

BD MAX™ ExK™ DNA-3

REF 442821

P0125(06)

2015-10

Swab Specimen in Universal Transport Media (UTM) or Neat Urine
For use with the BD MAX™ System



IVD


INTENDED USE

The BD MAX ExK DNA-3 is intended to extract DNA from swab specimens in Universal Transport Media (UTM) or neat urine specimens. The DNA Extraction Tube contains a Sample Processing Control sequence from *Drosophila melanogaster* (GenBank*: AC246436; nucleotides 35779 to 35978) cloned in a pUC119 derivative (GenBank: U07650.1). The BD MAX ExK DNA-3 has not been validated for use with any specific test method.

PRINCIPLES OF THE PROCEDURE

The specimen is mixed with the BD MAX Sample Buffer Tube and processed using the BD MAX System. The BD MAX System automates sample lysis, DNA extraction and concentration, reagent rehydration, nucleic acid amplification and detection of the target nucleic acid sequence using real-time polymerase chain reaction (PCR). The BD MAX System contains a combination of lytic and extraction reagents designed to perform cell lysis and DNA extraction. Following cell lysis, the released DNA is captured by magnetic affinity beads. The beads with the bound DNA are washed and then the DNA is eluted using 12.5 µL of Elution Buffer. The solution may be prepared for PCR using Neutralization Buffer from the Unitized Reagent Strip. The eluted DNA may be used for applications on the BD MAX System or another PCR Amplification/Detection System.

REAGENTS

REF	COMPONENT NAME	QUANTITY
442821	BD MAX™ Extraction Tubes (A8) <i>Dried extraction reagent containing magnetic affinity beads, Proteinase K and Sample Processing Control</i>	 24
	BD MAX™ Sample Buffer Tube (SB-3) <i>(with 25 septum caps)</i>	
	BD MAX™ DNA Reagent Strip (DNA) <i>Unitized Reagent Strip containing all liquid reagents and disposable pipette tips necessary for specimen processing and DNA extraction</i>	
	BD MAX™ Conical Tubes	

EQUIPMENT AND MATERIALS REQUIRED BUT NOT PROVIDED

- BD MAX™ System: REF 441916 or 441927
- Micropipettes (accurate between 2 and 1000 µL)
- Aerosol resistant micropipette tips
- Disposable gloves/lab coat
- Specimen collection container(s)
- Swabs in UTM
- PCR Cartridges (REF 437519), if applicable
- BD MAX™ DNA MMK (SPC) (REF 442829) or BD MAX™ DNA MMK (REF 442848), if applicable
- BD MAX™ Conical Tubes (REF 437016), if applicable



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WARNINGS AND PRECAUTIONS

Danger



H360 May damage fertility or the unborn child.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P308+P313 IF exposed or concerned: Get medical advice/attention.

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

- The BD MAX ExK DNA-3 is for *in vitro* diagnostic use.
- Do not use expired reagents and/or materials.
- Do not use the kit if the label that seals the outer box is broken upon arrival.
- Do not use reagents if the protective pouches are open or broken upon arrival.
- Do not use reagents if desiccant is not present or is broken inside reagent pouches.
- Do not remove desiccant from reagent pouches.
- Close protective pouches of reagents promptly with the zip seal after each use. Remove any excess air in the pouches prior to sealing.
- Protect reagents against heat and humidity. Prolonged exposure to humidity may affect product performance.
- Do not use reagents if the foil has been broken or damaged.
- Do not mix reagents from different pouches and/or kits and/or lots.
- Do not interchange or reuse caps, as contamination may occur and compromise test results.
- Check Unitized Reagent Strips for proper liquid fills (ensure that the liquids are at the bottom of the tubes) (refer to Figure 1).
- Check Unitized Reagent Strips to ensure that all pipette tips are present (refer to Figure 1).
- Proceed with caution when using chemical solutions as Extraction Tube barcode readability may be altered.
- Good laboratory technique is essential for the proper use of this product. Extreme care should be taken to preserve the purity of all materials and reagents.
- In cases where other PCR tests are conducted in the same general area of the laboratory, care must be taken to ensure that the BD MAX DNA-3, any additional reagents required for testing, and the BD MAX System are not contaminated. Avoid microbial and ribonuclease (RNase)/deoxyribonuclease (DNase) contamination of reagents at all times. The use of sterile RNase/DNase-free disposable aerosol resistant or positive displacement pipette tips is recommended. Use a new tip for each specimen. Gloves must be changed before manipulating reagents and cartridges.
- To avoid contamination of the environment by amplicons, do not break apart the BD MAX PCR Cartridge after use. The seals of the BD MAX PCR Cartridges are designed to prevent contamination.
- The laboratory should routinely perform environmental monitoring to minimize the risk of cross-contamination.
- Always handle specimens as if they are infectious and in accordance with safe laboratory procedures such as those described in CLSI Document M29¹ and in Biosafety in Microbiological and Biomedical Laboratories².
- Wear protective clothing and disposable gloves while handling all reagents.
- Wash hands thoroughly after performing the test.
- Do not pipette by mouth.
- Do not smoke, drink, chew or eat in areas where specimens or kit reagents are being handled.
- Dispose of unused reagents and waste in accordance with local, state, provincial and/or federal regulations.
- Consult the BD MAX System User's Manual³ for additional warnings, precautions and procedures.

STORAGE AND STABILITY

- BD MAX ExK DNA-3 components are stable at 2–25 °C through the stated expiration date. Do not use if expired.
- The BD MAX DNA Extraction Tubes (A8) are provided in sealed pouches. To protect product from humidity, immediately re-seal after opening. The Extraction Tubes are stable for up to 7 days at 2–25 °C after initial opening and re-sealing of the pouch.

INSTRUCTIONS FOR USE

Specimen Collection

1. Collect specimen and label appropriately.
2. Collected specimens should be maintained per the conditions validated by the user.
3. Proceed to Extraction Preparation.

Extraction Preparation:

Note: The following extraction preparation procedures are provided as guidance. Some specimens may require pre-processing. Application-specific extraction preparation procedures should be developed and validated by the user.

1. Pipette 750 µL of specimen into a BD MAX DNA Sample Buffer Tube SB-3 and close the tube with a septum cap. Ensure complete mixing by vortexing the sample.
2. Proceed to BD MAX System Operation.

BD MAX System Operation

Note: Refer to the BD MAX System User's Manual³ for detailed instructions (Operation section).

1. Power on the BD MAX System (if not already done) and log in by entering <user name> and <password>.
2. Gloves must be changed before manipulating reagents and cartridges.
3. Remove the required number of Unitized Reagent Strips from the BD MAX ExK DNA-3 kit. Gently tap each strip onto a hard surface to ensure that all the liquids are at the bottom of the tubes.
4. Remove the required number of Extraction Tube(s) and Master Mix Tube(s) (if applicable) from their protective pouches. Remove excess air, and close pouches with the zip seal.
5. For each specimen to be tested, place one (1) Unitized Reagent Strip on the BD MAX System Rack, starting with Position 1 of Rack A. Assemble the strip as follows:

Note: A tube is fully seated in the strip when a 'click' is heard. Refer to Figure 1 for reagent placement in the Unitized Reagent Strip.

a) Extraction only:

- Position 1 = Snap the DNA Extraction Tube into position 1.
- Position 2 = Leave position 2 empty.
- Position 3 = Snap a BD MAX Conical Tube into position 3.

b) Type 1: BD MMK or MMK(SPC) and Dried Primers and Probes:

- Position 1 = Snap the DNA Extraction Tube into Position 1.
- Position 2 = Snap the BD MAX DNA MMK (SPC) or BD MAX DNA MMK Master Mix Tube into position 2.
- Position 3 = Snap a BD MAX Conical Tube containing dried-down primer and probe mixture (at a final concentration of 2X) into position 3.

c) Type 2: BD MMK or MMK(SPC) and Liquid Primers and Probes:

- Position 1 = Snap the DNA Extraction Tube into Position 1.
- Position 2 = Snap the BD MAX DNA MMK (SPC) or BD MAX DNA MMK Master Mix Tube into position 2; follow the instructions for use accompanying that product.
- Position 3 = Snap a BD MAX Conical Tube into position 3. Pipette 12.5 µL of user supplied primer and probe mixture (at a final concentration of 2X) into the bottom of the Conical Tube in position 3.

d) Type 3: Liquid MM with Primers and Probes:

- Position 1 = Snap the DNA Extraction Tube into Position 1.
- Position 2 = Leave position 2 empty.
- Position 3 = Snap a BD MAX Conical Tube into position 3. Pipette 12.5 µL of the user supplied master mix, primer and probe mixture (at a final concentration of 2X) into the BD MAX Conical Tube in position 3.

e) Type 4: Lyophilized MM with Primers and Probes:

- Position 1 = Snap the DNA Extraction Tube into Position 1.
- Position 2 = Snap a BD MAX Conical Tube containing user-supplied lyophilized master mix in position 2.
- Position 3 = Snap a BD MAX Conical Tube into position 3. Pipette 12.5 µL of user-supplied rehydration buffer into the BD MAX Conical Tube in position 3.

f) Type 5: Lyophilized MM with Primers and Probes:

- Position 1 = Snap the DNA Extraction Tube into Position 1.
- Position 2 = Snap a BD MAX Conical Tube containing user-supplied lyophilized master mix in position 2.
- Position 3 = Snap a BD MAX Conical Tube into position 3. Pipette 25 µL of user-supplied rehydration buffer into the BD MAX Conical Tube in position 3.

6. Click on the Run icon and enter the kit lot number for the BD MAX ExK DNA-3 (for lot traceability) by either scanning the barcode with the scanner or by manual entry.

Note: Repeat step 6 each time a new kit lot is used.

7. Navigate to the Worklist. Using the pull down menu select <ExK DNA-3>.
8. Enter the Sample Buffer Tube ID, Patient ID and Accession Number (if applicable) into the Worklist, either by scanning the barcode with the scanner or by manual entry.
9. Select the appropriate kit lot number (found on the outer box) from the pull down menu.
10. Repeat Steps (7-9) for all remaining Sample Buffer Tubes.
11. Place the Sample Buffer Tubes in the BD MAX System Rack(s) corresponding to the Unitized Reagent Strips assembled in step 5.
Note: Place the Sample Buffer Tubes in the sample rack(s) with the 1D barcode labels facing outward (this makes scanning Sample Buffer Tubes easier during sample login).
12. If the BD MAX System is also being used for DNA amplification, place the required number of BD MAX PCR Cartridge(s) into the BD MAX System (see Figure 2).
 - Each cartridge accommodates 2 runs of up to 12 samples for a total of 24 samples.
 - The BD MAX System will automatically select the position and row on the PCR Cartridge for each run.
 - PCR Cartridges are used on a per-run AND rack basis (2 runs per cartridge and 1 cartridge per rack).

Figure 1: BD MAX Unitized Reagent Strip

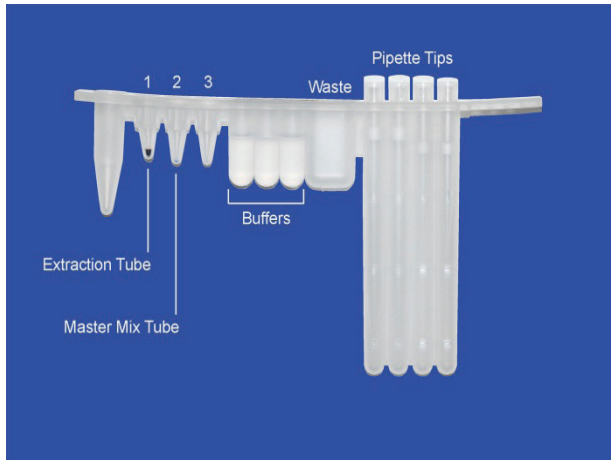
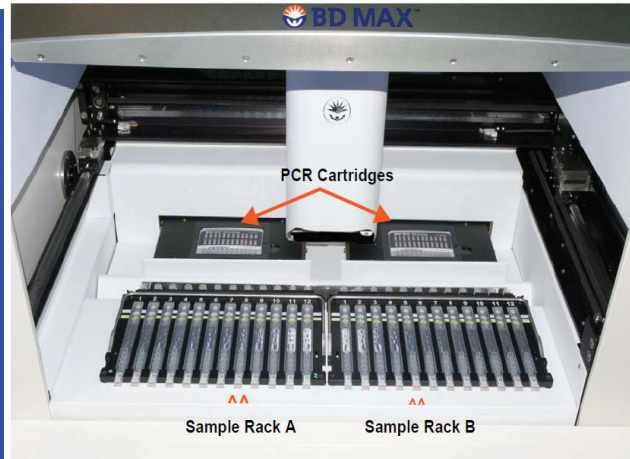


Figure 2: BD MAX System



13. Load rack(s) onto the BD MAX System (Figure 2).
14. Close the BD MAX System lid and click **<Start>** to begin processing.

LIMITATIONS OF THE PROCEDURE

1. The BD MAX ExK DNA-3 can only be used on the BD MAX System by trained personnel.
2. Use of the BD MAX ExK DNA-3 for clinical specimen types other than those specified have not been validated.
3. Urine samples with pH > 7.5 may interfere with the extraction process. It is recommended that the pH of alkaline urine samples be adjusted to a pH < 7.5 prior to processing. Alkaline conditions may impact the predictivity of the sample processing control when used for DNA amplification with BD MAX DNA MMK (SPC).
4. The selected application of this product must be validated by the user. Validations should be performed in accordance with country, federal, provincial, state, local and/or accrediting organization guidelines, regulations and standards.

REFERENCES

1. Clinical and Laboratory Standards Institute. Protection of laboratory workers from occupationally acquired infections; Approved Guideline. Document M29 (Refer to the latest edition).
2. Centers for Disease Control and Prevention, and National Institutes of Health. Biosafety in microbiological and biomedical laboratories. Chosewood L.C. and Wilson D.E. (eds) (2009). HHS Publication No. (CDC) 21-1112.
3. BD MAX System User's Manual (US Open System version 8089571 or International version 8089570 refer to the latest revision) BD Diagnostics, Sparks, MD USA.



Manufacturer / Производител / Výrobce / Fabrikant / Hersteller / Κατασκευαστής / Fabricante / Toolja / Fabricant / Proizvođač / Gyártó / Fabbicante / Аткарушы / 제조업체 / Gamintojas / Ražotājs / Tilvirker / Producent / Producător / Производител / Výrobca / Proizvođač / Tillverkare / Üretici / Виробник / 生产厂商



Use by / Исползвайте до / Spofebujtje do / Brug før / Verwendbar bis / Χρήση έως / Usar antes de / Kasutada enne / Date de péremption / 사용 기한 / Uпотrijebiti do / Felhasználhatóság dátuma / Usare entro / Дейин пайдалануга / Naudokite iki / Izlijetot līdz / Houdbaar tot / Brukes for / Stosować do / Prazo de validade / A se utiliza până la / Исползовать до / Použite do / Uпотrebiti do / Använd före / Son kullanma tarihi / Використати до/line / 使用截止日期
 YYYY-MM-DD / YYYY-MM (MM = end of month)
 ГТГГ-ММ-ДД / ГТГГ-ММ (ММ = края на месеца)
 RRRR-MM-DD / RRRR-MM (MM = koniec miesiąca)
 AAAA-MM-DD / AAAA-MM (MM = slutning 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)
 ÉÉÉÉ-HH-NN / ÉÉÉÉ-HH (HH = hónap utolsó napja)
 AAAA-MM-GG / AAAA-MM (MM = fine mese)
 ЖӨЖӨК-АА-КК / ЖӨЖӨК-АА / (АА = айдың соңы)
 YYYY-MM-DD/YYYY-MM (MM = 월말)
 MMMM-MM-DD / MMMM-MM (MM = mēnesio pabaiga)
 GGGG-MM-DD/GGGG-MM (MM = mēneša beigas)
 JJJJ-MM-DD / JJJJ-MM (MM = einde maand)
 AAAA-MM-DD / AAAA-MM (MM = slutten av måneden)
 RRRR-MM-DD / RRRR-MM (MM = koniec miesiąca)
 AAAA-MM-DD / AAAA-MM (MM = fim do mês)
 AAAA-LL-ZZ / AAAA-LL (LL = sfârșitul lunii)
 ГТГГ-ММ-ДД / ГТГГ-ММ (ММ = конец месяца)
 RRRR-MM-DD / RRRR-MM (MM = koniec miesiąca)
 GGGG-MM-DD / GGGG-MM (MM = kraj mjeseca)
 AAAA-MM-DD / AAAA-MM (MM = slutet av månaden)
 YYYY-AA-GG / YYYY-AA (AA = ayın sonu)
 PPPP-MM-DD / 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 / Katalooginumber / Numéro catalogue / Kataloški broj / Katalogszám / Numero di catalogo / Каталог номери / 카탈로그 번호 / Katalogo / numeris / Kataloga numurs / Catalogus nummer / Numer katalogowy / Număr de catalog / Номер по каталогу / Katalogové číslo / Kataloški broj / Katalog numarası / Номер за каталогом / 目录号



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Temperature limitation / Температурни ограничения / Teplotní omezení / Temperaturbegrænsning / Temperaturbegrenzung / Περιορισμοί θερμοκρασίας / Limitación de temperatura / Temperaturpirang / Limites de température / Dozvoljena temperatura / Hörmérsékleti határ / Limiti di temperatura / Температураны шектеу / 온도 제한 / Laikymo temperatūra / Temperaturās ierobežojumi / Temperaturlimiet / Temperaturbegrensning / Ograniczenie temperatury / Limites de temperatura / Limite de temperatură / Ograničenje temperature / Ograničenje teploty / Ograničenje temperature / Temperaturgräns / Sıcaklık sınırlaması / Обмеження температури / 温度限制



Batch Code (Lot) / Код на партидата / Kód (číslo) sarže / Batch-code (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) / Partijos kods (laidiens) / Lot nummer / Batch-kode (parti) / Kod partii (serie) / Código do lote / Cod de serie (Lot) / Код партии (лот) / Kód série (sarža) / Kod serije / Partinummer (Lot) / Parti Kodu (Lot) / Код партии / 批号 (亚批)



Contains sufficient for <n> tests / Съдържанието е достатъчно за <n> теста / Dostatečné množství pro <n> testů / Inneholder tilstrækkelig til <n> tests / Ausreichend für <n> Tests / Περιέχει επαρκή ποσότητα για <n> εξετάσεις / Contenido suficiente para <n> pruebas / KÜllaldane <n> testide jaoks / Contenu suffisant pour <n> tests / Sadržaj za <n> testova / <n> teszthez elegendő / Contenuto sufficiente per <n> test / <n> тесттери үшін жеткілікті / <n> 테스트가 충분히 포함됨 / Pakankamas kiekis atlikti <n> testų / Satur pietiekami <n> pārbaudēm / Inhoud voldoende voor "n" testen / Innholder tilstrekkelig til <n> tester / Zawiera ilość wystarczającą do <n> testów / Conteúdo suficiente para <n> testes / Conținut suficient pentru <n> teste / Достаточное для <n> тестов(а) / Obsah vystačí na <n> testov / Sadržaj dovoljan za <n> testova / Innehåller tillräckligt för <n> analyser / <n> test için yeterli malzeme içerir / Вистачить для аналізис: <n> / 足够进行 <n> 次检测



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Serial number / Серийн номер / Sériové číslo / Seriennummer / Seriennummer / Σειριακός αριθμός / Nº de serie / Seerianumber / Numéro de série / Serijski broj / Sorozatszám / Numero di serie / Топтамалық номери / 일련 번호 / Serijos numeris / Sērijas numurs / Serie nummer / Numer serjiny / Número de serie / Număr de serie / Серийный номер / Seri numarasi / 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 / Réserve à l'évaluation des performances IVD / Samo u znanstvene svrhe za In Vitro Dijagnostiku / Kizárólag in vitro diagnosztikához / Solo per valutazione delle prestazioni IVD / Жасанды жағдайда «пробирка ішінде» диагностикада тек жұмысты бағалау үшін / IVD 성능 평가에 대해서만 사용 / Tik IVD prietaisų veikimo charakteristikoms tikrinti / Vienīgi IVD darbības novērtēšanai / Uitsluitend voor doeltreffendheidsonderzoek / Kun for evaluering av IVD-ytelse / Tylko do oceny wydajności IVD / Uso exclusivo para avaliação de IVD / Numai pentru evaluarea performanței IVD / Только для оценки качества диагностики in vitro / Určené iba na diagnostiku in vitro / Samo za procenu učinka u in vitro dijagnostici / Endast för utvärdering av diagnostisk användning in vitro / Yalnızca IVD Performans değerlendirilmesi için / Тільки для оцінювання якості діагностики in vitro / 仅限 IVD 性能评估



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 / Najnižā dozvoljena temperatura / Alsó hőmérsékleti határ / Limite inferiore di temperatura / Temperaturāņu tēmēnri rukāt šeri / 하한 온도 / Žemiausia laikymo temperatūra / Temperatūras zemākā robeža / Laagste temperatuurimiet / Nedre temperaturgrænse / Dolna granica temperatury / Limite minimo de temperatura / Limiti minimā de temperatură / Нижний предел температуры / Spodná hranica teploty / Donja granica temperature / Nedre temperaturgräns / Sıcaklık alt sınırı / Мінімальна температура / 温度下限



Control / Контролно / Kontrola / Kontrol / Kontrolle / Μάρτυρας / Kontroll / Contrôle / Controllo / Бақылау / 컨트롤 / Kontrolé / Kontrolle / Controle / Controllo / Контроль / kontroll / Kontrolle / 对照



Positive control / Положителен контрол / Pozitivní kontrola / Positiv kontrol / Positive Kontrolle / Θετικός μάρτυρας / Control positivo / Positivne kontroll / Contrôle positif / Pozitivna kontrola / Pozitiv kontrol / Controllo positivo / Оң бақылау / 양성 컨트롤 / Teigjama kontrolé / Pozitivná kontrolé / Positive controle / Kontrola dodatnia / Controllo positivo / Control pozitiv / Положительный контроль / Pozitif kontrol / Позитивный контроль / 阳性对照试剂

CONTROL Negative control / Отрицателен контрол / Negativní kontrola / Negativ control / Negative Kontrolle / Αρνητικός έλεγχος / Control negativo / Negative control / Contrôle négatif / Negativná kontrola / Negativ kontroll / Controllo negativo / Negativтік бақылау / 음성 컨트롤 / Neigama kontrolė / Negativa kontrolle / Negative controle / Kontrola ujemna / Controllo negativo / Control negativ / Отрицательный контроль / Negatif kontrol / Негативний контроль / 阴性对照试剂

STERILE Method of sterilization: ethylene oxide / Метод на стерилизация: этиленов оксид / Způsob sterilizace: etylenoxid / Sterilisierungsmetode: ethylenoxid / Sterilisationsmethode: Ethylenoxid / Μέθοδος αποστείρωσης: αιθυλενοξείδιο / Método de esterilización: óxido de etileno / Sterilisierungsmethode: etilēnoksīds / Méthode de stérilisation : oxyde d'éthylène / Metoda sterilizacije: etilen oksid / Sterilizálás módszere: etilén-oxid / Metodo di sterilizzazione: ossido di etilene / Стерилизация әдісі – этилен тотығы / 소독 방법: 에틸렌옥사이드 / Sterilizavimo būdas: etileno oksidas / Sterilizācijas metode: etilēnoksīds / Gesteriliseerd met behulp van ethylenoxide / Sterilisierungsmetode: etylenoksid / Metoda sterilizacije: tenek etylu / Método de esterilização: óxido de etileno / Metoda de sterilizare: oxid de etilenă / Метод стерилизации: этиленоксид / Metoda sterilizácie: etylénoxid / Metoda sterilizacije: etilen oksid / Sterilisierungsmetode: etenoxid / Sterilization yöntemi: etilen oksit / Метод стерилизації: этиленоксидом / 灭菌方法: 环氧乙烷

STERILE R Method of sterilization: irradiation / Метод на стерилизация: ирадиация / Způsob sterilizace: záření / Sterilisierungsmetode: bestrahlung / Sterilisationsmethode: Bestrahlung / Μέθοδος αποστείρωσης: ακτινοβολία / Método de esterilización: irradiación / Sterilisierungsmethode: kiirgus / Méthode de stérilisation : irradiation / Metoda sterilizacije: zračenje / Sterilizálás módszere: besugárzás / Metoda di sterilizzazione: irradiazione / Стерилизация әдісі – сәулелік тәсіл / 소독 방법: 방사 / Sterilizavimo būdas: radiacija / Sterilizācijas metode: apstarošana / Gesteriliseerd met behulp van bestraling / Sterilisierungsmetode: bestrahlung / Metoda sterilizacije: napromienianie / Método de esterilização: irradiação / Metoda de sterilizare: iradiere / Метод стерилизации: облучение / Metoda sterilizácie: ožiarenie / Metoda sterilizacije: ozračavanje / Sterilisierungsmetode: strahlung / Sterilization yöntemi: iradyasyon / Метод стерилизації: опроміненням / 灭菌方法: 辐射



Biological Risks / Биологични рискове / Biologická rizika / Biologisk fare / Biogefährdung / Βιολογικοί κίνδυνοι / Riesgos biológicos / Biologisk risk / Risques biologiques / Biološki rizik / Biológiallag veszélyes / Rischio biologico / Биологичлык төвекелдер / 생물학적 위험 / Biologinis pavojus / Biológiskie riski / Biologisch risiko / Biologisk risiko / Zagrożenia biologiczne / Perigo biológico / Riscuri biologice / Биологическая опасность / Biologické riziko / Biološki rizici / Biologisk risk / Biyojik Riskler / Биологічна небезпека / 生物学风险



Caution, consult accompanying documents / Внимание, направте 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 / Ettenaustust! Lugeada kaasnevat dokumentatsiooni / Attention, consulter les documents joints / Urozorenje, koristi prateću dokumentaciju / Figyelem! Olvassa el a mellékelt tájékoztatót / Attenzione: consultare la documentazione allegata / Абайлаңыз, тиісті құжаттармен танысыңыз / 주의, 동봉된 설명서 참조 / Demesio, ziurēkite priedamus dokumentus / Piesardzība, skatīt pavadokumentus / Voorzichtig, raadpleeg bijgevoegde documenten / Forsiktig, se vedlagt dokumentasjon / Należy zapoznać się z dołączonymi dokumentami / Cuidado, consulte a documentação fornecida / Atenție, consultați documentele însoțitoare / Внимание: см. прилагаемую документацию / Vystraha, pozri sprievodné dokumenty / Pažnja! Pogledajte priložena dokumenta / Obs! Se medföljande dokumentation / Dikkat, perhatikan venien belgelere başvurun / 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 / Температураның руқсат етілген жоғарғы шеі / 상한 온도 / Aukščiausia laikymo temperatūra / Augšējā temperatūras robeža / Hoogste temperatuurlimiet / Øvre temperaturgrense / 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 / Παзете сухо / Skladujte v suchém prostředí / Opbevars tørt / Trocklagern / Φυλάξτε το στεγνό / Mantener seco / Hoida kuivaa / Conserver au sec / Držati na suhom / Száraz helyen tartandó / Tenere all'asciutto / Құрғақ күйінде ұста / 건조 상태 유지 / Laikykite sausiai / Uzglabāt sausu / Droog houden / Holdes tørt / Przechowywać w stanie suchym / Manter seco / A se feri de umezeală / Не допускать попадания влаги / Uchovávaťe v suchu / Držite na suvom mestu / Förvaras tørt / Kuru bir şekilde muhafaza edin / Берегти від вологи / 请保持干燥



Collection time / Време на събиране / Čas odběru / Opsamlingsstidspunkt / Entnahmehzeit / Ώρα συλλογής / Hora de recogida / Kogumisaeg / Heure de prélèvement / Sati prikupljanja / Mintavétel időpontja / Ora di raccolta / Жинау уақыты / 수집 시간 / Paėmimo laikas / Savākšanas laiks / Verzameltijd / Tid prøvetaking / Godzina pobrania / Hora de colheita / Ora colectării / Время сбора / Doba odberu / Vreme prikupljanja / Urpsamlingstid / Toplama zamanı / Час забору / 采集时间



Peel / Obenere / Otevfete zde / Abn / Abziehen / Αποκολλήστε / Desprender / Koorida / Décoller / Ontvoirt skini / Húzza le / Staccare / Устіңгі қабатын алып таста / 벗기기 / Plešti čia / Atliņēt / Schillen / Trekk av / Oderwać / Destacar / Se dezlipeste / Отклеить / Odrhните / Oljuštiti / Dra isår / Айрма / Відклеїти / 撕下



Perforation / Перфорация / Perforace / Perforeng / Διότρηση / Perforación / Perforatsioon / Perforacija / Perforálás / Perforazione / Текіс тесу / 절취선 / Perforacija / Perforacija / Perforatie / Perforacja / Perfuração / Perforare / Перфорация / Perforacia / Perforasyon / Перфорация / 穿孔



Do not use if package damaged / Не използвайте, ако опаковката е повредена / Nepoužívejte, je-li obal poškozený / Må 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 paket bұзылған болса, пайдаланба / Nelietot, ja iepakojums bojāts / Niet gebruiken indien de verpakking beschadigd is / Må 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 / Не использовать при повреждении упаковки / Nepoužívejte, ak je obal poškozený / Ne koristite ako je pakovanje oštećeno / Använd ej om förpackningen är skadad / Ambalaj hasar görmüşse kullanmayın / Не використовувати за пошкодженої упаковки / 如果包装破损, 请勿使用



Keep away from heat / Παзете от топлина / Nevystavujte přibližněmu teplu / Må ikke udsættes for varme / Vor Wärme schützen / Κρατήστε το μακριά από τη θερμότητα / Mantener alejado de fuentes de calor / Hoida eemal valgusest / Protéger de la chaleur / Držati dalje od izvora topline / Övja a melegtől / Tenere lontano dal calore / Сақын жерде сақта / 열을 피해야 함 / Laikyti atokiau nuo šilumos šaltinių / Sargát no karstuma / Beschermen tegen warmte / Må ikke utsettes for varme / Przechowywać z dala od źródeł ciepła / Manter ao abrigo do calor / A se feri de căldură / Не нагревать / Uchovávaťe mimo zdroja tepla / Držite dalje od toplote / Får ej utsättas för värme / Isidan uzak tutun / Берегти від дії тепла / 请远离热源



Cut / Срежете / Odstfihňte / Klip / Schneiden / Κόψτε / Cortar / Lögista / Découper / Reži / Vágja ki / Tagliare / 절라내기 / Kirpti / Nogriet / Knippen / Kutt / Odciać / Cortar / Decupați / Отрезать / Odstrihnite / Iseći / Klipp / Kesme / Розрізати / 剪下



Collection date / Дата на събиране / Datum odběru / Opsamlingsdato / Entnahmehdatum / Ημερομηνία συλλογής / Fecha de recogida / Kogumiskuupäev / Date de prélèvement / Dani prikupljanja / Mintavétel dátuma / Data di raccolta / Жинаған тізбекүні / 수집 날짜 / Paėmimo data / Savākšanas datums / Verzameldatum / Dato prøvetaking / Data pobrania / Data de colheita / Data colectării / Дата сбора / Datum odberu / Datum prikupljanja / Urpsamlingsdatum / Toplama tarihi / Дата забору / 采集日期



Keep away from light / Παзете от светлина / Nevystavujte svėtu / Må ikke udsættes for lys / Vor Licht schützen / Κρατήστε το μακριά από το φως / Mantener alejado de la luz / Hoida eemal valgusest / Conserver à l'abri de la lumière / Držati dalje od svjetla / Fény nem érheti / Tenere al riparo dalla luce / Қараңғыланған жерде ұста / 빛을 피해야 함 / Laikyti atokiau nuo šilumos šaltinių / Sargát no gaismas / Niet blootstellen aan zonlicht / Må ikke utsettes for lys / Przechowywać z dala od źródeł światła / Manter ao abrigo da luz / Feriti de lumină / Хранить в темноте / Uchovávaťe mimo dosahu svetla / Držite dalje od svetlosti / Får ej utsättas för ljus / Isiktan uzak tutun / Берегти від дії світла / 请远离光线



Hydrogen gas generated / Образован е водород газ / Možnost úniku plyného vodíku / Frembringer hydrogengas / Wasserstoffgas erzeugt / Δημιουργεί αερίου υδρογόνου / Producción de gas de hidrógeno / Vesinikgaasi tekitatud / Produit de l'hydrogène gazeux / Sadržaji hydrogen vodik / Hydrogēn gāzt fejleszt / Produzione di gas idrogeno / Газетектес сүетпй пайда болды / 수소 가스 생성됨 / İsskiria vandenilio dujas / Rodas ūdeņradis / Waterstoffgas gegenereerd / Hydrogengass generert / Powoduje powstanie wodoru / Produção de gás de hidrogénio / Generare gaz de hidrogen / Выделение водорода / Vyrobené použitím vodíka / Oslobada se vodonik / Geneereerd vätgas / Acığa çıkan hidrojen gazı / Реакция з виділенням водню / 会产生氢气



Patient ID number / ИД номер на пациента / ID patienta / Patients ID-number / 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 paziente / Пациенттн идентификациялык нөмірі / 환자 ID 번호 / Paciento identifikavimo numeris / Pacienta ID numurs / Identificatienummer van de patiënt / Patientens ID-number / Numer ID pacienta / Número da ID do doente / Număr ID pacient / Идентификационный номер пациента / Identifikačné číslo pacienta / ID broj pacijenta / Patientnummer / Hasta kimlik numarasi / Идентификатор пациента / 患者标识号



Fragile, Handle with Care / Чупливо, Работете с необходимото внимание. / Křehké. Při manipulaci postupujte opatrně. / Forsiktig, kan gå i stykker. / Zerbrechlich, vorsichtig handhaben. / Εύθραστο. Χειρστείτε το με προσοχή. / Frágil. Manipular con cuidado. / Órn, kásitsege ettevaatlíkul. / Fragile. Manipuler avec précaution. / Lomljivo, rukujte pažljivo. / Törékeny! Óvatosan kezelendő. / Fragile, maneggiare con cura. / Сынгыш, абайлап пайдаланыңыз. / 조심 깨지기 쉬운 처리 / Trapu, etikėtas atsargiai. / Trausis; rikoties uzmanigi / Breekbaar, voorzichtig behandelen. / Ømtåligt, håndter forsigtig. / Krucha zawartość, przenosić ostrożnie. / Frágil, Manuseie com Cuidado. / Fragil, manipulați cu atenție. / Хрупкое! Обращаться с осторожностью. / Křehké, vyžaduje sa opatrná manipulácia. / Lomljivo - rukujte pažljivo. / Bräckligt. Hantera försiktigt. / Kolay Kırılır, Dikkatli Taşınır. / Тендітна, звертатися з обережністю / 易碎, 小心轻放

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

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