

# **BD MAX™ ExK™ DNA-2**

REF **442819**

P0123(06)

2015-10

Cerebral Spinal Fluid or Dry Swabs  
For use with the BD MAX™ System



IVD


## INTENDED USE

The BD MAX ExK DNA-2 is intended to extract DNA from cerebral spinal fluid (CSF) or dry swab 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-2 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
442819	<b>BD MAX™ Extraction Tubes (A8)</b> <i>Dried extraction reagent containing magnetic affinity beads, Proteinase K and Sample Processing Control</i>	 24
	<b>BD MAX™ Sample Buffer Tube (SB-2)</b> <i>(with 25 septum caps)</i>	
	<b>BD MAX™ DNA Reagent Strip (DNA)</b> <i>Unitized Reagent Strip containing all liquid reagents and disposable pipette tips necessary for specimen processing and DNA extraction</i>	
	<b>BD MAX™ Conical Tubes</b>	

## 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)
- Dry swabs
- 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



P0123(06)

## 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-2 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-2, 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 M29<sup>1</sup> and in Biosafety in Microbiological and Biomedical Laboratories<sup>2</sup>.
- 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 Manual<sup>3</sup> for additional warnings, precautions and procedures.

## STORAGE AND STABILITY

- BD MAX ExK DNA-2 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. **CSF:** Pipette 200 µL of specimen into a BD MAX DNA Sample Buffer Tube SB-2 and close the tube with a septum cap. Ensure complete mixing by vortexing the sample.
2. **Dry Swab:** Insert swab into a BD MAX DNA Sample Buffer Tube SB-2 and swirl at least three times. Lift the swab out of the liquid and press against the side of the Sample Buffer Tube to expel residual specimen. Completely remove the swab from the tube, discard appropriately and close the tube with a septum cap. Ensure complete mixing by vortexing the sample.
3. Proceed to BD MAX System Operation.

## BD MAX System Operation

**Note: Refer to the BD MAX System User's Manual<sup>3</sup> 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-2 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:**

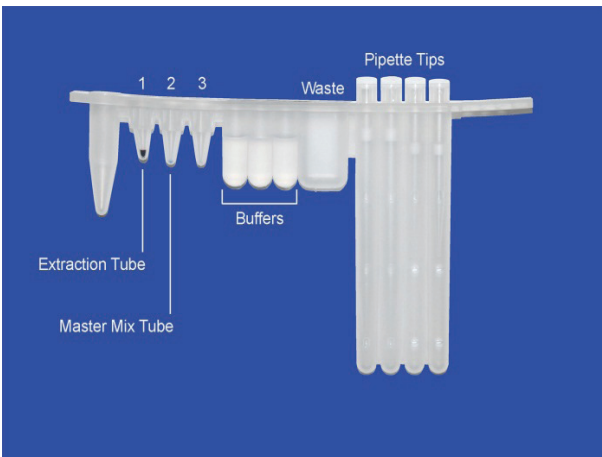
- Position 1 = Snap the DNA Extraction Tube into Position 1.
- Position 2 = Leave position 2 empty.
- Position 3 = Snap a BD MAX Conical Tube into position 3. Pipette 12.5 µL of the user supplied master mix, primer and probe mixture (at a final concentration of 2X) into the BD MAX Conical Tube in position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

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

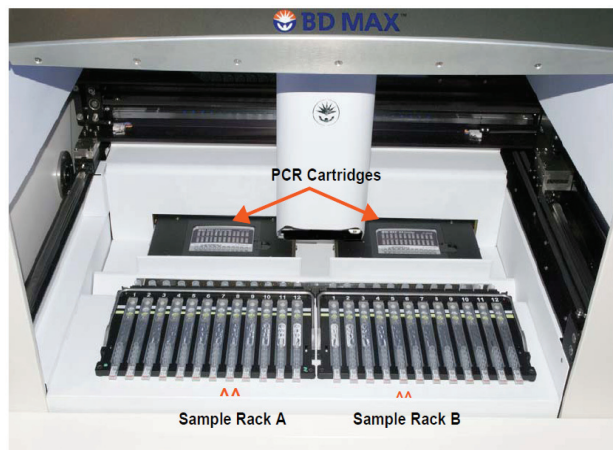
- Position 1 = Snap the DNA Extraction Tube into Position 1.
- Position 2 = Snap a BD MAX Conical Tube containing user-supplied lyophilized master mix in position 2.
- Position 3 = Snap a BD MAX Conical Tube into position 3. Pipette 12.5 µL of user-supplied rehydration buffer into the BD MAX Conical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

6. Click on the Run icon and enter the kit lot number for the BD MAX ExK DNA-2 (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-2>.
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-2 can only be used on the BD MAX System by trained personnel.
2. Use of the BD MAX ExK DNA-2 for clinical specimen types other than those specified have not been validated.
3. 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.



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 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)  
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 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)  
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 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)



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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-ydelse / Tylko do oceny wydajności IVD / Uso esclusivo 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 değerlendirmesi 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 / Temperaturānšs tēmēnri rukšat šeri / 하한 온도 / Žemiausia laikymo temperatūra / Temperatūras zemākā robeža / Laagste temperatuurlimiet / 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 / Положительен 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 / Negativный контроль / 阴性对照试剂

**STERILE** ED Method of sterilization: ethylene oxide / Метод на стерилизация: этиленов оксид / Způsob sterilizace: etylenoxid / Steriliseringmethode: 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 этилен – этилен тотығы / 소독 방법: 에틸렌옥사이드 / Sterilizavimo būdas: etileno oksidas / Sterilizācijas metode: etilēnoksīds / Gesteriliseerd met behulp van ethylenoxide / Steriliseringmethode: 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 / Steriliseringsmethode: etenoxid / Sterilization yöntemi: etilen oksit / Метод стерилизации: этиленоксидом / 灭菌方法: 环氧乙烷

**STERILE** R Method of sterilization: irradiation / Метод на стерилизация: ирадиация / Způsob sterilizace: záření / Steriliseringmethode: bestråling / 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 адиси – сауле түсірілу / 소독 방법: 방사 / Sterilizavimo būdas: radiacija / Sterilizācijas metode: apstarošana / Gesteriliseerd met behulp van bestraling / Steriliseringmethode: bestråling / Metoda sterylizacji: napromienianie / Método de esterilização: irradiação / Metoda de sterilizare: iradiere / Метод стерилизации: облучение / Metoda sterilizácie: ožiarenie / Metoda sterilizacije: ozračavanje / Steriliseringsmethode: stråling / Sterilization yöntemi: irradyasyon / Метод стерилизации: опроминенням / 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 төуекелдер / 생물학적 위험 / Biologinis pavojus / Biológiskie riski / Biologisch risico / 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! Lugada kaasnevat dokumentatsiooni / Attention, consulter les documents joints / Urozorenje, koristi prateču 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, birlikte verilen 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 temperaturgrense / 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 / Пазете сухо / Skladujte v suchém prostředí / Opbevars tørt / Trocklagern / Φυλάξτε το στεγνό / Mantener seco / Hoida kuivasa / 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 / Åbn / 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 / Айırма / Відклеїти / 撕下



Perforation / Перфорация / Perforace / Perforeng / Διότρηση / Perforación / Perforatsioon / Perforacija / Perforálás / Perforazione / Текіс тесу / 절취선 / Perforacija / Perforacija / Perforatie / Perforacja / Perfuração / Perforare / Перфорация / Perforácia / 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 / Nepoužívaťe, ak je obal poškodený / 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 / Пазете 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 / Саққын 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 / Lögita / Découper / Reži / Vágja ki / Tagliare / 절라내기 / Kirpti / Nogriet / Knippen / Kutt / Odciać / Cortar / Decupați / Отрезать / Odstrihните / 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



µL/test / µL/тест / µL/Test / µL/έξέταση / µL/prueba / µL/teszt / µL/테스트 / мкл/тест / µL/tyrimas / µL/pārbaude / µL/teste / мкл/анализ / µL/检测



Keep away from light / Пазете 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 / Isktan uzak tutun / Берегти від дії світла / 请远离光线



Hydrogen gas generated / Образован е водород газ / Možnost úniku plynného vodíku / Frembringer hydrogengas / Wasserstoffgas erzeugt / Δημιουργεί αερίου υδρογόνου / Producción de gas de hidrógeno / Vesinikgaasi tekitatud / Produit de l'hydrogène gazeux / Sadrží hydrogen vodík / Hydrogėn gázt fejleszt / Produzione di gas idrogeno / Газтєктєс сүетї пайдa 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 / Acıđa cıkan hidrojen gazı / Реакция з виділенням водню / 会产生氢气



Patient ID number / ИД номер на пациента / ID paciența / 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 paziente / Пациенттн идентификациялык нөмірі / 환자 ID 번호 / Paciento identifikavimo numeris / Paciența ID numurs / Identificatienummer van de patiënt / Patientens ID-nummer / Numer ID paciența / 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. / Ömtåligt, händter försiktig. / 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](http://www.bd.com/ds).

 GeneOhm Sciences Canada, Inc.  
2555 Boul. du Parc Technologique  
Québec, QC, G1P 4S5, Canada

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