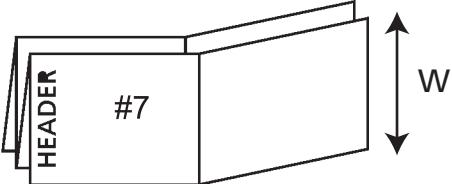
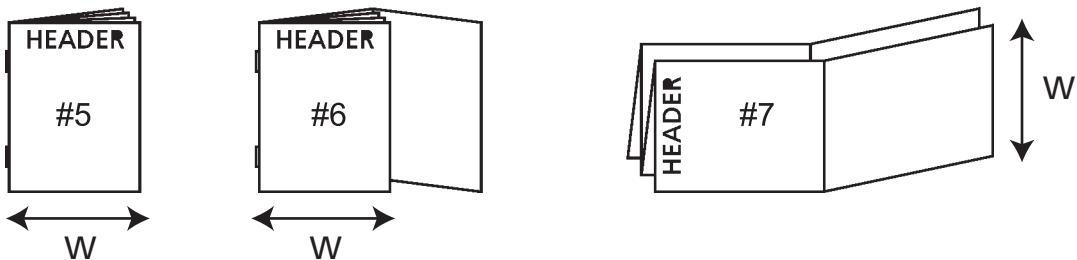
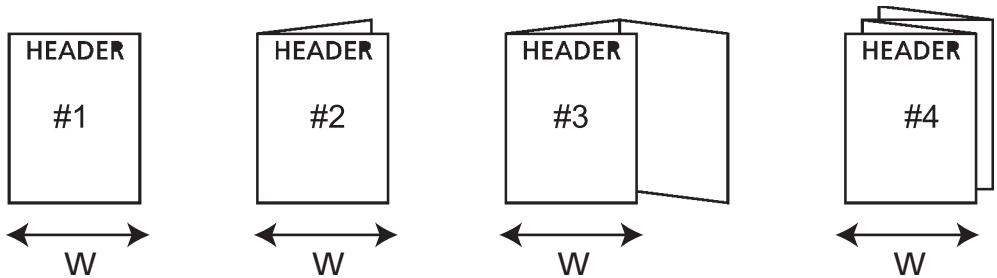


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02	03	9072-17

## NOTES:

1. BD Catalog Number: 240917
2. Blank (Sheet) Size: Length: 6.25" Width: 10.5"
3. Number of Pages: 12 Number of Sheets: 3
4. Page Size: Length: 6.25" Width: 5.25" Final Folded Size: 5.25" x 3.125"
5. Ink Colors: No. of Colors: 2 PMS#: 032 Red, Standard Black
6. Printed two sides: Yes  No
7. Style (see illustrations below): # 5



8. Vendor Printed  Online/In House Printed  Web
9. See specification control no. N/A for material information.
10. Graphics are approved by Becton, Dickinson and Company. Supplier has the responsibility for using the most current approved revision level.

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Proofer	PROOFING APPROVED BY By Natalie Morio at 8:08 am, Feb 07, 2017		
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Part Number:	L010796	Category and Description	Sheet: 1 of 13
		Package Insert, BBL Streptocard Acid Latex Test	Scale: N/A
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# BD BBL™ Streptocard™ Acid Latex Test Kit (for *in vitro* diagnostic use)

R<sub>x</sub> Only



L010796(03)  
2017-02

## INTENDED USE

The BD BBL™ Streptocard™ Acid Latex Test Kit provides a rapid platform for the serological identification of beta-haemolytic streptococci belonging to Lancefield groups A, B, C, D, F and G.

## SUMMARY AND EXPLANATION

Clinical, epidemiological and microbiological studies have conclusively shown that the diagnosis of streptococcal infections based on clinical symptoms always requires microbiological verification.<sup>4</sup> Beta-haemolytic streptococci are the most frequently isolated human pathogens among the representatives of the genus *Streptococcus*. Nearly all the beta-haemolytic streptococci possess specific carbohydrate antigens (streptococcal group antigens). Lancefield showed that these antigens can be extracted in soluble form and identified by precipitation reactions with homologous antisera. Different procedures for extraction of streptococcal antigens are currently in use.<sup>1,2,6,7,10,11</sup> The BD BBL Streptocard Acid Latex Test Kit is based on liberation of specific antigen from bacteria cell walls by modified nitrous acid extraction. The extracted antigen in conjunction with latex agglutination offers a rapid, sensitive and specific method for identification of streptococcal groups A, B, C, D, F and G from primary culture plates.

## PRINCIPLE OF THE TEST

The BD BBL Streptocard Grouping method involves chemical extraction of group specific carbohydrate antigens using specially developed nitrous acid extraction reagents. The Extraction Reagents 1 and 2 provided in the kit contain a chemical substance able to extract the streptococcal group specific antigens at room temperature. Extraction Reagent 3 contains a neutralizing solution. The neutralized extracts can be easily identified using blue polystyrene latex particles sensitized with purified group specific rabbit immunoglobulins. These blue latex particles agglutinate very strongly in the presence of homologous antigen and will not agglutinate when homologous antigen is absent.

## MATERIALS PROVIDED

Each kit is sufficient for 50 tests. Materials are supplied ready for use.

- **BD BBL Streptocard Acid Test Latex:** Each dropper bottle contains 2.5 mL of blue latex particles coated with purified rabbit antibodies to Lancefield groups A, B, C, D, F or G. The blue latex particles are suspended in a pH 7.4 buffer containing 0.098% sodium azide as a preservative.
- **BD BBL Streptocard Acid Positive Control:** One dropper bottle containing 2.5 mL of ready to use polyvalent antigens extracted from inactivated streptococci of Lancefield groups A, B, C, D, F and G.
- **BD BBL Streptocard Acid Extraction Reagent 1:** One dropper bottle containing 2.7 mL of the reagent with 0.098% sodium azide as a preservative.
- **BD BBL Streptocard Acid Extraction Reagent 2:** One dropper bottle containing 2.7 mL of extraction reagent 2.

- **BD BBL Streptocard Acid Extraction Reagent 3:** Two dropper bottles each containing 6.8 mL of the reagent with 0.098% sodium azide as a preservative.
- Test Cards
- Mixing sticks
- Instructions for use

#### MATERIALS REQUIRED BUT NOT PROVIDED

- Inoculating loop or needle
- Pasteur pipettes
- 12 x 75 mm test tubes
- Timer

#### STABILITY AND STORAGE

All kit components should be stored at 2–8 °C. **Do not freeze.** Reagents stored under these conditions will be stable until the expiry date shown on the product label.

#### WARNINGS AND PRECAUTIONS

240922, 240923, 240926, 240927, 240929, 240930

##### 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.

240925

##### Warning



**H302** Harmful if swallowed. **H315** Causes skin irritation. **H319** Causes serious eye irritation. **H400** Very toxic to aquatic life.

**P280** Wear protective gloves/protective clothing/eye protection/face protection. **P305+P351+P338** IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. **P301+P312** IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. **P302+P352** IF ON SKIN: Wash with plenty of soap and water. **P501** Dispose of contents/container in accordance with local/regional/national/international regulations.

## Warning



**H302** Harmful if swallowed. **H315** Causes skin irritation. **H319** Causes serious eye irritation.

**P280** Wear protective gloves/protective clothing/eye protection/face protection. **P305+P351+P338** IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. **P301+P312** IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. **P302+P352** IF ON SKIN: Wash with plenty of soap and water. **P501** Dispose of contents/container in accordance with local/regional/national/international regulation

## Danger



**H302** Harmful if swallowed. **H314** Causes severe skin burns and eye damage. **H318** Causes serious eye damage.

**P280** Wear protective gloves/protective clothing/eye protection/face protection. **P303+P361+P353** IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. **P301+P330+P331** IF SWALLOWED: rinse mouth. Do NOT induce vomiting. **P405** Store locked up. **P501** Dispose of contents/container in accordance with local/regional/national/international regulations.

## PRECAUTIONS

1. Do not use the reagents after the expiration date shown on the product label.
2. Some reagents contain a small amount of sodium azide. Sodium azide can react explosively with copper or lead plumbing if allowed to accumulate. Although the amount of sodium azide in the reagents is minimal, large quantities of water should be used if the reagents are flushed down the sink.
3. The extraction reagents contain a mildly caustic agent. In case of skin contact, immediately wash the area with soap and copious amounts of water. If the reagent comes into contact with an eye, flush with water for at least 15 minutes.
4. Universal precautions should be taken in handling, processing and discarding all clinical specimens. All test materials should be considered potentially infectious during and after use and should be handled and disposed of appropriately.
5. The kit is intended for *in vitro* diagnostic use only.
6. The procedures, storage conditions, precautions and limitations specified in these directions must be adhered to in order to obtain valid test results.
7. These reagents contain materials of animal origin and should be handled as a potential carrier and transmitter of disease.

## SPECIMEN COLLECTION AND PREPARATION OF CULTURES

For specific procedures regarding specimen collection and preparation of primary cultures refer to a standard microbiology textbook. A fresh (18–24 hour) culture on blood agar should be used. One to four large colonies should be adequate for grouping; however if the colonies are small, an increased number of colonies (loopful) should be used.

## TEST PROCEDURE

All components should be at room temperature prior to use.

1. Re-suspend the test latex reagents by gently inverting the dropper bottle several times. Examine the dropper bottles to ensure that the latex particles are properly suspended before use. Do not use if the latex fails to re-suspend.
2. Label one test tube for each isolate to be tested.
3. Add 1 drop of Extraction Reagent 1 to each tube.
4. Select 1–4 beta-haemolytic colonies using a disposable loop or needle and suspend them in the Extraction Reagent 1. If the colonies are small, pick several well isolated colonies to be tested such that the Extraction Reagent 1 solution becomes turbid. In all cases the streptococcal colonies should be picked from an area which will afford the lowest probability of contamination with another organism.
5. Add 1 drop of Extraction Reagent 2 to each tube.
6. Mix the reaction by gently tapping the tube with a finger for 5–10 seconds.
7. Add 5 drops of Extraction Reagent 3 to each tube and mix by gently tapping the tube with a finger for 5–10 seconds.
8. Dispense one drop of each group latex reagent onto separate circles on separate test cards labelled for each isolate being tested.
9. Using a Pasteur pipette, for each test place one drop of extract beside each drop of latex reagent.
10. Mix the latex and the extract with the sticks provided, using the complete area of the circles. A new stick should be used with each test circle.
11. Gently rock the cards allowing the mixture to flow slowly over the entire test ring area.
12. Observe for agglutination for up to one minute.

## QUALITY CONTROL PROCEDURES

The routine quality control procedure for each **BD BBL Streptocard** lot involves testing the latex and extraction reagents with each streptococcal group A, B, C, D, F and G using the ATCC® strains or equivalent as listed in this section. The extract from these strains will agglutinate with the homologous latex reagent. The polyclonal **BD BBL Streptocard** Acid Positive Control is used to test the individual latex reagents.

Organism	Lancefield Group	Reference
<i>Streptococcus pyogenes</i>	Group A	ATCC 19615
<i>Streptococcus agalactiae</i>	Group B	ATCC 12386
<i>Streptococcus dysgalactiae</i> subsp. <i>equisimilis</i>	Group C	ATCC 12388
<i>Enterococcus faecalis</i>	Group D	ATCC 19433
<i>Streptococcus</i> sp. type 2	Group F	ATCC 12392
<i>Streptococcus dysgalactiae</i> subsp. <i>equisimilis</i>	Group G	ATCC 12394

## INTERPRETATION OF RESULTS

**Positive result:** Rapid strong agglutination of the blue latex particles within one minute with one of the latex reagents indicates the specific identification of the streptococcal isolate. A weak reaction with a single latex reagent should be repeated using a heavier inoculum. The repeat test is considered positive if agglutination occurs with only one of the latex reagents. Figure 1 on page 6 illustrates a suggested scheme for the grouping of streptococci.

**Negative result:** No agglutination of the latex particles. If traces of granulation are seen in the test circle the test should also be regarded as negative.

**Inconclusive result:** If weak clumping or a non-specific reaction (stringiness) is present in the test circle after one minute, the test should be repeated using a fresh subculture. If the same result is seen after retesting, biochemical testing should be performed to identify the isolate.

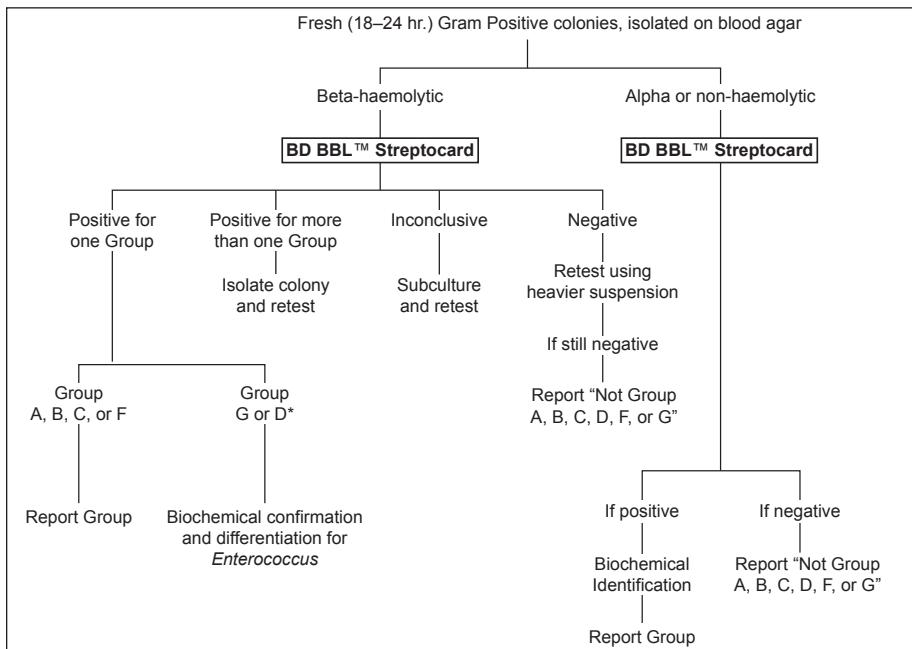
**Non-specific result:** On a rare occasion you may see agglutination with more than one group. If this occurs please check the purity of the culture used to perform the test. If it looks pure, repeat the test and confirm the identification of the isolate with biochemical testing.

## LIMITATIONS OF THE PROCEDURE

1. False negative and false positive results can occur if the kit is not used as directed and if an inadequate amount of culture is used for extraction.
2. The kit is intended for use in identification of beta-haemolytic streptococci only. If alpha or non-haemolytic streptococci are tested, the identification should be confirmed by biochemical testing<sup>5,9</sup> (Refer to the suggested scheme for grouping streptococci).
3. False positive reactions have been known to occur with organisms from unrelated genera, e.g. *Escherichia coli*, *Klebsiella* or *Pseudomonas*.<sup>3,8</sup> These are likely to non-specifically agglutinate all of the latex reagents.
4. Some strains of Group D streptococci have been found to cross react with Group G antisera; these strains can be confirmed as Group D by the bile-esculin test. Some strains of *Enterococcus faecium* and *Streptococcus bovis* might be difficult to be grouped.
5. *Listeria monocytogenes* may cross react with the Group B and G Streptococcal latex reagents. The catalase test may be performed to distinguish between *Listeria*, which are catalase-positive, and streptococci, which are catalase-negative. Gram staining and motility testing may be performed as further aids to differentiation.

6. Some strains of *Streptococcus milleri* (*Streptococcus anginosus*) typically non-haemolytic possess A, C, F or G antigens and can give positive reaction with Strep A, C, F or G latex reagents. Morphology on blood agar and biochemical testing should be used to identify these organisms.

**Figure 1: Suggested Scheme For Grouping Streptococci**



\* Some strains of group D have been found to cross-react with group G antisera.  
 [Harvey, C. L. and McIlmurray, M.B (1984) Eur. J. Clinical Microbiol,10,641].

## PERFORMANCE CHARACTERISTICS

### A. Cross-reactivity studies:

The **BD BBL Streptocard** Acid Latex Test Kit was tested for cross-reactivity using 33 ATCC reference strains. The kit successfully grouped all streptococci containing Lancefield groups A, B, C, D, F and G (N=16). No cross-reactivity was observed during the testing of other streptococcal strains (n=7) nor of other non-streptococcal organisms (n=10).

### B. Clinical performance studies:

1. The **BD BBL Streptocard** Acid Latex Test Kit was evaluated as part of a comparison of five commercially available streptococcal grouping kits. The study was performed by S. Davies et. al. at the Northern General Hospital in Sheffield, England. All of the kits were challenged with a panel of 302 beta-haemolytic streptococci composed of 64, 67, 44, 55, 56 and 4 strains of Lancefield groups A, B, C, D, G and F respectively. The results showed that 12 of the strains failed to group with any of the kits tested. Of the remaining 290 strains the **BD BBL Streptocard** Acid Latex Test Kit correctly identified 286 (98.6%). The authors concluded that the **BD BBL Streptocard** Acid Latex Test Kit proved to be both accurate and rapid, with a sensitivity and specificity of 99% and 100% respectively. Furthermore, the average time to agglutination was substantially less than that achieved by three of the other four kits evaluated. Data available upon request.
2. A second performance study was carried out at a Health Centre in Ontario, Canada. In this study, 111 primary cultures were included (110 tested, 1 inadequate). All the strains were originally grouped by Lancefield precipitation reactions. All group D were further biochemically confirmed using a BE (bile esculin) and PYR (pyrrolidonyl aminopeptidase) assay protocol. The primary cultures were tested in parallel using the **BD BBL Streptocard** Acid Latex Test Kit and an alternative grouping kit. In this study, the overall agreement between **BD BBL Streptocard** and Lancefield results occurred with 109 of 110 isolates tested (99%), while overall agreement between the alternative kit and Lancefield results occurred with 106 of 110 isolates tested (96.3%). The 110 primary isolates used in this study included 15 group A, 40 group B, 13 group C, 4 group D, 11 group F, 12 group G and 15 non-groupable strains.

## AVAILABILITY

### Cat. No. Description

240917	<b>BD BBL™ Streptocard™</b> Acid Latex Test Kit, 50 Tests.
240918	<b>BD BBL™ Streptocard™</b> Enzyme Latex Kit, 50 Tests.
240923	<b>BD BBL™ Streptocard™</b> Acid Test Latex A, one 2.5 mL bottle.
240922	<b>BD BBL™ Streptocard™</b> Acid Test Latex B, one 2.5 mL bottle.
240926	<b>BD BBL™ Streptocard™</b> Acid Test Latex C, one 2.5 mL bottle.
240929	<b>BD BBL™ Streptocard™</b> Acid Test Latex D, one 2.5 mL bottle.
240930	<b>BD BBL™ Streptocard™</b> Acid Test Latex F, one 2.5 mL bottle.
240927	<b>BD BBL™ Streptocard™</b> Acid Test Latex G, one 2.5 mL bottle.
240925	<b>BD BBL™ Streptocard™</b> Acid Extraction Reagents 1, 2 and 3, (Reagent 1, 1 x 2.7 mL bottle; Reagent 2, 1 x 2.7 mL bottle; Reagent 3, 2 x 6.8 mL bottles).
240931	<b>BD BBL™ Streptocard™</b> Acid Positive Control, one 2.5 mL bottle.
240928	<b>BD BBL™ Streptocard™</b> Test Cards, box of 48.

## REFERENCES

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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](http://www.bd.com).



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YYYY-MM-DD / YYYY-MM (MM = end of month)  
ГГГГ-ММ-ДД / ГГГГ-ММ (ММ = края на месеца)

RRRR-MM-DD / RRRR-MM (MM = konec měsíce)

AAAA-MM-DD / AAAA-MM (MM = slutning af måneden)

JJJJ-MM-TT / JJJJ-MM (MM = Monatsende)

EEEE-MM-NN / EEEE-MM (MM = τέλος του μήνα)

AAAA-MM-DD / AAAA-MM (MM = fin del mes)

AAAA-KK-PP / AAAA-KK (KK = кuu lopp)

AAAA-MM-JJ / AAAA-MM (MM = fin du mois)

GGGG-MM-DD / GGGG-MM (MM = kraj mjeseca)

ЕЕЕЕ-НН-НН / ЕЕЕЕ-НН (НН = hónap utolsó napja)

AAAA-MM-GG / AAAA-MM (MM = fine mese)

ЖОҚОҚ-АА-КК / ЖОҚОҚ-АА (АА = айдық соңы)

YYYY-MM-DD/YYY-MM/MM (MM = 월별)

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 = slutet av måneden)

RRRR-MM-DD / RRRR-MM (MM = koniec miesiąca)

AAAA-MM-DD / AAAA-MM (MM = fin do měsíce)

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 mesecea)

AAAA-MM-DD / AAAA-MM (MM = slutet av månaden)

YYYY-AA-GG / YYYY-AA (AA = aypın sonu)

PPPP-MM-ДД / PPPP-MM (MM = киңеъ мисяця)

YYYY-MM-DD / YYYY-MM (MM = 月末)



Catalog number / Каталожен номер / Katalogové číslo / Katalognummer / Αριθμός καταλόγου / Número de catálogo / Kataloeginumber / Numéro catalogue / Kataloški broj / Katalóggusszám / Numero di catalogo / Каталог номери / 카탈로그 번호 / Katalogo / numeris / Kataloga numurs / Catalogus nummer / Numer katalogowy / Număr de catalog / Номер по каталогу / Katalógové číslo / Kataloški broj / Katalog numerası / Номер за каталогом / 目录号



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In Vitro Diagnostic Medical Device / Медицински уред за диагностика и витро / Lékařské zařízení určené pro diagnostiku in vitro / In vitro diagnostisk medicinsk anordning / Medizinisches In-vitro-Diagnostikum / In vitro биоаналитик яткыл өзүккөн / Dispositivo médico para diagnóstico in vitro / In vitro diagnostika medische apparatuur / Dispositif médical de diagnostic in vitro / Medicinska pomagala za In Vitro Dijagnostiku / In vitro diagnostikai orvosi eszköz / Dispositivo medicele per diagnostica in vitro / Жасанды жағдайда жүргізетін медициналық диагностика аспабы / In Vitro Diagnostic 의료 기기 / In vitro diagnostikos prietaisais / Medicinas ierīces, ko lieto in vitro diagnostikā / Medisch hulpmiddel voor in-vitro diagnostiek / In vitro diagnostisk medisinskt ustyr / Urządzenie medyczne do diagnostyki in vitro / Dispositivo médico para diagnóstico in vitro / Dispositiv medical pentru diagnostic in vitro / Медицински прибор для диагностики in vitro / Medicinska pomôcka na diagnostiku in vitro / Medicinski uređaj za in vitro diagnostiku / Medicinteknisk produkt for in vitro-diagnostik / In Vitro Diagnostik Tibbi Cihaz / Медицинский пристрой для диагностики in vitro / 体外诊断医疗设备



Temperature limitation / Температурни ограничения / Teplotni omrežni / Temperaturbegrenzung / Temperatúrny obmedzenie / Θερμοκρασίας / Limitación de temperatura / Temperatuuri piirang / Limites de température / Dozvoljena temperatura / Hörmérési határ / Limiti di temperatura / Температурные шекпу / 운도 제한 / Laikymo temperatūra / Temperatūras ierobežojumi / Temperaturumreit / Temperaturbegrenzung / Ograniczenie temperatury / Limites de temperatura / Ограничение температуры / Ohranjanie teploty / Ograničenje temperature / Temperaturgrāns / Sticakilim sınırlaması / Обмеження температури / Temperaturen begrenzung / Ограничение температура / Temperaturgrāns / Sticakilim sınırlaması / Обмеження температури / 温度限制

**LOT** Batch Code (Lot) / Код на партидата / Kód (číslo) Šárže / Batch-kode (lot) / Batch-Code (Charge) / Κωδικός παρτίδας (τοπρίδα) / Código de lote (lote) / Parti kood / Numéro de lot / Lot (lot) / テーブル száma / Código batch (lotto) / Топтама коды / پارتیسون (پارتی) / Partijos numeris (LOT) / Partijas kods (laideņi) / Lot number / Batch-koda (parti) / Kod parti (seria) / Código do lote / Cod de serie (Lot) / Kod partii (parti) / Kod série (šárza) / Kod serie / Partnummer (Lot) / Parti Kodu (Lot) / Код партii / 批号 (アバ)



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For US: "For Investigational Use Only"



Lower limit of temperature / Долни лимит на температурата / Dolni hranice teploty / Nedre temperaturgrænse / Temperaturuntergrenze / Катошко ограничение на температурата / Limite inferior de temperatura / Aluminie temperatuurpij / Limite inférieure de température / Najnižja dozvoljena temperatura / Alsoš hómeréseklet hárta / Limite inferior de temperatura / Температурни ограничения / Теменгри рускаг шери / 하한 온도 / Zemljausiai laikymo temperatūra / Temperaturas zemaičių robežė / Laagste temperatuurlimiet / Nedre temperaturgrenzen / Dolna granična temperatura / Limit mínimo da temperatura / Limită minimă de temperatură / Нижните предел температура / Spodnja hranica teploty / Donja granica temperature / Nedre temperaturgrænse / Sicakliklî ait sının / Minimumalna tempraturanın / 温度下限

CONTROL

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

**CONTROL** -

Positive control / Позитивен контрол / Pozitívna kontrola / Positive kontroll / Positive Kontrolle / Επιτελής μόρφωσης / Control positivo / Positive Kontroll / Contrôle positif / Pozitivna kontrola / Pozitív kontroll / Kontrollo positivo / Оң байқылу / Yesil kontrol / Teigima kontrole / Pozitív kontrole / Positieve controle / Kontrola dodatnia / Control positivo / Control positiv / Положительный контроль / Pozitif kontrol / Позитивният контрол / 阳性对照试剂

CONTROL -

**STERILE** | **EO** Method of sterilization: ethylene oxide / Метод на стерилизация: этиленов оксид / Způsob sterilizace: etylenoxid / Sterilisierungsmetode: ethylenoxid / Sterilisationsmethode: Ethylenoxid / Μέθοδος αποστείρωσης: αιθαλονιξίδιο / Método de esterilización: óxido de etileno / Steriliseerimismetood: etüleenoksidi / Méthode de stérilisation: oxyde d'éthylène / Metoda sterilizacije: etilen oksid / Sterilizálás módszere: etilén-oxid / Metodo di sterilizzazione: ossido di etilene / Стерилизация ёдси – этилен тутыны / 소독 방법: 에틸렌옥사이드 / Sterilizavimo būdas: etileno oksidas / Sterilizācijas metode: etilēnoksīds / Gesteriliseerd met behulp van ethylenoxide / Steriliseringssmetode: etylenoksid / Metoda sterilizacji: etylenoksyd / Metoda de sterilizare: oxid de etilen / Метод стерилизации: этиленоксид / Metoda sterilizacije: etilen oksid / Steriliseringssmetod: etenoxid / Sterilizasyon yöntemi: etilen oksit / Метод стерилазацији: этиленоксидом / 灭菌方法: 环氧乙烷

**STERILE** | **R** Method of sterilization: irradiation / Метод на стерилизация: иридиация / Způsob sterilizace: záření / Sterilisierungsmetode: bestrahlung / Sterilisationsmethode: Bestrahlung / Μέθοδος αποτελέσματος: ακτινοβολία / Méthode de stérilisation: irradiation / Metoda sterilizacije: besugárzáás / Método de sterilización: irradiación / Steriliseerimismetood: kuumien säteily / Sterilizavimo būdas: radiacija / Sterilizācijas metode: apstarošana / Gesteriliseerd met behulp van bestraling / Steriliseringssmetode: bestraling / Metoda sterlizacji: napromienianie / Método de sterilizar: irradiação / Metoda da sterilização: irradiação / Метод стерилизации: облучение / Metoda sterilizacije: ozračenje / Metoda sterilizacije: ozračavanje / Steriliseringssmetod: strålning / Sterilizirajúci výmetem: iradyasyon / Метод стерилазацији: опромінення / 灭菌方法: 辐射

**Biological Risks** / Биологични рискове / Biologické rizika / Biologisk fare / Biogefährdung / Биологички кільчук / Riesgos biológicos / Biologilised riskid / Risques biologiques / Biološki rizik / Biologialag risiko / Rischio biologico / Biologicheskiy tsayekedir / 생물학적 위험 / Biologinis pavojus / Biologische risiko / Biologisk risiko / Zagrożenia biologiczne / Perigo biológico / Riscuri biologice / Биологическая опасность / Biologički riziko / Biološki rizici / Biologisk risk / Biologisk Risiko / Биологични небезпека / 生物学风险

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Upper limit of temperature / Горен лимит на температурата / Horní hranice teploty / Øvre temperaturgrænse / Temperaturobergrenze / Avuretero övre temperaturgräns / Limite superior de temperatura / Ülennine temperaturpiiril / Limite supérieure de température / Gornja dozvoljena temperatura / Felšő hőmérséklet határ / Limite superiore de temperatura / Temperaturgränsen riktar ejtengen johagjára / 상한 온도 / Aukščiausiai laikymo temperatūra / Augšėjā temperatūras robeža / Hoogste temperatuurmeliet / Øvre temperaturgrense / Górná granica temperatury / Limite máximo de temperatura / Верхний предел температуры / Horná hranica teploty / Gornja granična temperatura / Øvre temperaturgrader / Стислік оштук / Максимальна температура / 温度上限

Keep dry / Пазете сухо / Skladujte v suchém prostředí / Opbevares tørt / Trocklagen / Φυλάξτε το στεγνό / Mantener seco / Hoida kuivana / Conserver au sec / Držati na suhom / Száraz helyen tartandó / Tenere all'asciutto / Kurak күйинде ұста / 건조 상태 유지 / Laikykite sausai / Uzglabāt sausai / Droog houden / Holdes tørt / Przechowywać w stanie suchym / Mantener seco / A se feri de imezzeala / Не допускать попадания влаги / Uchovávajte v suchu / Držte na suvom mesteu / Förvaras tørt / Kurak ber şekilde muhafaza edin / Bergergi від вологи / 请保持干燥

Collection time / Время на събиране / Čas odberu / Opsamlingstidspunkt / Entrahmehrzeit / Ήora συλλογής / Hora de recogida / Kogumisaeg / Heure de prélevement / Satí prikupljanja / Mintavétel időpontja / Ora di raccolta / Жинау үақыты / 수집 시간 / Paêmimo laikas / Savâkšanas laiks / Verzameltijd / Tid prøvetaking / Godzina pobrania / Hora de colheita / Ora colectării / Время сбора / Doba odberu / Vreme prikupljanja / Uppsamlingstid / Toplama zamanı / Час забора / 采集时间

Reel / Обелите / Otevřete zde / Abn / Abziehen / Attkoalås / Desprender / Koorda / Décoller / Otvoriti skin / Hüzza le / Staccare / Үстүнгө кабайтын айлан таста / 벗기기 / Plésti čia / Atlīmēt / Schillen / Trekk av / Oderwač / Destacar / Se dezipește / Otklepnit / Odtrhnite / Oljušiti / Dra isär / Ayrma / Відклепти / 撕下

Perforation / Перфорация / Perforace / Perförer / Διάγρηση / Perforación / Perforatsioon / Perforacija / Perforálás / Perforazione / Tesic tesci / 절취선 / Perforacija / Perforacijsa / Perforatie / Perforação / Perforare / Перфорация / Perforácia / Perforasyon / Перфорация / 穿孔

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Cut / Срежете / Odstrñete / Klip / Schneiden / Кóпте / Cortar / Loigata / Découper / Reži / Vágja ki / Tagliare / Kecíz / 잘라내기 / Kirpti / Nogriezt / Knippen / Kutt / Odcięć / Cortar / Decupať / Отрезать / Odstrñite / Iseci / Klipp / Kesme / Rozřízti / 剪下



Collection date / Дата на събиране / Datum odběru / Opsamlingsdato / Entnahmedatum / Ниеџуондига олдлоңгыз / Fecha de recogida / Kogumiskuupäev / Date de prélevement / Dani prikupljanja / Mintavétele dátuma / Data di raccolta / Жинаган тізбекін / 수집 날짜 / Paémimo data / Saválkásnak datums / Verzameledatum / Dato prevetakning / Data pobrania / Data de colectări / Дата сбора / Dátum odboru / Datum prikupljanja / Uppsamlingsdatum / Toplama tarhi / Дата забора / 采集日期



µL/test / µL/rect / µL/Test / µL/εξέσοπ / µL/prueba / µL/teszt / µL/Էլ տր / մկր/տքտ / µL/tyrimas / µL/párbaude / µL/teste / мкн/анализ / µL/檢測



Keep away from light / Пазете от светлина / Nevvystavujte světlu / Má ikke udsættes for lys / Vor Licht schützen / Кръгът отточка / 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 / Карапыланган жерде уста / 빛을 피해야 함 / Laikytis atokiau nuo šilumos šaltinių / Sargāt no gaismas / Niet blootstellen aan zonlicht / Má ikke utsättas för lys / Przechowywać z dala od źródła światła / Manter ao abrigo da luz / Ferit de lumină / Хранить в темноте / Uchovávajte mimo dosah světla / Držite dalje od svetlosti / Får ej utsättas för ljus / İşitanan uzak tutun / Берегти від сонячного світла / 请远离光线



Hydrogen gas generated / Образуван в водород газ / Možnost úniku plynného vodíku / Frembringer hydrogengas / Wasserstoffgas erzeugt / Адиурорија аирюону ишароону / Producción de gas de hidrógeno / Vesinikaasi tekitätö / Produkt di l'hydrogène gazeux / Sadzří hydrogen vodík / Hydrogén gáz fejlesz / Produzione di gas idrogeno / Газетекст сүртөн пайда болып / 수소 가스 생성됨 / İşskiria vandenilio dujas / Rodas üdenpradis / Waterstofgas gegenerererd / Hydrogengass generert / Powoduje powstawanie wodoru / Produção do gás de hidrogénio / Generare gaz de hidrogen / Выделение водорода / Vyrobene použitím vodíka / Oslobada se vodonik / Genererade vätgas / Açıga çıkan hidrojen gazı / Реакция з видленним водню / 会产生氢气



Patient ID number / ИД номер на пациент / ID pacienta / Patientens ID-nummer / Patienten-ID / Αριθμός αναγνώσισης ασθενούς / Número de ID del paciente / Patiensendi ID / No d'identification du patient / Identifikacijski broj pacijenta / Beteg azonosító száma / Numero ID paziente / Пациенттн идентификациялык нөмөр / 환자 ID 번호 / Paciento identifikavimo numeris / Pacienta ID numurs / Identificatiunenummer van de patiënt / Pasientens ID-nummer / Numer ID pacienta / Número da ID do paciente / Număr ID pacient / Идентификационный номер пациента / Identifikacičné číslo pacienta / ID broj pacijenta / Patientennummer / Hasta kimlik numarası / Идентификатор пациента / 患者标识号



Fragile, Handle with Care / Чуливо, Работите с необходимото внимаване. / Kerehké. Při manipulacii postupujte opatrne. / Forsiktig, kan gå i stykker. / Zerbrechlich, vorsichtig handhaben. / Еўфраство. Херістітэ то ю працох, / Frágil. Manipular com cuidado. / Órn, kásitsége ettévaatikult. / Fragile. Manipuler avec précaution. / Lomljivo, rukujte pažljivo. / Törekény! Övatosan kezelendő. / Fragile, maneggiare con cura. / Сынъыш, абылай пайдаланыныз. / 조심 개지기 쉬운 처리 / Trapu, elkitési atsargiai. / Trauslis: ritkoties uzmanīgi / Breekaar, voorzichtig behandelen. / Ømältig, håndter forsiktig. / Krucha zawartość, przenosić ostrożnie. / Frágil, Manuseie com Cuidado. / Fragil, manipulați cu atenție. / Хрупко! Обращаться с осторожностью. / Krehké, vyžaduje sa opatrna manipulácia. / Lomljivo - rukujte pažljivo. / Bräcklig! Hantera forsiktig. / Kolay Kirılır, Dikkatli Taşıyın. / Тенденция, звертатися з обережністю / 易碎，小心轻放



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