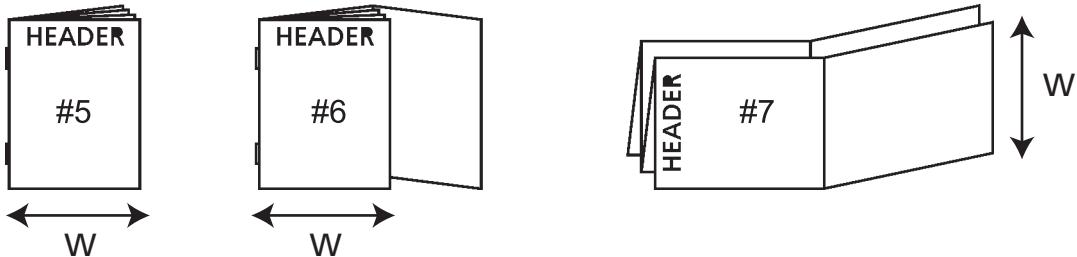
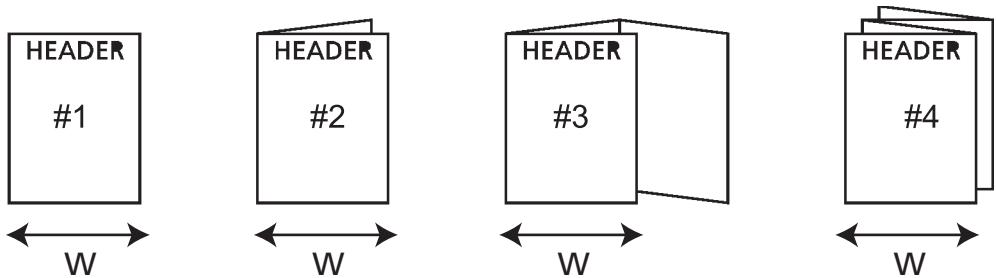


Rev from	Rev to	JOB #
02	03	9085-17

NOTES:

1. BD Catalog Number: 299970
2. Blank (Sheet) Size: Length: 11" Width: 8.5"
3. Number of Pages: 2 Number of Sheets: 1
4. Page Size: Length: 11" Width: 8.5" Final Folded Size: N/A
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 Nancy Carlsen at 3:24 pm, Feb 08, 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.	Category and Description Product Insert, BBL™ OFPBL Agar	Sheet: 1 of 3	A
Proofer	PROOFING APPROVED BY By Natalie Morio at 5:20 pm, Feb 08, 2017				
Checked By	THIRD EYE BY By Sarah Henderson at 9:59 am, Feb 09, 2017				
Part Number:	8806561JAA			Scale: N/A	

BD BBL™ Prepared Plated Media for Isolation of *Burkholderia (Pseudomonas) cepacia*

OFPBL Agar

 8806561JAA(03)
2017-02

Contact your local BD representative for instructions. / Свържете се с местния представител на BD за инструкции. / Pokyny vám poskytne místní zástupce společnosti BD. / Kontakt den lokale BD repräsentant for at få instruktioner. / Επικοινωνήστε με τον τοπικό αντιπρόσωπο της BD για σύγκριση. / Kasutusjuhiste suhtes kontaktteeruge oma kohaliku BD esindajaga. / Ota yhteys lähipäätä BD:n edustajaan ohjeiden saamiseksi. / Kontaktiraj lokalnog predstavnika BD za upute. / A használati utasítást kérje a BD helyi képviseletétől. / Нүскүнап ушын жергілікти BD екімімен хабарласыңыз. / Lai sajētu norādījumus, sazinieties ar vietējo BD pārstāvi. / Naudojimo instrukcijų teitaukėties vietas BD įgaliotovo atstovo. / Neem contact op met uw plaatselijke BD-vertegenwoordiger voor instructies. / Kontakt din lokale BD-representant for mer informasjon. / Aby uzyskać instrukcję użytkowania, skontaktuj się z lokalnym przedstawicielem BD. / Contacte o representante local da BD para instruções. / Pentru instrucțiuni, contactați reprezentantul local BD. / Для получения указаний обратитесь к местному представителю компании BD. / Instrukcie získate u miestneho zástupcu spoločnosti BD. / Obratite se svom lokalnom predstavniku kompanije BD za uputstva. / Kontaktá nármaste BD-representant för anvisningar. / Talimatlar için yerel BD temsilcilinizle temasla geçin. / За інструкціями зверніться до місцевого представника компанії BD.

INTENDED USE

OFPBL Agar is used in the selective isolation and detection of *Burkholderia* (formerly *Pseudomonas*) *cepacia* from clinical and nonclinical specimens.

SUMMARY AND EXPLANATION

Burkholderia cepacia is an opportunistic pathogen generally associated with nosocomial infections.¹ Studies indicate that *B. cepacia* may be an important pulmonary pathogen for patients with cystic fibrosis (CF).² The incidence of this organism in the respiratory tract of CF patients is often accompanied by rapid deterioration in pulmonary status and death.³

Recovery of this organism on commonly-used media, such as blood agar or MacConkey Agar, is difficult because common isolates, such as *Pseudomonas aeruginosa*, *Escherichia coli* and *Staphylococcus aureus*, overgrow the slower-growing colonies of *B. cepacia* and mask its presence.

Gilligan et al. developed PC Agar for improved recovery of *B. cepacia*.² Crystal violet, bile salts and two antimicrobial agents are used as selective agents. They reported isolating *B. cepacia* on PC Agar from respiratory secretions of 35 CF patients, but isolated the organism from only 21 patients on MacConkey Agar.²

Welch et al. developed a differential but less selective medium for the recovery of *B. cepacia*.^{4,5} This medium, OFPBL Agar, is OF (oxidation-fermentation) basal medium supplemented with polymyxin B, bacitracin, lactose and agar. The indicator, bromthymol blue, aids in the detection of *B. cepacia* isolates through a color change in the medium. These investigators reported isolating *B. cepacia* on OFPBL Agar from 58 CF patients, while only isolating this organism from 19 patients on MacConkey Agar.⁴

PRINCIPLES OF THE PROCEDURE

This medium provides a variety of enzymatic digests of proteinaceous substrates, inorganic salts and other nutrients to satisfy the nutritional requirements of these organisms. In addition, selective agents are incorporated to improve the recovery of *B. cepacia* by inhibiting common contaminants. For example, polymyxin B inhibits gram-negative flora, while bacitracin inhibits the gram-positive organisms and *Neisseria*.⁴

OFPBL Agar contains the pH indicator bromthymol blue to facilitate detection of *B. cepacia*. Acid end products from the metabolism of lactose lower the pH of the medium resulting in a yellow color change. *B. cepacia* colonies will also have a yellow color.

REAGENTS

Formula

Approximate Formula* Per Liter Purified Water

Pancreatic Digest of Casein	2.0 g
Sodium Chloride	5.0 g
Dipotassium Phosphate	0.3 g
Agar	15.0 g
Bromthymol Blue	0.03 g
Lactose	10.0 g
Bacitracin	500 U
Polymyxin B	300,000 U

*Adjusted and/or supplemented as required to meet performance criteria.

Warnings and Precautions:

For *in vitro* Diagnostic Use.

If excessive moisture is observed, invert the bottom over an off-set lid and allow to air dry in order to prevent formation of a seal between the top and bottom of the plate during incubation.

Pathogenic microorganisms, including hepatitis viruses and Human Immunodeficiency Virus, may be present in clinical specimens. "Standard Precautions"⁶⁻⁹ and institutional guidelines should be followed in handling all items contaminated with blood and other body fluids. Prior to discarding, sterilize prepared plates, specimen containers and other contaminated materials by autoclaving.

Storage Instructions: On receipt, store plates in the dark at 2–8 °C. Avoid freezing and overheating. Do not open until ready to use. Minimize exposure to light. Prepared plates stored in their original sleeve wrapping at 2–8 °C until just prior to use may be inoculated up to the expiration date and incubated for recommended incubation times. Allow the medium to warm to room temperature before inoculation.

Product Deterioration: Do not use plates if they show evidence of microbial contamination, discoloration, drying, cracking or other signs of deterioration.

SPECIMEN COLLECTION AND HANDLING

Specimens include bronchoalveolar lavage fluid (preferred, but difficult to obtain), sputum, nasolaryngeal aspirates and oropharyngeal swabs.¹⁰

Refer to appropriate texts for details of specimen collection and handling procedures.^{11,12}

PROCEDURE

Material Provided: OFPBL Agar

Materials Required But Not Provided: Ancillary culture media, reagents, quality control organisms and laboratory equipment as required for this procedure.

Test Procedure: Observe aseptic techniques. The agar surface should be smooth and moist, but without excessive moisture.

Inoculate the medium as soon as possible after the specimen arrives at the laboratory. Inoculate by streaking the specimen over the medium with a sterile inoculating loop.

Incubate the plates in an inverted position (agar-side up) at 30–35 °C for a minimum of 4 days to allow sufficient time for colony development and for the color of the indicator to change.^{10,13}

User Quality Control:

1. Examine plates for signs of deterioration as described under "Product Deterioration."
2. Check performance by inoculating a representative sample of plates with pure cultures of stable control organisms that produce known, desired reactions. The following test strains are recommended:

TEST STRAIN	EXPECTED RESULT
<i>Burkholderia cepacia</i> ATCC® 25416	Growth; yellow colonies with yellow zones.
<i>Stenotrophomonas maltophilia</i> ATCC 13637	No growth to trace growth.
<i>Staphylococcus aureus</i> ATCC 25923	No growth to trace growth.

Quality control requirements must be performed in accordance with applicable local, state and/or federal regulations or accreditation requirements and your laboratory's standard Quality Control procedures. It is recommended that the user refer to pertinent CLSI guidance and CLIA regulations for appropriate Quality Control practices.

RESULTS

The plates should show isolated colonies in streaked areas and confluent growth in areas of heavy inoculation.

Typical colonies of *B. cepacia* on OFPBL Agar are yellow with yellow zones in the surrounding medium.

LIMITATIONS OF THE PROCEDURE

Other organisms, e.g., *B. gladioli*, may grow on OFPBL Agar and resemble *B. cepacia* (yellow colonies). Therefore, this medium should not be used as the sole method of identification of *B. cepacia*.¹⁴

For identification, the organism must be in pure culture. Morphological, biochemical and/or serological tests should be performed for final identification. Consult appropriate texts for detailed information and recommended procedures.^{1,15}

A single medium is rarely adequate for detecting all organisms of significance in a specimen. The agents in a selective medium may inhibit some strains of the desired species or permit growth of a species it was designed to inhibit, especially if the species is present in large numbers in the specimen. Specimens cultured on selective media should, therefore, also be cultured on nonselective media to obtain additional information and help ensure recovery of potential pathogens.

PERFORMANCE CHARACTERISTICS

B. cepacia was isolated on OFPBL Agar from 58 (8%) of 725 respiratory specimens collected from 428 cystic fibrosis patients. Most of the isolates were detected by 48 hours of incubation.⁴

AVAILABILITY

Cat. No.	Description
299970	BD BBL™ OFPBL Agar

REFERENCES

1. Gilligan, P.H. 1995. *Pseudomonas and Burkholderia*, p. 509-519. In P.R. Murray, E.J. Baron, M.A. Pfaller, F.C. Tenover, and R.H. Yolken (ed.), *Manual of clinical microbiology*, 6th ed. American Society for Microbiology, Washington, D.C.
2. Gilligan, P.H., P.A. Gage, L.M. Bradshaw, D.V. Schidlow, and B.T. DeCicco. 1985. Isolation medium for the recovery of *Pseudomonas cepacia* from respiratory secretions of patients with cystic fibrosis. *J. Clin. Microbiol.* 22:5-8.
3. Gilligan, P.H., and D.V. Schidlow. 1984. The role of *Pseudomonas cepacia* in pulmonary disease of cystic fibrosis patients. *Clin. Microbiol. News.* 6:42-44.
4. Welch, D.F., M.J. Muszynski, C.H. Pai, M.J. Marcon, M.M. Hribar, P.H. Gilligan, J.M. Matsen, P.A. Ahlin, B.C. Hilman, and S.A. Chartrand. 1987. Selective and differential medium for recovery of *Pseudomonas cepacia* from the respiratory tracts of patients with cystic fibrosis. *J. Clin. Microbiol.* 25:1730-1734.
5. Carson, L.A., O.C. Tablan, L.B. Cusick, W.R. Jarvis, M.S. Favero, and L.A. Bland. 1988. Comparative evaluation of selective media for isolation of *Pseudomonas cepacia* from cystic fibrosis patients and environmental sources. *J. Clin. Microbiol.* 26:2096-2100.
6. Clinical and Laboratory Standards Institute. 2005. Approved Guideline M29-A3. Protection of laboratory workers from occupationally acquired infections, 3rd ed. CLSI, Wayne, Pa.
7. Garner, J.S. 1996. Hospital Infection Control Practices Advisory Committee, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. Guideline for isolation precautions in hospitals. *Infect. Control Hospital Epidemiol.* 17:53-80.
8. U.S. Department of Health and Human Services. 1999. Biosafety in microbiological and biomedical laboratories, HHS Publication (CDC), 4th ed. U.S. Government Printing Office, Washington, D.C.
9. Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC). Official Journal L262, 17/10/2000, p. 0021-0045.
10. MacDonald, N., P. Gilligan, D. Welch, B. Reller, and M. Menegus. May 1994. Microbiology of cystic fibrosis. In Consensus conference: microbiology and infectious disease in cystic fibrosis, vol. 5 (sect. 1): 1-26. Cystic Fibrosis Foundation, Washington, D.C.
11. Isenberg, H.D. (ed.). 2004. Clinical microbiology procedures handbook, vol. 1, 2 and 3, 2nd ed. American Society for Microbiology, Washington, D.C.
12. Miller, J.M., H.T. Holmes and K. Krisher. 2003. General principles of specimen collection and handling, p. 55-66. In P.R. Murray, E.J. Baron, J.H. Jorgensen, M.A. Pfaller and R.H. Yolken (ed.), *Manual of clinical microbiology*, 8th ed. American Society for Microbiology, Washington, D.C.
13. Gilligan, P. 1996. Report on the consensus document for microbiology and infectious diseases in cystic fibrosis. *Clin. Microbiol. News.* 18:83-87.
14. Christenson, J.C., D.F. Welch, G. Mukwaya, M.J. Muszynski, R.E. Weaver, and D.J. Brenner. 1989. Recovery of *Pseudomonas gladioli* from respiratory tract specimens of patients with cystic fibrosis. *J. Clin. Microbiol.* 27:270-273.
15. Holt, J.G., N.R. Krieg, P.H.A. Sneath, J.T. Staley, and S.T. Williams (ed.). 1994. Bergey's Manual™ of determinative bacteriology, 9th ed. Williams & Wilkins, Baltimore.

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

 Becton, Dickinson and Company
7 Loveton Circle
Sparks, MD 21152 USA

 Benex Limited
Pottery Road, Dun Laoghaire
Co. Dublin, Ireland

ATCC is a trademark of the American Type Culture Collection.

© 2017 BD. BD, the BD Logo and BBL are trademarks of Becton, Dickinson and Company.

 Manufacturer / Производител / Výrobce / Fabrikant / Hersteller / Κατασκευαστής / Fabricante / Tootja / Fabricant / Proizvodča / Gyártó / Fabbricante / Аткарушы / 제조업체 / Gamintojas / Razotājs / Tilvirker / Producent / Producător / Производитель / Výrobcu / Proizvodač / Tillverkare / Üretici / Virobník / 生产厂商

 Use by / Использование до / Spotrebujte do / Brug før / Verwendbar bis / Χρόνιο έως / Usar antes de / Kasutada enne / Date de péremption / 사용 기한 / Upotrijebiti do / Felhasználhatóság dátuma / Usare entro / Дейній пайданура / Naudokite iki / Izletot līdz / Houdbaar tot / Brukes for / Stosowac do / Prazo da validade / A se utiliza pān la / Использовать до / Použíte do / Upotrebiti do / Använd före / Son kullanma tarifi / Використати дoLine / 使用截止日期 YYYY-MM-DD / YYYY-MM (MM = end of month)
ГГГГ-ММ-ДД / ГГГГ-ММ (ММ = края на месеца)
RRRR-MM-DD / RRRR-MM (MM = конец месіце)
AAAA-MM-DD / AAAA-MM (MM = slutning af måned)
JJJJ-MM-TT / JJJJ-MM (MM = Monatsende)
EEEE-MM-HH / EEEE-MM (MM = тέλος του μήνα)
AAAA-MM-DD / AAAA-MM (MM = fin del mes)
AAAA-KK-PP / AAAA-KK (KK = кuu lõpp)
AAAA-MM-JJ / AAAA-MM (MM = fin du mois)
GGGG-MM-DD / GGGG-MM (MM = kraj mjeseca)
ÉÉÉÉ-HH-NN / ÉÉÉÉ-HH (HH = hónap utolsó napja)
AAAA-MM-GG / AAAA-MM (MM = fine mese)
ЖЮЖОК-АА-КК / ЖЮЖОК-АА / (AA = айдын соңы)
YYYY-MM-DD/YYYY-MM (MM = 월말)
ММММ-MM-DD / ММММ-MM (MM = мінесінде рабаға)
GGGG-MM-DD/GGGG-MM (MM = мénéša beigas)
JJJJ-MM-DD / JJJJ-MM (MM = einde maand)
AAA-MM-DD / AAAA-MM (MM = slutteet av måneden)
RRRR-MM-DD / RRRR-MM (MM = koniec miesiąca)
AAAA-MM-DD / AAAA-MM (MM = fim do mês)
AAAA-LZ-ZZ / AAAA-LZ (LL = sāfārstūl lunii)
ГГГГ-ММ-ДД / ГГГГ-ММ (ММ = конец месяца)
RRRR-MM-DD / RRRR-MM (MM = koniec meseaca)
GGGG-MM-DD / GGGG-MM (MM = kraj meseca)
AAA-MM-DD / AAAA-MM (MM = slutet av månaden)
YYYY-AA-GG / YYYY-AA (AA = ayin sonu)
PPP-P-MM-DD / PPPP-MM (MM = кінець місяця)
YYYY-MM-DD / YYYY-MM (MM =月末)

 REF Catalog number / Каталожен номер / Katalogové číslo / Katalognummer / Αριθμός καταλόγου / Número do catálogo / Katalooginumero / Numero catalogue / Kataloški broj / Kataloguszám / Numero di catalogo / Katalanor nömrö / 카탈로그 번호 / Katalogo / numeris / Kataloga numerus / Catalogus numer / Numer katalogowy / Număr de catalog / Номер по каталогу / Katalogové číslo / Kataloški broj / Katalog numarası / Номер за каталогом / 目录号

 EC REP Authorized Representative in the European Community / Оторизиран представител в Европейската общност / Autorizovaný zástupce pro Evropském společenství / Autoriseret repræsentant i De Europæiske Fællesskaber / Autorisierte Vertreter in der Europäischen Gemeinschaft / Εξουπολιμένος αντιπρόσωπος στην Ευρωπαϊκή Κούνια / Representante autorizado en la Comunidad Europea / Volitatitud esindaja Euroopa Nõukogus / Reprézentant autorisé pour la Communauté européenne / Autorizuarani predstavnik u Europskoj uniji / Meghatalmazott képviselőt az Európai Közösségen / Rappresentante autorizzata nella Comunità Europea / Европейското съобщество / Autorizovaný zástupca v Evropském společenství / Autorizovaný zástupce v Evropské unii / Autoriseret representant i EU / Autoryzowane przedstawicielstwo we Wspólnocie Europejskiej / Representante autorizado na Comunidade Europeia / Reprézentantul autorizat pentru Comunitatea Europeană / Уполномоченный представитель в Европейском сообществе / Autorizovaný zástupca v Evropském společenství / Autorizovaný zástupce v Evropské unii / Autorisert representant i EU / Autorizzato rappresentante in Europa / Autorizovaný zástupce v Evropském společenství / Autorizovaný zástupce v Evropské unii / Autorisert representant i Europeiska gemenskapen / Avrupa Topluluğu Yetkilisi Temsilcisi / Упновованжений представник у краинах ЄС / 欧洲共同体授权代表

 IVD In Vitro Diagnostic Medical Device / Медицински уред за диагностика ин vitro / Lékařské zařízení určené pro diagnostiku in vitro / In vitro diagnostisk medicinsk anordning / Medizinisches In-vitro-Diagnostikum / In vitro διαγνωστική ιατρική συσκευή / Dispositivo médico para diagnóstico in vitro / In vitro diagnostika meditsinsiaparatuur / Dispositif médical de diagnostic in vitro / Medicinska pomagala za In Vitro Dijagnostiku / In vitro diagnosztikai orvosi eszköz / Dispositivo medicaile per diagnostica in vitro / Касанды жаддайда жүргізетін медициналық диагностика аспабы / In Vitro Diagnostic 의료 기기 / In vitro diagnostikos prietaisais / Medicinais ierīces, ko liet in vitro diagnostikā / Medisch hulpmiddel voor in-vitro diagnostiek / In vitro diagnostisk medisinsk utstyr / Urzadzenie medyczne do diagnostyki in vitro / Dispositivo médico para diagnóstico in vitro / Dispositivo medical pentru diagnostic in vitro / Медицинский прибор для диагностики in vitro / Medicinska pomôcka na diagnostiku in vitro / Medicinski uredaj za in vitro dijagnostiku / Medicinteknisk produkt för in vitro-diagnoskit / In Vitro Dijagnostik Cihazı / Медицински пристрой для диагностики in vitro / 体外診断医疗设备

 Temperature limitation / Температурни ограничения / Teplotní omezení / Temperaturbegrensning / Temperaturbegrenzung / Περιορισμό θερμοκρασίας / Limitación de temperatura / Temperaturi piirang / Limites de température / Dozvoljena temperatura / Hőmérsékleti határ / Limiti di temperatura / Температурны шектр / 온도 제한 / Laikymo temperatūra / Temperatūras ierobežojumi / Temperaturu limit / Temperaturbegrensning / Ograniczenie temperatury / Limites de temperatura / Limite de temperatură / Ограничение температуры / Ограничение теплоты / Ograničenje temperature / Temperaturgräns / Sicaklık sınırlaması / Обмеження температури / 温度限制

 LOT Batch Code (Lot) / Код на партидата / Kód (císlo) šarže / Batch-kode (lot) / Batch-Code (Charge) / Кодът към партидата (тагриб) / Código de lote (lote) / Partii kood / Numéro de lot / Lot (kod) / Tétel száma (Lot) / Codice batch (lotto) / Томтама коды / 배치 코드(로트) / Partijos numeris (LOT) / Partijas kods (laidiens) / Lot nummer / Batch-kode (parti) / Kod partii (seria) / Código do lote / Cod de serie (Lot) / Код партии (нор) / Kód série (šarža) / Kod serije / Partinummer (Lot) / Parti Kodu (Lot) / Код партии / 批号 (亚批)

 EC REP Consult Instructions for Use / Направете справка в инструкциите за употреба / Prostudiujte pokyny k použití / Se brugsanvisningen / Gebrauchsanweisung beachten / Συμβουλεύετε τις οδηγίες χρήσης / Consultar las instrucciones de uso / Lügeda kasutusjuhendit / Consulter le instructions d'emploi / Koristi upute za upotrebu / Olvassa el a használati utasítás / Consultare le istruzioni per l'uso / Пайдалану нұсқалысымен танысып алыңыз / 사용 지침 참조 / Skaitlykite naudojimo instrukcijas / Skaitlīt lietošanas pamācību / Raadpleeg de gebruiksaanwijzing / Se i bruksanvisningen / Zobacz instrukcję użytkowania / Consultar as instruções de utilização / Consultați instrucțiunile de utilizare / См. руководство по эксплуатации / Pozri Pokyny na používanie / Pogledajte uputstvo za upotrebu / Se bruksanvisningen / Kullanım Talimatları'na başvurun / Див. інструкції з використання / 请参阅使用说明