

BD MAX™ ExK™ DNA-1

REF **442818**

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English

For Laboratory Use
For use with the BD MAX™ System



PRODUCT DESCRIPTION

The BD MAX™ ExK™ DNA-1 is intended to extract DNA from plasma, serum 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-1 has not been validated for use with any specific test method.

PRINCIPLES OF THE PROCEDURE

The specimen is mixed with the BD MAX ExK DNA-1 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 AND MATERIALS

REF	Contents	Quantity
442818	BD MAX DNA Extraction Tubes (A8) <i>Dried extraction reagent containing magnetic affinity beads, Proteinase K and Sample Processing Control.</i>	24 (2 x 12 tubes)
	BD MAX ExK DNA-1 Sample Buffer Tube (SB-1)	24 (2 x 12 tubes)
	BD MAX DNA-1 Reagent Strip <i>Unitized Reagent Strip containing all liquid reagents and disposable pipette tips necessary for specimen processing and DNA extraction.</i>	24
	Conical Tubes	24
	Septum Caps	25

EQUIPMENT AND MATERIALS REQUIRED BUT NOT PROVIDED

- BD MAX™ System (BD Cat. No. 441916 or 441927)
- Micropipettes (accurate between 2 and 1,000 µL)
- Aerosol resistant micropipette tips
- Disposable gloves/lab coat
- Specimen collection container(s)
- BD MAX PCR Cartridges (BD Cat. No. 437519), if applicable
- BD MAX™ DNA MMK (SPC) (BD Cat. No. 442829) or BD MAX DNA MMK (BD Cat. No. 442848), if applicable
- BD MAX™ Conical Tubes (BD Cat. No. 437016), if applicable

WARNINGS AND PRECAUTIONS

- The BD MAX ExK DNA-1 is for *Laboratory Use*.
- Extraction of neat urine specimens using a lysis temperature other than 62 °C has not been evaluated. Select <ExK DNA-1 (Urine) [4-Snap]> from the pull down menu of the Worklist, as selection of <ExK DNA-1 (Plasma/Serum) [4-Snap]> will result in an incorrect lysis temperature of 37 °C.
- 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 re-use 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 ExK DNA-1, 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 Laboratories.²
- 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-1 components are stable at 2–25 °C through the stated expiration date. Do not use expired components.
- BD MAX DNA Extraction Tubes 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.
Note: Plasma specimens must be obtained from sodium citrate or EDTA anticoagulated blood. Other anticoagulants have not been evaluated.
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 ExK DNA-1 Sample Buffer Tube SB-1 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-1 kit. Gently tap each Unitized Reagent 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.
- Position 4 = Leave Position 4 empty.

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.
- Position 4 = Leave Position 4 empty.

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, being careful to avoid bubble formation.
- Position 4 = Leave Position 4 empty.

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, being careful to avoid bubble formation.
- Position 4 = Leave Position 4 empty.

e) Type 4: Lyophilized MM with Rehydration Buffer:

- 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, being careful to avoid bubble formation.
- Position 4 = Leave Position 4 empty.

f) Type 5: Concentrated Lyophilized MM with Rehydration Buffer:

- 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, being careful to avoid bubble formation.
- Position 4 = Leave Position 4 empty.

- g) **Dual Master Mix: Lyophilized MM with Rehydration Buffer (Type 4):**
- 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, being careful to avoid bubble formation.
 - Position 4 = Snap a BD MAX Conical Tube containing user-supplied lyophilized master mix in Position 4.
- h) **Dual Master Mix: Liquid MM with Primers and Probes (Type 3):**
- Position 1 = Snap the DNA Extraction Tube into Position 1.
 - Position 2 = Snap a BD MAX Conical Tube into Position 2. Pipette 12.5 µL of user-supplied master mix, primer and probe mixture 1 (at a final concentration of 2X) into the BD MAX Conical Tube in Position 2, being careful to avoid bubble formation.
 - 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, being careful to avoid bubble formation.
 - Position 4 = Snap a BD MAX Conical Tube into Position 4. Pipette 12.5 µL of user-supplied master mix, primer and probe mixture 2 (at a final concentration of 2X) into the BD MAX Conical Tube in Position 4, being careful to avoid bubble formation.
- i) **Dual Master Mix: Concentrated Lyophilized MM with Rehydration Buffer (Type 5):**
- 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 40 µL of user-supplied rehydration buffer into the BD MAX Conical Tube in Position 3, being careful to avoid bubble formation.
 - Position 4 = Snap a BD MAX Conical Tube containing user-supplied lyophilized master mix in Position 4.
6. Click on the Run icon, then Inventory. Enter the kit lot number for the BD MAX ExK DNA-1 (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-1 (Plasma/Serum) [4-Snap]>** if testing plasma or serum specimens, or **<ExK DNA-1 (Urine) [4-Snap]>** if testing neat urine.
- Note: Take care to select the correct assay from the pull down menu as the default lysis temperatures differ between Plasma/Serum and Urine specimens. The default lysis temperature for Plasma/Serum is 37 °C whereas the default lysis temperature for Urine is 62 °C.**
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 to 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 into 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 up to 24 samples.
 - The BD MAX System will automatically select the position and row on the BD MAX PCR Cartridge for each run. BD MAX PCR Cartridges may be used multiple times until all lanes have been utilized.
 - To maximize use of BD MAX PCR Cartridges, using 2000 Sample Mode, select Run Wizard under the Worklist tab for lane assignments.
 - Consult the BD MAX System User's Manual³ for more details.

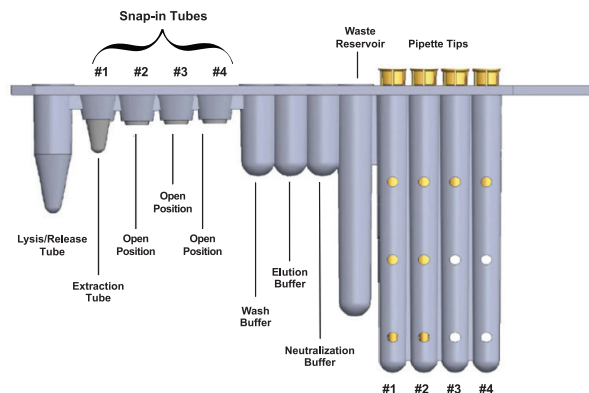


Figure 1: BD MAX Open System Unitized Reagent Strip Configuration

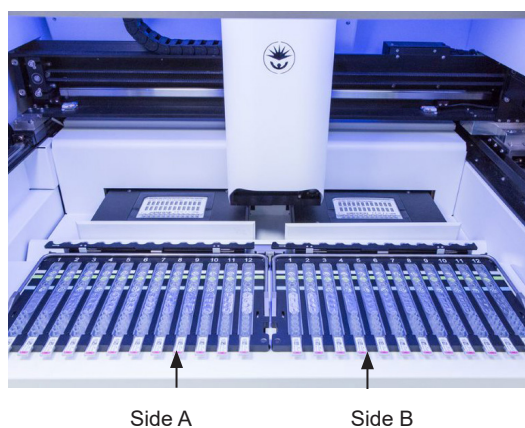


Figure 2: BD MAX System

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

- The BD MAX ExK DNA-1 can only be used on the BD MAX System by trained laboratory personnel.
- Use of the BD MAX ExK DNA-1 for clinical specimen types other than those specified have not been validated.
- Plasma obtained from blood anticoagulated by methods other than sodium citrate and EDTA have not been validated.
- Use of BD MAX ExK DNA-1 for neat urine specimens has only been validated with a lysis temperature of 62 °C. Select **<ExK DNA-1 (Urine) [4-Snap]>** from the pull down menu of the Worklist, as selection of **<ExK DNA-1 (Plasma/Serum) [4-Snap]>** will result in an incorrect lysis temperature of 37 °C.
- 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 Life Sciences, Sparks, MD 21152 USA.

Change History

Revision	Date	Change Summary
(08)	2018-06	Updated BD MAX System Operation section. Updated Figure 1.
(09)	2020-06	Converted printed instructions for use to electronic format and added access information to obtain the document from bd.com/e-labeling. Added detail to Materials and Reagents section. Made clarification in Warning and Precautions. Updated Figure 2. Made typographical edits.



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Use by / Използвайте до / Spotřebujte do / Brug før / Verwendbar bis / Χρήση έως / Usar antes de / Kasutada enne / Date de péremption / 사용 기한 / Upotrijebiti do / Felhasználhatóság dátuma / Usare entro / Дейін пайдалануға / Naudokite iki / Izlietot līdz / Houdbaar tot / Brukes for / Stosować do / Prazo de validade / A se utiliza până la / Исползовать до / Použite do / Upotrebiti do / Använd före / Son kulanma tarihi / Використати до / 使用截止日期
 YYYY-MM-DD / YYYY-MM (MM = end of month)
 GTT-MM-DD / GTT-MM (MM = kraj na meseca)
 RRRR-MM-DD / RRRR-MM (MM = konec měsíce)
 AAAA-MM-DD / AAAA-MM (MM = slutning af måned)
 JJJ-MM-TT / JJJ-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)
 GGG-MM-DD / GGG-MM (MM = kraj mjeseca)
 ÉÉÉÉ-HH-NN / ÉÉÉÉ-HH (HH = hónap utolsó napja)
 AAAA-MM-GG / AAAA-MM (MM = fine mese)
 ЖОЖЖ-АА-КК / ЖОЖЖ-АА / (АА = айдың соңы)
 YYYY-MM-DD/YYYY-MM (MM = 월말)
 MMMM-MM-DD / MMMM-MM (MM = mēnesio pabaiga)
 GGG-MM-DD/GGG-MM (MM = mēneša beigas)
 JJJ-MM-DD / JJJ-MM (MM = einde maand)
 AAAA-MM-DD / AAAA-MM (MM = slutten av månaden)
 RRRR-MM-DD / RRRR-MM (MM = koniec miesiąca)
 AAAA-MM-DD / AAAA-MM (MM = fim do mês)
 AAAA-L-L-ZZ / AAAA-L-L (LL = sfârșitul lunii)
 GTT-MM-DD / GTT-MM (MM = конец месяца)
 RRRR-MM-DD / RRRR-MM (MM = koniec miesiąca)
 GGG-MM-DD / GGG-MM (MM = kraj meseca)
 AAAA-MM-DD / AAAA-MM (MM = slutet av månaden)
 YYYY-AA-GG / YYYY-AA (AA = ayın sonu)
 PPP-MM-DD / PPP-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 / Katalogusszám / Numero di catalogo / Каталог номер / 카탈로그 번호 / Katalog / 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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In Vitro Diagnostic Medical Device / Медицински уред за диагностика ин витро / Lékařské zařízení určené pro diagnostiku in vitro / In vitro diagnostisk medicinsk anordning / Medizinisches In-vitro-Diagnostikum / In vitro διαγνωστική ιατρική συσκευή / Dispositivo médico para diagnóstico in vitro / In vitro diagnostika meditsinaparatuur / Dispositif médical de diagnostic in vitro / Medicinska pomagala za In Vitro Diagnostiku / In vitro diagnostikai orvosi eszköz / Dispositivo medicale per diagnostica in vitro / Жасанды жағдайда жүргізілетін медициналық диагностика аспабы / In Vitro Diagnostic 의료 기기 / In vitro diagnostikos prietaisai / Medicinska ierices, ko lieto in vitro diagnostika / Medisch hulpmiddel voor in-vitro diagnostiek / In vitro diagnostisk medisinsk utstyr / Urządzenie medyczne do diagnostyki in vitro / Dispositivo médico para diagnóstico in vitro / Dispositiv medical pentru diagnostic in vitro / Медицинский прибор для диагностики in vitro / Medicinska pomôcka na diagnostiku in vitro / Medicinski uređaji za in vitro dijagnostiku / Medicinteknisk produkt för in vitro-diagnostik / In Vitro Diagnostik Tibbi Cihaz / Медицинский прибор для диагностики in vitro / 体外诊断医疗设备



Temperature limitation / Температурни ограничения / Teplotní omezení / Temperaturbegrænsning / Temperaturbegrenzung / Περιορισμοί θερμοκρασίας / Limitación de temperatura / Temperaturi piirang / Limites de température / Dozvoljena temperatura / Hőmérsékleti határ / Limiti di temperatura / Температураны шектеу / 온도 제한 / Laikymo temperatūra / Temperatūras ierobežojumi / Temperaturilimiet / Temperaturbegrensning / Ograniczenie temperatury / Limites de temperatura / Limite de temperatură / Ограничения температуры / Ograničenje toploty / Ograničenje temperature / Temperaturgräns / Sicaklık sinirlamasi / 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 number / Batch-kode (parti) / Kod partii (serie) / Código do lote / Cod de serie (Lot) / Код партии (not) / Kód série (šarža) / Kod serije / Partinummer (Lot) / Parti Kodu (Lot) / Код партії / 批号 (亚批)



Contains sufficient for <n> tests / Съдържанието е достатъчно за <n> теста / Dostatečné množství pro <n> testů / Indeholder tilstrækkeligt 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> тесттегі үшін жеткілікті / <n> 테스트가 충분히 포함됨 / Pakankamas kiekis atlikti <n> testų / Satur pietiekami <n> pārbaudēm / Inhoud voldoende voor <n> testen / Inholder tilstrækkelig til <n> tester / Zawiera ilość wystarczającą do <n> testów / Conteúdo suficiente para <n> testes / Conținut suficient pentru <n> teste / Достаточно для <n> тестов(а) / Obsah vystačí na <n> testov / Sadržaj dovoljan za <n> testova / Innehåller tillräckligt för <n> analyser / <n> test için yeterli miktarda içerir / Вистачить для аналізів: <n> / 足够进行 <n> 次检测



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	Control / Контролно / Kontrola / Kontrol / Kontrolle / Μάρτυρας / Kontroll / Contrôle / Controlla / Бақылау / 컨트롤 / Kontrolè / Kontrolle / Controle / Controlo / Контроль / kontroll / Контроль / 对照
	Positive control / Положительный контроль / Pozitivní kontrola / Positiv kontrol / Positive Kontrolle / Θετικός μάρτυρας / Control positivo / Positiivne kontroll / Contrôle positif / Pozitivna kontrola / Pozitiv kontroll / Controlla positivo / Оң бақылау / 양성 컨트롤 / Teigiama kontrolė / Pozitivá kontrola / Positieve controle / Kontrola dodatnia / Controlo positivo / Control pozitiv / Положительный контроль / Pozitif kontrol / Позитивний контроль / 阳性对照试剂
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	Method of sterilization: ethylene oxide / Метод на стерилизация: этиленов оксид / Způsob sterilizace: ethylenoxid / Steriliseringmetode: ethylenoxid / Sterilisationsmethode: Ethylenoxid / Μέθοδος αποστείρωσης: αιθυλενοξείδιο / 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 / Стерилизация әдісі – этилен тотығы / 소독 방법: 에틸렌옥사이드 / Sterilizavimo būdas: etileno oksidas / Sterilizēšanas metode: etilēnoksīds / Gesteriliseerd met behulp van ethyleenoxide / Steriliseringmetode: etylenoksid / Metoda sterylizacji: tlenek etylu / Método de esterilização: óxido de etileno / Metodă de sterilizare: oxid de etilenă / Метод стерилизации: этиленоксид / Metoda sterilizácie: etylenoxid / Metoda sterilizacije: etilen oksid / Steriliseringmetod: etenoxid / Sterilizasyon yöntemi: etilen oksit / Метод стерилизації: этиленоксидом / 灭菌方法: 环氧乙烷
	Method of sterilization: irradiation / Метод на стерилизация: ирадиация / Způsob sterilizace: záření / Steriliseringmetode: 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 / Sterilizavimo būdas: radiacija / Sterilizēšanas metode: apstarošana / Gesteriliseerd met behulp van bestraling / Steriliseringmetode: bestraling / Metoda sterylizacji: napromienianie / Método de esterilização: irradiação / Metodă de sterilizare: iradiere / Метод стерилизации: облучение / Metoda sterilizácie: ožarovanie / Metoda sterilizacije: ozračevanje / Steriliseringmetod: strålning / Sterilizasyon yöntemi: irradyasyon / Метод стерилизації: опроміненням / 灭菌方法: 辐射
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	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 юғарғы етінген жоғарғы шегі / 상한 온도 / Aukščiausia laikymo temperatūra / Augšējā 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 temperatury / Øvre temperaturgräns / Sicaklık üst sınırı / Максимальна температура / 温度上限
	Keep dry / Пазете сухо / Skladujte v suchém prostredí / Opbevaras tørt / Trockklagen / Φυλάξτε το στεγνό / Mantener seco / Hoida kuivas / Conserver au sec / Držati na suhom / Száraz helyen tartandó / Tenere all'asciutto / Құрғақ күйінде ұста / 건조 상태 유지 / Laikykite sausi / Uzglabāt sausu / Droog houden / Holdes tørt / Przechowywać w stanie suchym / Manter seco / A se feri de umezeală / Не допускать попадания влаги / Uchovávajte v suchu / Držite na suvom mestu / Förvaras tørt / Kuru bir şekilde muhafaza edin / Берегти від вологості / 请保持干燥
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	Peel / Обелете / Otefete zde / Åbn / Abziehen / Αποκολλήστε / Desprendre / Koorida / Décoller / Otvoriti kinni / Húzza le / Staccare / Ўстиңгі қабатын алып таста / 벗기 / Plešti čia / Atimmet / Schillen / Trek w / Oderwac / Destacar / Se dezlipeste / Отклеить / Odrhните / Oljuštiti / Dra isär / Ayırma / Відклеїти / 撕下
	Perforation / Перфорация / Perforace / Perforering / Διείσθηση / Perforación / Perforatsioon / Perforacija / Perforálás / Perforazione / Тесик тесу / 절취선 / Perforacija / Perforância / Perforatie / Perforacia / Perfuração / Perforare / Перфорация / Perforácia / Perforasyon / Перфорация / 穿孔
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	Cut / Срежете / Odstřihněte / Klip / Schneiden / Κόψτε / Cortar / Lõigata / Découper / Reži / Vágja ki / Tagliare / Keciңiz / 잘라내기 / Kirpti / Nogriez / Knippen / Kutt / Odciać / Cortar / Decupați / Отрезать / Odstřihněte / Iseći / Klipp / Kesme / Pozрізати / 剪下
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	µL/test / µL/тест / µL/Test / µL/εξέταση / µL/prueba / µL/teszt / µL/테스트 / мкл/тест / µL/tyrimas / µL/pārbaude / µL/teste / мкл/анализ / µL/검출



Keep away from light / Πазете от светлина / Nevystavujte světlu / 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 svetla / Fény nem érheti / Tenere al riparo dalla luce / Қараңғыланған жерде ұста / 빛을 피해야 함 / Laikyti atokiau nuo šilumos šaltinių / Sargāt no gaismas / Niet blootstellen aan zonlicht / Må ikke utsettes for lys / Przechowywać z dala od źródeł światła / Manter ao abrigo da luz / Feriți de lumină / Хранить в темноте / Uchovávať mimo dosahu svetla / Držite dalje od svetlosti / Får ej utsättas för ljus / Işıktan uzak tutun / Беретти від дії світла / 请远离光线



Hydrogen gas generated / Образуван е водород газ / Možnost úniku plynného vodíku / Frembringer hydrogengas / Wasserstoffgas erzeugt / Δημιουργία αερίου υδρογόνου / Producción de gas de hidrógeno / Vesinikgaasi tekitatud / Produit de l'hydrogène gazeux / Sadržaj hidrogena / Hidrogén gázt fejleszt / Produzione di gas idrogeno / Газтөктөс сутері пайда болды / 수소 가스 생성됨 / Išskiria vandenilio dujas / Rodas ūdenradis / Waterstofgas gegenereerd / Hydrogengass generert / Powoduje powstawanie wodoru / Produção de gás de hidrogénio / Generare gaz de hidrogen / Выделение водорода / Vyrobene použitím vodíka / Oslobada se vodonik / Genererad vätegas / Açığa çıkan hidrojen gazı / Реакція з виділенням водню / 会产生氢气



Patient ID number / ИД 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 paziente / Пациенттің идентификациялық нөмірі / 환자 ID 번호 / Paciento identifikavimo numeris / Pacienta ID numurs / Identificatienummer van de patiënt / Pasientens ID-nummer / Numer ID pacienta / 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. / Εύθραστο. Χειριστείτε το με προσοχή. / Frágil. Manipular con cuidado. / Örn, käsitsege ettevaatlikult. / Fragile. Manipuler avec précaution. / Lomljivo, rukujte pažljivo. / Törékeny! Óvatosan kezelendő. / Fragile, maneggiare con cura. / Сыңғыш, абайлап пайдаланыңыз. / 조심 깨지기 쉬운 처리 / Trapu, elkités atsargiai. / Trausls; rikoties uzmanīgi / Breekbaar, voorzichtig behandelen. / Ømtåligh, 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 Taşıyın. / Тендітна, звертатися з обережністю / 易碎，小心轻放

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CA	+1 855 805 8539	RO 0800 895 084
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LI	+31 20 796 5692	VN 122 80297



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

GeneOhm Sciences Canada, Inc.
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