроорганизъм / Organizam / Organismus / Organisme / Организм / Mikroorganizmus / Microrganimo / Организм / Mikroorganizmas / Drobnoústrój / Microorganism / Микроорганизм / Organizmus / Microorganismo / Mikroorganism / Organizma / Mikroorganizm	Not Reported / Неочетени / Nije zabilježeno / Nenahlášeno / Ikke rapporteret / Esitamata / Non rendu / Nicht berichtet / Δεν съчленяват / Nincs eredmény / Non riportato / Берілген / Nepranešta / Ikke rapportert / Nie zgłoszono / Não reportado / Nu sunt raportate / Не указано / Nisu prijavljeni / Neuvedza sa / No informado / Ej rapporterad / Raporlanmadı / Не включается до звіту	Alternate Method / Алтернативен метод / Drugačija metoda / Alternativni metoda / Alternativ metode / Alternativne metod / Autre méthode / Alternative Methode / Evaľактик мéтодос / Alternativ módszer / Metodo alternativo / Балама адис / Alternatyvus metodás / Metoda zamieniona / Método alternativo / Metodă alternativă / Альтернативный метод / Druga metoda / Alternatívna metóda / Alternativ metod / Alternatif Yöntem / Альтернативний метод
Proteus mirabilis	Tigecycline	
All Providencia species	Tigecycline	
Yersinia frederiksenii	Aztreonam	