

Part Number:	8800781JAA	BALTSO0191 Version 13.0 Template 4 Inserts	
Category and Description: Package Insert, BD BBL™ GasPak™ Anaerobic Systems	Rev from: 01 Rev to: 02		
	Job Number: 579-18		

Catalog Number: 260626, 260627, 260628, 260629

Blank (Sheet) Size: Length: 10 7/8" Width: 15 3/8"

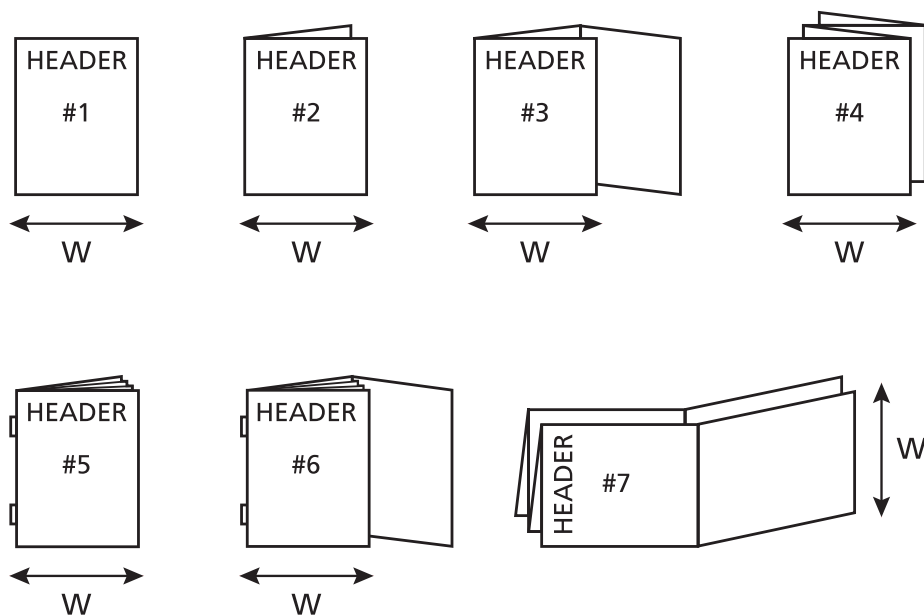
Number of Pages: 1 page; 8 panels Number of Sheets: 1

Page Size: Length: 10 7/8" Width: 15 3/8" Final Folded Size: 5 7/16" L X 3 7/8" W

Ink Colors: Number of Colors: 1 PMS #: Standard Black

Printed Two Sides: Yes: ☒ No: ☐

Style (see illustrations below): # 4



Vendor Printed: ☒ Online / In House Printed: ☐ Web Printed: ☐

See Specification control no. VS-88-0078-1PR for material information.



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

Company confidential. This document is the property of Becton, Dickinson and Company and is not to be used outside the company without written permission. Graphics are approved by Becton, Dickinson and Company. Supplier has the responsibility for using the most current approved revision level.

Revised By: **REVISED BY**
By Maria Zacharias at 5:13 pm, Sep 21, 2018

Proofing
Approved By: **PROOFING APPROVED BY**
By Natalie Morio at 11:35 am, Sep 25, 2018

Third Eye By: **THIRD EYE BY**
By Nichole Graham at 3:23 pm, Sep 25, 2018

INTENDED USE

BD BBL™ GasPak™ systems are multiple-use, self-contained systems that produce atmospheres suitable to support the primary isolation and cultivation of anaerobic or microaerophilic bacteria by use of gas-generating envelopes or, alternatively, externally introduced gases.¹⁻³

SUMMARY AND EXPLANATION

Prior to the mid-1960s, routine isolation and cultivation of anaerobes from clinical and other specimens was handicapped by the cumbersome methods necessary to achieve anaerobiosis in anaerobic jars.

The performance of anaerobic bacteriology as a routine laboratory procedure was greatly facilitated when, in 1966, Brewer and Allgeier introduced a disposable hydrogen generator envelope and a self-contained anaerobic system which eliminated the requirement for gas cylinders, vacuum pumps and other external equipment.⁴

The BD BBL GasPak 100 jar with rack holds up to 12, 100 x 15 mm-style Petri dishes. The BD BBL GasPak 150 jar with rack holds up to 36, 100 x 15 mm Petri dishes; the jar alone will hold 12, 150 x 15 mm-style dishes.

BD BBL GasPak Plus and BD CampyPak™ Plus are disposable hydrogen and carbon dioxide generator envelopes with integral catalyst, which eliminates the requirement for catalyst pellets in the reaction chambers of BD BBL GasPak systems when these envelopes are used.

PRINCIPLES OF THE PROCEDURE

The BD BBL GasPak anaerobic system, vented, combines the flexibility of an evacuation-replacement system using tank gasses with the safety of a room temperature catalyst. The system may also be used with the BD BBL GasPak Plus and BD CampyPak Plus hydrogen and carbon dioxide generator envelopes by closing the vent.

PRODUCT DESCRIPTION

Each BD BBL GasPak 100 Anaerobic System (260626 and 260627) contains:

- One Jar, polycarbonate, 2.5 L – Cat. No. 260463,
- One Lid, non-vented with O-ring Gasket – Cat. No. 260637,
- or vented with O-ring Gasket – Cat. No. 260638,
- One Clamp and Clamp Screw – Cat. No. 260414,
- One Wire Rack – Cat. No. 260619,
- One Tube Holder – Cat. No. 260630,
- One Rubber Tubing and Tubing Clamp (260627 only).

Each BD BBL GasPak 150 Anaerobic System (260628 and 260629) contains:

- One Jar, polycarbonate, non-vented – Cat. No. 260607,
- or vented – Cat. No. 260608,
- One Outer Lid with Thumbscrew – Cat. No. 271031,
- One Inner Lid with O-ring Gasket – Cat. No. 270124,
- One Wire Rack – Cat. No. 260618,
- One Tube Holder – Cat. No. 260630,
- One Rubber Tubing and Tubing Clamp (260629 only).

Warnings and Precautions: For Laboratory Use

Hydrogen is a flammable gas. A mixture of hydrogen with oxygen or air in a confined area will explode if ignited by a spark, flame, or other source of ignition. All usual precautions attendant to handling hydrogen gas should be observed when employing BD BBL GasPak Plus hydrogen plus carbon dioxide generator envelopes or BD CampyPak Plus envelopes. The historical incidence rate of reported hydrogen gas ignition is approximately two (2) incidents per million envelopes.

Do not use envelopes if there is evidence of premature activation, which may cause the package to appear bloated.

BD BBL GasPak Plus hydrogen and carbon dioxide envelopes, and BD CampyPak Plus hydrogen and carbon dioxide envelopes, are intended for use in properly maintained and operated BD BBL GasPak 100 jars and BD BBL GasPak 150 jars. Their use in other systems may yield misleading results and may even be hazardous to laboratory personnel. For satisfactory and safe use, carefully follow the instructions provided with each system.

ANY UNSATISFACTORY ENVELOPE MUST BE CUT OPEN AND EXAMINED FOR INTACT OR PARTIALLY INTACT TABLETS. ANY REMAINING TABLETS SHOULD BE PLACED IN A CONVENIENT SINK AND DISSOLVED IN FLOWING WATER. DO NOT DISCARD INTACT ENVELOPES.

Product Deterioration: Do not use BD BBL GasPak lids, clamps and jars that show cracks, chips, split O-ring grooves, or other irregularities.

PROCEDURE

Material Provided: BD BBL GasPak Anaerobic System – Cat. Nos. 260626, 260627, 260628 or 260629.

Materials Required But Not Provided:

- BD BBL GasPak Plus hydrogen and carbon dioxide envelopes – Cat. Nos. 271040 and 271041.
- BD CampyPak Plus hydrogen and carbon dioxide envelope – Cat. No. 271045.
- BD BBL GasPak Anaerobic Indicator – Cat. No. 271051.
- Pipette, 10 mL, or syringe.
- Materials required for operation of a vented system; manometer, gas source and vacuum source.

Test Procedure

BD BBL GasPak 100 and BD BBL GasPak 150 Anaerobic Systems

- The use of catalyst pellets is not required when using BD BBL GasPak Plus (271040) or BD CampyPak Plus (271045) envelopes.
- Place inoculated plates or tubes in the appropriate BD BBL GasPak 100 or BD BBL GasPak 150 rack. When using either the BD BBL GasPak Plus or BD CampyPak Plus envelope cut off the corner of the envelope and place behind the shielded clip of the rack with the printed side facing the *inside* of the jar (catalyst sachet toward the outside). One envelope is to be used in each BD BBL GasPak 100 system and three envelopes are to be used in each BD BBL GasPak 150 system. **Do not crease, fold or crush the envelope(s).**
- When using BD BBL GasPak Plus envelopes always use an anaerobic indicator (Cat. No. 271051). Place indicator strip in center of metal indicator holder (see Fig. 1,A) with indicator pad upright. Place the rack in the BD BBL GasPak jar. (**Note:** No indicator clip is available on the 150 rack.)

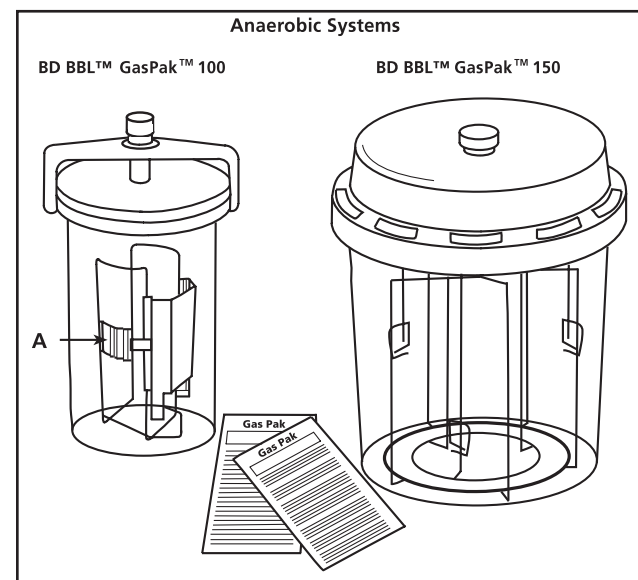


Figure 1

- Add 10 mL of tap, distilled or deionized water through the open/cut corner of the envelope. Use a pipette or syringe inserting only the tip into the open corner. **Never push any object down into the envelope.**
- Close the BD BBL GasPak jar promptly after activation and *finger tighten only* the BD BBL GasPak 100 lid clamp or BD BBL GasPak 150 lid assembly.
- Incubate at conditions appropriate for the organisms being cultured.
- Periodically during incubation, observe that the indicator is decolorized.
- After use, jar should be opened and allowed to aerate for approximately 15 s *prior* to removing rack and its contents so as to achieve atmosphere equilibration.

BD BBL GasPak Vented Set-up

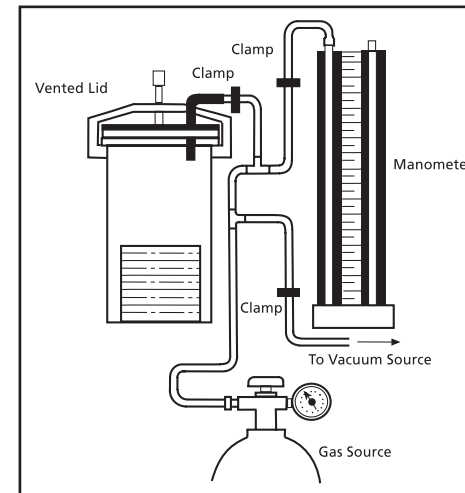


Figure 2

Evacuation-Replacement Procedure for BD BBL GasPak 100 and BD BBL GasPak 150 Systems, Vented

- Place inoculated plates or tubes (in tube holders) in the appropriate BD BBL GasPak 100 or BD BBL GasPak 150 rack.
- Place an anaerobic indicator in rack as described in Fig. 1 for BD BBL GasPak 100 and BD BBL GasPak 150 Anaerobic Systems, step 3. If using Dry Anaerobic Indicator Strips, dip indicator pad in water before placing in rack. Place the rack in the GasPak jar.
- Close the GasPak jar and *finger tighten only* the BD BBL GasPak 100 lid clamp or the BD BBL GasPak 150 lid assembly.
- Attach a short rubber tube on the vent of the BD BBL GasPak 100 lid or the BD BBL GasPak 150 jar to multiple stopcock or plug (Fig. 2). Outlets are needed for a manometer, gas source (hydrogen, nitrogen, methane, carbon dioxide, or a mixture of hydrogen plus carbon dioxide), and a vacuum source.
- Close the valve on the gas source. Open clamps to the vacuum source, the manometer, and the lid vent. Evacuate the jar with a vacuum pump to approximately 700 mm of mercury.
- Close the clamp to the vacuum source and open the valve on the gas source. Fill the jar to atmospheric pressure with desired gas. Always exercise caution when using combustible gases.
- Evacuate and fill the jar three times or more.
- Incubate at conditions appropriate for the organisms being cultured.
- Periodically during incubation, observe that the indicator is decolorized.
- After use, jar should be opened and allowed to aerate for approximately 15 s *prior* to removing rack and its contents so as to achieve atmosphere equilibration.

NOTE: The BD BBL GasPak 100 and BD BBL GasPak 150 Anaerobic Systems, Vented, may also be used with the BD BBL GasPak Plus or BD CampyPak Plus hydrogen and carbon dioxide generator envelope. This eliminates the need for external connections. Prior to use, close the vent clamp and follow directions for use for the BD BBL GasPak Anaerobic System.

Maintenance Recommendations:

Jar and Lid

Both the jar and lid assembly of the BD BBL GasPak 100 and BD BBL GasPak 150 system are designed to provide long, trouble-free life with a minimum of care. Proper care consists of the following:

- Avoid contact with abrasives.
- Avoid contact with solvents and detergents.
- Rinse and dry thoroughly after cleaning with a mild detergent.
- Never** autoclave jar or lid.

Rack and Tube Holder

The BD BBL GasPak 100 and BD BBL GasPak 150 racks are constructed of stainless steel and may be autoclaved.

The tube holder is autoclavable. It may be washed with mild soap and rinsed thoroughly after washing. Drainage holes are located at the bottom of the unit. **Note:** contact with solvents, disinfectants and detergents will craze the polycarbonate.

The Polycarbonate Lid Assembly (BD BBL GasPak 150 System)

The large capacity jar includes a two piece lid for positive locking and sealing. The lid serves as a carrier for the catalyst reaction chambers and has a recessed crown to permit stacking of jars if desired. The polycarbonate lid consists of an outer lid and thumbscrew, and an inner lid with an O-ring gasket and three double-screened reaction chambers (See Figs. 3a and 3b).

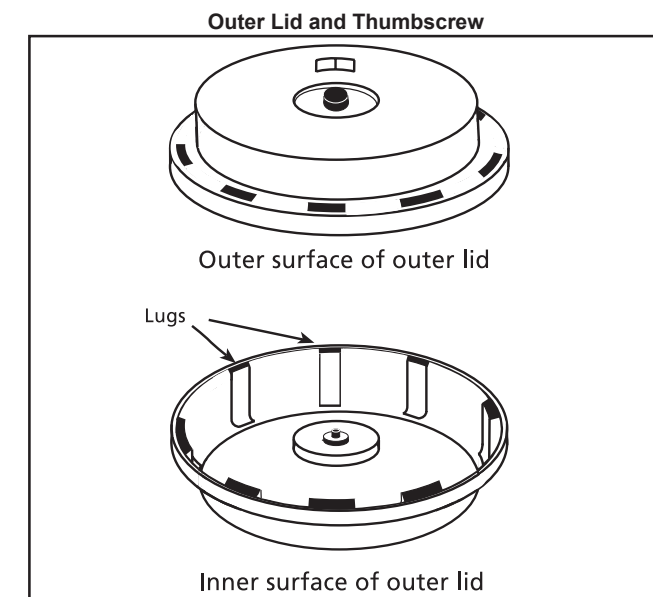


Figure 3a

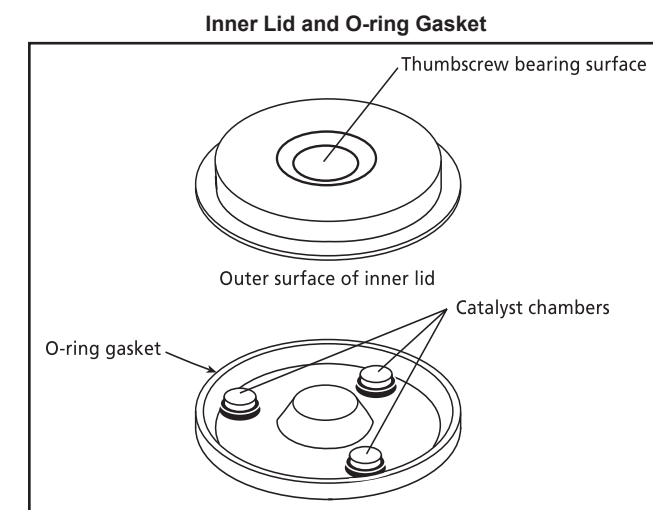


Figure 3b

User Quality Control:

- Each BD BBL GasPak system should be tested periodically for its ability to provide adequate conditions for the growth of appropriate bacteria.
- If visible condensation does not occur within 60 min after a BD BBL GasPak Plus, or BD CampyPak Plus envelope is activated, the reaction should be terminated by opening the system. Check the condition of the BD BBL GasPak 100 or BD BBL GasPak 150 lid and O-ring gasket as described below.
- The following quality control checklist, if followed regularly, will help assure proper performance:
 - The BD BBL GasPak system should be maintained upright at all times while in operation.
 - Gas generating envelopes must be kept upright and cut along the dotted line at the upper right hand corner, as indicated on each envelope. The gas-generating tablets must be present and not displaced or crushed, and the foil channels and reaction chambers must not be crushed or distorted and must be able to accept 10 mL of water. Improper positioning of the envelope or use of a damaged envelope may lead to imbalances in reactivity. Damage may result in spattering and “boiling over” of the contents of the envelope and hence inadequate gas output.
 - Plastic lid and clamp – Inspect for cracks, chips, split O-ring grooves, and other irregularities. Most cracks (craze or stress lines) develop on prolonged use and forced or excessive tightening of clamps on lids. Early cracks may appear as fine black lines near the center of the lid, or along the upper edges of the BD BBL GasPak 100 clamp near the screw. Cracked lids and clamps which exhibit these fine black lines should not be used.
 - O-ring gasket – Examine for cracks, bumps, dirt, and improper seating in the O-ring groove. Examine O-ring groove wall for splitting or cracking. The O-ring must be resilient, clean and snugly retained within the O-ring groove for satisfactory operation of the system. Replace as necessary.

RESULTS

Anaerobic conditions are achieved rapidly, generally reaching a redox potential of –100mV within 1 h and –200 mV within 2 h in media of pH 7.0 at room temperature. Within 1 h of incubation at 35 °C, the carbon dioxide concentration is approximately 4 to 10%. At 35 °C anaerobic indicator Cat. No. 271051 becomes decolorized within 9 h.

AVAILABILITY

Cat. No.	Description
260626	BD BBL™ GasPak™ 100 Anaerobic System
260627	BD BBL™ GasPak™ 100 Anaerobic System, Vented
260628	BD BBL™ GasPak™ 150 Anaerobic System
260629	BD BBL™ GasPak™ 150 Anaerobic System, Vented

REFERENCES

- Murray, P.R., and D.M. Citron. 1991. General processing of specimens for anaerobic bacteria, p. 488-504. *In* A. Balows, W.J. Hausler, Jr., K.L. Hermann, H.D. Isenberg, and H.J. Shadomy (ed.), Manual of clinical microbiology, 5th ed. American Society for Microbiology, Washington, D.C.
- Penner, J.L. 1991. *Campylobacter*, *Helicobacter*, and related spiral bacteria, p. 402-409. *In* A. Balows, W.J. Hausler, Jr., K.L. Hermann, H.D. Isenberg, and H.J. Shadomy (ed.), Manual of clinical microbiology, 5th ed. American Society for Microbiology, Washington, D.C.
- Morello, J.A., W.M. Janda, and G.V. Doern. 1991. *Neisseria* and *Branhamella*, p. 258-276. *In* A. Balows, W.J. Hausler, Jr., K.L. Hermann, H.D. Isenberg, and H.J. Shadomy (ed.), Manual of clinical microbiology, 5th ed. American Society for Microbiology, Washington, D.C.
- Brewer, J.H., and D.L. Allgeier. 1965. Disposable hydrogen generator. *Science* **147**:1033–1034.

	Manufacturer / Производител / Výrobce / Fabrikant / Hersteller / Κατασκευαστής / Fabricante / Tootja / Fabricant / Produčad / Gyártó / Fabricante / Аткарушы / 제조업체 / Gamintojas / Ražotājs / Tilvirker / Proizvod / Produčtor / Производителъ / Výrobca / Proizvođač / Tilverkare / Üretici / Виробник / 生产厂商
	Use by / Използвайте до / Spotføjbedt do / Brug før / Verwendbar bis / Χρήση έως / Usar antes de / Kasutada enne / Date de péremption / 사용 기한 / Upotrijebiti do / Felhasználhatóság dátuma / Usare entro / Дейн пайдаланура / Naudokite iki / Izlietot līdz / Houdbaar tot / Brukes for / Stosować do / Prazo de validade / A se utiliza până la / Исползовать до / Použít do / Upotrebiti do / Använd före / Son kullanna tanhi / Використати доline / 使用截止日期 YYYY-MM-DD / YYYY-MM (MM = end of month) ГГТТ-ММ-ДД / ГГТТ-ММ (ММ = края на месеца) RRRR-MM-DD / RRRR-MM (ММ = koniec miesiąca) AAAA-MM-DD / AAAA-MM (PDM = sluiting af måned) JJJJ-MM-TT / JJJJ-MM (MM = Monatsende) EEEE-MM-HH / EEEE-MM (MM = τέλος του μήνα) AAAA-MM-DD / AAAA-MM (MM = fin del mes) AAAA-KK-PP / AAAA-KK (KK = kuu lõpp) AAAA-MM-JJ / AAAA-MM (MM = fin du mois) GGGG-MM-DD / GGGG-MM (MM = kraj mjeseca) EEEE-HH-NN / EEEE-HH (HH = hónap utolsó napja) AAAA-MM-GG / AAAA-MM (MM = fine mese) ЖОЖОЖ-АА-КК / ЖОЖОЖ-АА / (АА = айдың соңы) YYYY-MM-DD/YYYY-MM(MM = 월말) MMMM-MM-DD / MMMM-MM (MM = mêseno pabaiga) GGGG-MM-DD/GGGG-MM (MM = mêsena beigas) JJJJ-MM-DD / JJJJ-MM (MM = einde maand) AAAA-MM-DD / AAAA-MM (MM = sluttten av måneden) RRRR-MM-DD / RRRR-MM (MM = koniec miesiaca) AAAA-MM-DD / AAAA-MM (MM = fim do mês) AAAA-LL-ZZ / AAAA-LL (LL = sfârşitul lunii) ГГТТ-ММ-ДД / ГГТТ-ММ (ММ = концу месяца) RRRR-MM-DD / RRRR-MM (MM = koniec miesiaca) GGGG-MM-DD / GGGG-MM (MM = kraj meseca) AAAA-MM-DD / AAAA-MM (MM = slutet av månaden) YYYY-AA-GG / YYYY-AA (AA = ayın sonu) PPPP-MM-ДД / PPPP-MM (MM = кінець місяця) YYYY-MM-DD / YYYY-MM (MM = 月末)
	Catalog number / Каталоген номер / Katalogové číslo / Katalognummer / Αριθμός καταλόγου / Número de catálogo / Katalognummer / Numéro catalogue / Kataloški broj / Katalogszám / Numero di catalogo / Каталог нөмірі / 카탈로그 번호 / Katalogo / numeris / Kataloga numurs / Catalogous number / Numer katalogowy / Număr de catalog / Номер по каталогу / Katalogové číslo / Kataloški broj / Katalog numarası / Номер за каталогом / 目録号
	Authorized Representative in the European Community / Оторизиран представител в Европейската общност / Autorizovaný zástupce pro Evropském společenství / Autoriseret representant i De Europæiske Fællesskaber / Autorisierter Vertreter in der Europäischen Gemeinschaft / Εξουσιοδοτημένος αντιπρόσωπος στην Ευρωπαϊκή Κοινότητα / Representante autorizado en la Comunidad Europea / Volitatud esindaja Euroopa Nõukogus / Représentant autorisé pour la Communauté européenne / Autorizuirani predstavnik u Evropskoj uniji / Meghatalmazott képviselő az Európai Közösségekben / Rappresentante autorizzato nella Comunità Europea / Еуропа қауымдастығындағы уәкілетті екіл / 유럽 공동체의 위임 대표 / Igaliotasis atstovas Europos Bendrijoje / Pilnvarotais pārstāvis Krievijas Kopienā / Bevoegde vertegenwoordiger in de Europese Gemeenschap / Autoriseret representant i EU / Autoryzowane przedstawicielstwo we Wspólnocie Europejskiej / Representante autorizado na Comunidade Europeia / Reprezentantul autorizat pentru Comunitatea Europeană / Уполномоченный представитель в Европейском сообществе / Autorizovaný zástupca v Európskom spoločenstve / Autorizovano predstavnístvo u Evropskoj uniji / Auktoriserad representant i Europeiska gemenskapen / Avnrupa Topiluluğu Yetkili Temsilcisi / Уповноважений представник у країнах ЄС / 欧洲共同体授权代表
	In Vitro Diagnostic Medical Device / Медициньски уред за диагностика ин витро / Lékařské zařízení určené pro diagnostiku in vitro / In vitro diagnostisk medicinsk anordning / Medizinisches In-vitro-Diagnostikum / In vitro diaγvayntikí iatpikí soueirgē / Dispositivo médico para diagnóstico in vitro / In vitro diagnostiska meditsiiniparatuur / Dispositif médical de diagnostic in vitro / Medicinska pomagala za In Vitro Diagnostiku / In vitro diagnostizkaí ovnosi eszköz / Dispositivo medicale pro diagnostica in vitro / Жасанды жағдайда жүзегізілетін медициналық диагностика аспабы / In Vitro Diagnostic 의뢰 기기 / In vitro diagnostikos prietaisai / Medicinas ierices, ko lieto in vitro diagnostikā / Medisch hulpmiddel voor in-vitro diagnostiek / In vitro diagnostisk medisinsk utstyr / Urządzenie medyczne do diagnostyki in vitro / Dispositivo médico para diagnóstico in vitro / Dispozitiv medical pentru diagnostic in vitro / Медицинский прибор для диагностики ин витро / Medicinska pomôcka na diagnostiku in vitro / Medicinski uređaj za in vitro dijagnostiku / Medicinteknisk produkt för in vitro-diagnostik / In Vitro Diyagnostik Tibbi Cihaz / Медицин пристрій для діагностики ин витро / 体外诊断医疗设备
	Temperature limitation / Температурини ограничения / Teplotní omezení / Temperaturbegrænsning / Temperaturbegrenzung / Περιορισμός θερμοκρασίας / Limitación de temperatura / Temperaturi pirang / Limites de température / Dozvoljena temperatura / Hőmérsékleti határ / Limiti di temperatura / Температураны шектеу / 온도 제한 / Laikymo temperatūra / Temperatūras ierobežojumi / Temperaturulimiet / Temperaturbegrensning / Organizenie temperatury / Limites de temperatura / Limite de temperatură / Органічення температури / Ohraničenie teploty / Ograničenje temperature / Temperaturgräns / Sicaklık sınırlaması / Обмеження температури / 温度限制
	Batch Code (Lot) / Код на партидата / Kód (číslo) šarže / Batch-kode (lot) / Batch-Code (Charge) / Κωδικός παρτίδας (παρτίδα) / Código de lote (lote) / Partii kood / Numéro de lot / Lot (kod) / Tétel száma (Lot) / Codice batch (lotto) / Топтама 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 (лот) / Kód série (šarža) / Kod serije / Partinummer (Lot) / Parti Kodu (Lot) / Код партії / 批号 (分批)
	Contains sufficient for <n> tests / Съдържанието е достатъчно за <n> теста / Dostatečné množství pro <n> testů / Ineholder tilstrækkeligt til <n> tests / Ausreichend für <n> Tests / Περιέχει επαρκή ποσότητα για <n> εξετάσεις / Contenido suficiente para <n> pruebas / Kullaldane <n> testide jaoks / Contenu suffisant pour <n> tests / Sadržaj za <n> testova / <n> teszthez elegendő / Contenuto sufficiente per <n> test / <n> тесттері үшін жеткілікті / <n> 테스트가 충분히 포함됨 / Pakankamas kiekis atlikti <n> testų / Satur pietiekami <n> pārbaudēm / Inhoud voldoende voor "n" testen / Innholder tilstrækkelig til <n> tester / Zawiera ilość wystarczającą do <n> testów / Conteúdo suficiente para <n> testes / Conținut suficient pentru <n> teste / Достаточно для <n> тестов(a) / Obsah vystačí na <n> testov / Sadržaj dovoljan za <n> testova / Innehåller tillräckligt för <n> analyser / <n> test için yeterli maldeme içerir / Вистачить для аналізів: <n> / 足够进行 <n> 次检测
	Consult Instructions for Use / Направете справка в инструкциите за употреба / Prostudujte pokyny k použití / Se brugsanvisningen / Gebrauchsanweisung beachten / Στιούβουλεύεστε τις οδηγίες χρήσης / Consultar las instrucciones de uso / Lugeda kasutusjuhendit / Consulter la notice d'emploi / Koristi upute za upotrebu / Olvassa el a használati utasítást / Consultare le istruzioni per l'uso / Пайдалану нұсқаулығымен танысуға алыңыз / 사용 지침 참조 / Skaitykite naudojimo instrukcijas / Skatīt lietošanas pamācību / Raadpleeg de gebruiksaanwijzing / Se i bruksanvisningen / Zobacz instrukcja użytkowania / Consultar as instruções de utilização / Consultăți instrucțiunile de utilizare / См. руководство по эксплуатации / Pozri Pokyny na používanie / Pogledajte uputstvo za upotrebu / Se bruksanvisningen / Kullanim Talimatları'na başvurun / Див. інструкції за використання / 请参阅使用说明

	Do not reuse / Не използвайте отново / Nepoužívejte opakovaně / Ikke til genbrug / Nicht wiederverwenden / Μην επαναχρησιμοποιείτε / No reutilizar / Mitte kasutada korduvalt / Ne pas réutiliser / Ne koristiti ponovo / Egyyszer használatos / Non riutilizzare / Παιδιδаланбаньы / 재사용 금지 / Tik vienkartiniam naudojimui / Nelietot atkārtoti / Niet opnieuw gebruiken / Kun til engangsbruk / Nie stosować powtórnie / Nău reutilize / Nu refolosiți / He isponzovať повторно / Nepoužívať opakovaně / Ne upotrebljavajte ponovo / Får ej återanvändas / Tekrar kullannayin / Не використовувати повторно / 请勿重复使用
	Serial number / Серийн номер / Sériové číslo / Seriennummer / Seriennummer / Σειριακός αριθμός / N° de série / Seerianumber / Número de série / Senjski broj / Sorozatszám / Numero di serie / Топтамалық нөмірі / 일련 번호 / Senjios numeris / Senjias nummers / Serie number / Numer serjynj / Número de série / Număr de serie / Серийный номер / Serí numarası / Номер серії / 序列号
	For IVD Performance evaluation only / Само за оценка качеството на работа на IVD / Pouze pro vyhodnocení výkonu IVD / Kun til evaluering af IVD ydelse / Nur für IVD-Leistungsbewertungszwecke / Μόνο για αξιολόγηση απόδοσης IVD / Sólo para la evaluación del rendimiento en diagnóstico in vitro / Ainult IVD seadme hindamiseks / Réservé à l'évaluation des performances IVD / Samo u znanstvene svrhe za In Vitro Diagnostiku / Kizárólag in vitro diagnosztikához / Solo per valutazione delle prestazioni IVD / Жасаңды жағдайда «пробирка ішінде» диагностикада тек жұмысты бағалау үшін / IVD 성능 평가에 대해서만 사용 / Tik IVD prietaisų veikimo charakteristikoms tikrinti / Vienigi IVD darbinas patvirtėšanai / Uitsluitend voor doeltreffendheidsonderzoek / Kun for evaluering av IVD-ytelse / Tylko do oceny wydajności IVD / Uso esclusivo para avaliação de IVD / Numai pentru evaluarea performanței IVD / Только для оценки качества диагностики ин витро / Určenie iba na diagnostiku in vitro / Samo za procenu učinka u in vitro diagnostici / Endast för utvärdering av diagnostisk användning in vitro / Yalnızca IVD Performans değerlendirmesi için / Тільки для оцінювання якості діагностики ин витро / 仅限 IVD 性能评估
	For US: “For Investigational Use Only”
	Lower limit of temperature / Долен лимит на температурата / Dolní hranice teploty / Nedre temperaturgrænse / Temperaturuntergrenze / Κατώτερο όριο θερμοκρασίας / Limite inferior de temperatura / Alumine temperatuuripiir / Limite inférieure de température / Najniža dozvoljena temperatura / Alsó hőmérsékleti határ / Limite inferiore di temperatura / Temperatuurən çemənı ruqsat şeri / 하한 온도 / Žemiausia laikymo temperatūra / Temperatūras zemākā robeža / Laagste temperatuurlimiet / Nedre temperaturgrænse / Dolna granica temperatury / Limite minimo de temperatura / Limită minimă de temperatură / Нижний предел температуры / Spodná hranica teploty / Donja granica temperature / Nedre temperaturgräns / Sicaklık alt sınırı / Мінімальна температура / 温度下限
	Control / Контролно / Kontrola / Kontrol / Kontrolle / Μάρτυρας / Kontroll / Contrôle / Controlo / Бақылай / 컨트롤 / Kontrolė / Kontrol / Kontrolle / Kontrol / Kontrol / Kontrol / Kontrol / 对照
	Positive control / Положителен контрол / Pozitivní kontrola / Positiv kontrol / Positive Kontrolle / Θετικός μάρτυρας / Control positivo / Positivne kontrol / Contrôle positif / Pozitivna kontrola / Pozitiv kontrol / Controllo positivo / Он бақылай / Yangsej 컨트롤 / Teigiama kontrolė / Pozitiv kontrolle / Positiveve controle / Kontrola dodatnia / Controllo positivo / Control pozitiv / Положительный контроль / Pozitif kontrol / Позитивний контроль / 阳性对照试剂
	Negative control / Отрицателен контрол / Negativní kontrola / Negativ kontrol / Negative Kontrolle / Αρνητικός μάρτυρας / Control negativo / Negativeve kontrol / Contrôle négatif / Negativna kontrola / Negativ kontrol / Controllo negativo / Негативтік бақылай / 음성 컨트롤 / Neigiama kontrolė / Negativá kontrolle / Negativeve controle / Kontrola ujemna / Controllo negativo / Control negativ / Отрицательный контроль / Negatif kontrol / Негативний контроль / 阴性对照试剂
	Method of sterilization: ethylene oxide / Метод на стерилизация: етиленов оксид / Způsob sterilizace: etylenoxid / Steriliseringsmetode: ethylenoxid / Sterilisationsmethode: Ethylenoxid / Μέθοδος αποστείρωσης: αιθυλένοξείδιο / Método de esterilización: óxido de etileno / Steriliseerimismeetod: etüleenoksiid / Méthode de stérilisation: oxyde d'éthylène / Metoda sterilizacije: etilen oksid / Sterilizálás módszere: etilén-oxid / Metodo di sterilizzazione: ossido di etilene / Sterilizacija adici – etilen tosyna / 소독 방법: 에틸렌옥사이드 / Sterilizavimo būdas: etileno oksidas / Sterilizšanas metode: etilēnoksīds / Gesteriliseerd met behulp van ethyleenoxide / Steriliseringsmetode: etylenoksid / Metoda sterylizacji: tlenek etylu / Método de esterilização: óxido de etileno / Metodă de sterilizare: oxid de etilenă / Метод стерилизации: этиленоксид / Metodă sterilizácie: etylénoxid / Metoda sterilizacije: etilen oksid / Steriliseringsmetod: etenoxid / Sterilizasyon yöntemi: etilen oksit / Метод стерилизації: етиленоксидом / 灭菌方法: 环氧乙烷
	Method of sterilization: irradiation / Метод на стерилизация: ирадиация / Způsob sterilizace: záření / Steriliseringsmetode: bestråling / Sterilisationsmethode: Bestrahlung / Μέθοδος αποστείρωσης: ακτινοβολία / Método de esterilización: irradiación / Steriliseerimismeetod: kiirgus / Méthode de stérilisation: irradiation / Metoda sterilizacije: zračenje / Sterilizálás módszere: besugárzás / Metodo di sterilizzazione: irradiazione / Sterilizacija adici – sąuyle tyrcipy / 소독 방법: 방사 / Sterilizavimo būdas: radiacija / Sterilizšanas metode: apstarošana / Gesteriliseerd met behulp van bestraling / Steriliseringsmetode: bestråling / Metoda sterylizacji: napromienianie / Método de esterilización: irradiación / Metodă de sterilizare: iradiere / Метод стерилизации: облучение / Metodă sterilizácie: ožiarenie / Metoda sterilizacije: ozračavanje / Steriliseringsmetod: strålning / Sterilizasyon yöntemi: ırdıyasyon / Метод стерилизації: опромінняням / 灭菌方法: 辐射
	Biological Risks / Биологични рискове / Biologická rizika / Biologisk fare / Biogefährdung / Βιολογικοί κίνδυνοι / Riesgos biológicos / Biologilised riskid / Risques biologiques / Biološki rizici / Biológiai veszélyes / Rischio biologico / Биологялык төуекелдер / 생물학적 위험 / Biologinis pavojus / Biologiskie risko / Biologisk risiko / Zagrożenia biologiczne / Perigo biológico / Riscuiri biologice / Биологическая опасность / Biologické riziko / Biološki rizici / Biologisk risk / Biyolojik Riskler / Bioloģina nebezpekā / 生物学风险
	Caution, consult accompanying documents / Внимание, направете справка в придружаващите документи / Pozor! Prostudujte si příloženou dokumentaci! / Forsigtig, se ledsagende dokumenter / Achtung, Begleitdokumente beachten / Προσοχή, συμβουλευτείτε τα συνοδευτικά έγγραφα / Precaución, consultar la documentación adjunta / Ettevaatus! Lugeda kaasnevat dokumentatsiooni / Attention, consulter les documents joints / Upozoreenje, koristi prateću dokumentaciju / Figyelem! Olvassa el a mellékelt tájékoztató! / Attenzione: consultare la documentazione allegata / Абайлаңыз, тиісті құжаттармен танысуңыз / 주의, 동봉된 설명서 참조 / Dėmesio, žiūrėkite pridėdamas dokumentus / Piesardzība, skatīt pavaddokumentus / Voorzichtig, raadpleeg bijgevoegde documenten / Cuidadit, se vedlagt dokumentasjon / Należy zapoznać się z dołączonymi dokumentami / Cuidado, consulte a documentação fornecida / Atenție, consultați documentele însoțitoare / Внимание: см. прилагаемую документацию / Výstraha, pozri sprievodné dokumenty / Pažnja! Pogledajte priložena dokumenta / Obs! Se medföljande dokumentation / Dikkat, bitkike verilien belgelere basyurun / Увага: див. супутню документацию / 小心, 请参阅附带文档
	Upper limit of temperature / Горен лимит на температурата / Horní hranice teploty / Øvre temperaturgrænse / Temperaturobergrenze / Ανώτερο όριο θερμοκρασίας / Limite superior de temperatura / Ülemine temperatuuripiir / Limite supérieure de température / Gornja dozvoljena temperatura / Felső hőmérsékleti határ / Limite superiore di temperatura / Temperatuurən çemənı ruqsat şeri / 상한 온도 / Aukščiausia laikymo temperatūra / Augšēja temperatūras robeža / Hoogste temperatuurlimiet / Øvre temperaturgrænse / Gorna granica temperatury / Limite máximo de temperatura / Limită maximă de temperatură / Верхний предел температуры / Horná hranica teploty / Gornja granica temperature / Øvre temperaturgräns / Sicaklık üst sınırı / Максимальна температура / 温度上限
	Keep dry / Пазете сухо / Skladujte v suchém prostředí / Opbevarens tørt / Trocklagern / Φυλάξτε το στεγνό / Mantener seco / Hoida kuivas / Conserver au sec / Držati na suhom / Száraz helyen tartandó / Tenere all'asciutto / Құрғақ күйдіңе ұста / 건조 상태 유지 / Laikyti sausai / Uzglabāt sausu / Droog houden / Hoides tørt / Przechowywać w stanie suchym / Manter seco / A se feri de umezeală / Не допускать попадания влаги / Uchovávať v suchu / Držite na suvom mestu / Förvaras tørt / Kuru bir şekilde muhafaza edin / Беретти від вологи / 请保持干燥

	Collection time / Време на събиране / Čas odběru / Opsamlingstidspunkt / Entnahmeuhrzeit / Décoller / Otvoriti skini / Húzza le / Staccare / Ψτήλη καβатын алып таста / 떼기기 / Pięści cia / Atłimēt / Schillen / Trekk av / Oderwać / Destacar / Se dezlipște / Откнеит / Otdhrnite / Oljusti / Dra isår / Ayırma / Відкрити / 撕下
	Peel / Обенете / Otevfete zde / Abn / Abziehen / Αποκολλήστε / Desprender / Koorida / Décoller / Otvoriti skini / Húzza le / Staccare / Ψτήλη καбатын алып таста / 떼기기 / Pięści cia / Atłimēt / Schillen / Trekk av / Oderwać / Destacar / Se dezlipște / Откнеит / Otdhrnite / Oljusti / Dra isår / Ayırma / Відкрити / 撕下
	Perforation / Перфорация / Perforace / Perforering / Διότρηση / Perforación / Perforatsioon / Perforacija / Perforálás / Perforazione / Tecik tesy / 찢히신 / Perforacija / Perforatie / Perforacia / Perforação / Perforare / Перфорация / Perforácia / Perforasyon / Перфорация / 穿孔
	Do not use if package damaged / Не използвайте, ако опаковката е повредена / Nepoužívejte, je-li obal poškozený / Mä ikke anvendes hvis emballagen er beskadiget / Inhal beschädigter Packungnicht verwenden / Μη χρησιμοποιείτε εάν η συσκευασία έχει υποστεί ζημιά / No usar si el paquete está dañado / Mitte kasutada, kui pakend on kahjustatud / Ne pas l'utiliser si l'emballage est endommagé / Ne koristiti ako je oštećeno pakiranje / Ne használja, ha a csomagolás sérült / Non usare se la confezione è danneggiata / Erep pakert buzyłgan bolca, pайдalanба / 패키지가 손상된 경우 사용 금지 / Jei pakuotė pažeista, nenaudoti / Nelietot, ja iepakojums bojāts / Niet gebruiken indien de verpakking beschadigd is / Mä ikke brukes hvis pakke er skadet / Nie używać, jeśli opakowanie jest uszkodzone / Não usar se a embalagem estiver danificada / A nu se folosi dacă pachetul este deteriorat / He isponzovať pri poškodení obalu / Nepoužívať, ak je obal poškodený / Ne koristite ako je pakovanje oštećeno / Använd ej om förpackningen är skadad / Ambalaj hasar görmüşse kullannayin / Не використовувати за пошкодженої упаковки / 如果包装破损, 请勿使用
	Keep away from heat / Пазете от топлина / Nevstavujte přílišnému teplu / Mä ikke udsættes for varme / Vor Wärme schützen / Κρατήστε το μακριά από τη θερμότητα / Mantener alejado de fuentes de calor / Hoida eemal valgest / Protègez de la chaleur / Držati dalje od izvora topline / Øvja a meglőt / Tenere lontano dal calore / Сақын жерде сакта / 열을 피해야 함 / Laikyti atokiau nuo šilumos šaltinių / Sargăt no karstuma / Beschermen tegen warmte / Mä ikke utsettes for varme / Przechowywać z dala od źródeł ciepła / Manter ao abrigo do calor / A se feri de căldură / He nærgævt / Uchovávať mimo zdroja tepla / Držite dalje od toplote / Får ej utsättas för värme / Isidan uzak tutun / Беретти від діт тenna / 请远离热源
	Cut / Крекете / Odstřihněte / Klip / Schneiden / Κόψτε / Cortar / Lõigata / Découper / Reži / Vágja ki / Tagliare / Кесіңізі / 잘라내기 / Kirpi / Nogriezt / Knippen / Kutt / Odciać / Cortar / Decupați / Отрезыть / Odstřihněte / Iseći / Klippo / Kesme / Pospiaziiti / 剪下
	Collection date / Дата на събиране / Datum odběru / Opsamlingsdato / Entnahmetermin / Ημερομηνία συλλογής / Fecha de recogida / Kogumiskupäev / Date de prélèvement / Dani prikupljanja / Mintavétel dátuma / Data di raccolta / Жинаған тібекүні / 수집 날짜 / Paėmimo data / Savākšanas datums / Verzameldatum / Dato prevatking / Data pobrania / Data de colectie / Data colectării / Data сбора / Datum odberu / Datum prikupljanja / Uppsamlingsdatum / Toplama tarihi / Дата забору / 采集日期
	μL/test / μL/тест / μL/Test / μL/έξταση / μL/prueba / μL/테스트 / мкл/тест / μL/tyrimas / μL/pārbaude / μL/teste / мкл/анализ / μL/检测
	Keep away from light / Пазете от светлина / Nevstavujte světlu / Mä ikke udsættes for lys / Vor Licht schützen / Κρατήστε το μακριά από το φως / Mantener alejado de la luz / Hoida eemal valgest / Conserver à l'abri de la lumière / Držati dalje od svetla / Fény nem érheti / Tenere al riparo dalla luce / Karaңғыланған жерде ұста / 빛을 피해야 함 / Laikyti atokiau nuo šilumos šaltinių / Sargat no gaismas / Niet blostellen aan zonlicht / Mä ikke utsettes for lys / Przechowywać z dala od źródeł światła / Manter ao abrigo da luz / Feriti de lumina / Хранити в темноте / Uchovávať mimo dosahu svetla / Držite dalje od svetlosti / Får ej utsättas för ljus / Iskitan uzak tutun / Беретти від діт світла / 请远离光线
	Hydrogen gas generated / Образуван е водород газ / Možnost úniku plyného vodíku / Frembringer hydrogengas / Wasserstoffgas erzeugt / Δημιουργεί αερίου υδρογόνου / Production de gas de hydrogène / Gásgenerálás / Gásgenerierung / Produitt de l'hydrogène gazeux / Sadrží hydrogen vodík / Hydrogen gázt fejleszt / Produzione di gas idrogeno / Газтөктес сытери пайда болды / 수소 가스 생성됨 / Išskiria vandenilio dujas / Rodas ūdegradis / Waterstofgas gegenereerd / Hydrogengass generert / Powoduje powstawanie wodoru / Produção de gás de hidrogénio / Generare gaz de hidrogen / Выделение водорода / Vyrobené použitím vodíka / Osloboda se vodonik / Genererad vätgas / Açığa çıkan hidrojen gazı / Реакция з видіненням водню / 会产生氢气
	Patient ID number / ID номер на пациента / ID pacienta / Patientens ID-nummer / Patienten-ID / Αριθμός αναγνώρισης ασθενούς / Número de ID del paciente / Patsiendi ID / No d'identification du patient / Identifikacijski broj pacijenta / Beteg azonosító száma / Numero ID paciente / Пациенттин идентификациялык нөмірі / 환자 ID 번호 / Paciento identifikavimo numeris / Pacienta ID numurs / Identificationnummer van de patiënt / Patientens ID-nummer / Numer ID pacjenta / Número da ID do doente / Număr ID pacient / Идентификационный номер пациента / Identifikačné číslo pacienta / ID broj pacijenta / Patientnummer / Hasta kimlik numarası / Идентификатор пациента / 患者标识号
	Fragile, Handle with Care / Чупливо, Работете с необходимото внимание. / Křehké. Při manipulaci postupujte opatrně. / Forsigtig, kan gå i stykker. / Zerbrechlich, vorsichtig handhaben. / Ευθραστο. Χειριστείτε το με προσοχή. / Frágil. Manipular con cuidado. / Őrn, káitsege ettevaatlikult. / Fragile. Manipuler avec précaution. / Lomljivo, rukujte pažljivo. / Törékeny! Óvatosan kezelendő. / Fragile, maneggiare con cura. / Сыныш, абайлан пайдаланыңыз. / 조심 깨지기 쉬운 처리 / Trape, elkités atsargiai. / Trausli; rikotes uzmanigi / Breekbaar, voorzichtig behandelen. / Ömtålig, händter försiktigt. / Krucha zawartość, przenosić ostrożnie. / Frágil, Manuseie com Cuidado. / Frágil, manipulatí cu atenție. / Хрупкое! Обращаться с осторожностью. / Křehké, vyžaduje sa opatrná manipulácia. / Lomljivo - rukujte pažljivo. / Bräckligt. Hantera försiktigt. / Kolay Kırılır, Dikkatli Taşının. / Тендітна, звертатися з обережністю / 易碎, 小心轻放

	Becton, Dickinson and Company
	7 Loveton Circle
	Sparks, MD 21152 USA
	800.638.8663
	© 2018 BD. BD, the BD Logo and all other trademarks are property of Becton, Dickinson and Company.