

INTENDED USE

BD Difco™ Haemophilus Influenzae Antisera are recommended for use in slide agglutination tests for serotyping *Haemophilus influenzae*.

SUMMARY AND EXPLANATION

H. influenzae constitutes part of the normal respiratory flora of humans and many animal species and can cause a variety of diseases from chronic respiratory infections to meningitis. Most of the *H. influenzae* isolates associated with meningitis belong to serotype b.¹

H. influenzae is a nonmotile, facultative anaerobe requiring both factor X (hemin) and factor V (nicotinamide adenine dinucleotide, NAD) for *in vitro* growth. In microscopic morphology, the organism is a pleomorphic gram-negative coccobacillus that sometimes forms threads or filaments.

The presence of a polysaccharide capsule is a major virulence factor for strains of *H. influenzae* that cause systemic infections. *H. influenzae* is divided into serologic groups a,b,c,d,e, and f based on capsular polysaccharides. Most encapsulated strains that cause infection belong to serotype b.² The encapsulated strains are referred to as "typeable strains." Unencapsulated or "nontypeable" strains may also cause infection, but infections caused by unencapsulated strains are usually limited to the upper respiratory tract.²

Antigenic similarities exist between *H. influenzae* and a number of unrelated bacteria. For example, *H. influenzae* serotype b shares cross-reacting antigens with *Streptococcus pneumoniae* serotypes 6, 15a, 29, and 35a (see "LIMITATIONS OF THE PROCEDURE").

PRINCIPLES OF THE PROCEDURE

Identification of *H. influenzae* includes the isolation of the microorganism, biochemical identification and serologic confirmation.

Serologic confirmation involves the reaction in which the microorganism (antigen) reacts with its corresponding antibody. This *in vitro* reaction produces macroscopic clumping called agglutination. The desired homologous reaction should be rapid, tightly binding (high affinity) and not dissociate (high avidity).

Because a microorganism (antigen) may agglutinate with an antibody produced in response to some other species, heterologous reactions are possible. Such unexpected and perhaps unpredictable reactions may lead to some confusion in serologic identification. A positive homologous agglutination reaction should support the morphological and biochemical identification of the microorganism.

REAGENTS

BD Difco Haemophilus Influenzae Antisera are stable, lyophilized, polyclonal rabbit antisera containing approximately 0.1% sodium azide as a preservative.

When properly rehydrated and used as described (see PROCEDURE) each vial of BD Difco Haemophilus Influenzae Antiserum is sufficient reagent for 20 slide tests.

Warnings and Precautions:

For *in vitro* Diagnostic Use.

This Product Contains Dry Natural Rubber.

Observe aseptic technique and established precautions against microbiological hazards throughout all procedures. After use, specimens, containers, slides, tubes and other contaminated material must be sterilized by autoclaving. Directions for use should be followed carefully.

WARNING: This product contains sodium azide. Sodium azide is toxic by inhalation, by skin contact, and if swallowed. Contact with acid liberates very toxic gas. After contact with skin, wash immediately with plenty of water. Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. On disposal, flush with a large volume of water to prevent azide build-up.

Warning



H302 Harmful if swallowed.

P264 Wash thoroughly after handling. **P270** Do not eat, drink or smoke when using this product. **P301+P312** IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. **P330** Rinse mouth. **P501** Dispose of contents/container in accordance with local/regional/national/international regulations.

Storage: Store lyophilized and rehydrated BD Difco Haemophilus Influenzae Antisera at 2–8 °C.

Expiration date applies to product in its intact container when stored as directed.

Prolonged exposure of reagents to temperatures other than those specified is detrimental to the products.

Discard any antiserum that is cloudy or has a precipitate after rehydration or storage unless it can be clarified by centrifugation or filtration and demonstrates proper reactivity with validated positive and negative controls. Gross turbidity indicates contamination and such antisera should be discarded.

SPECIMEN COLLECTION AND PREPARATION

H. influenzae can be recovered from clinical specimens on chocolate agar. For specific recommendations consult appropriate references.^{2,3} Serological typing is reliable only if the culture possesses a capsule. On chocolate agar, encapsulated strains appear large, round, and more mucoidal than non-encapsulated strains.⁵ Non-encapsulated strains appear as small, compact gray colonies.⁵ The ability to produce capsules may be lost over time. Do not perform serological typing on isolates suspected of being non-encapsulated as test results are unreliable. Determine that a pure encapsulated culture of the microorganism has been obtained and that biochemical test reactions are consistent with the identification of the organism as *H. influenzae*. After these criteria are met, serologic identification can be performed.

PROCEDURE

Materials Provided: BD Difco Haemophilus Influenzae Antiserum Poly, BD Difco Haemophilus Influenzae Antiserum Type a, BD Difco Haemophilus Influenzae Antiserum Type b, BD Difco Haemophilus Influenzae Antiserum Type c, BD Difco Haemophilus Influenzae Antiserum Type d, BD Difco Haemophilus Influenzae Antiserum Type e, and BD Difco Haemophilus Influenzae Antiserum Type f.

Materials Required But Not Provided: Agglutination slides, applicator sticks, sterile purified water, sterile 0.85% saline, and bacteriological loops.

Reagent Preparation

Equilibrate all materials to room temperature prior to performing the tests. Ensure that all glassware and pipettes are clean and free of residues, such as detergent.

To rehydrate BD Difco Haemophilus Influenzae Antisera, add 1 mL sterile purified water and rotate to completely dissolve the contents.

User Quality Control

At the time of use, test both positive and negative control cultures to check performance of the antisera, techniques and methodology. Quality control requirements must be performed in accordance with applicable local, state and/or federal regulations or accreditation requirements and your laboratory's standard Quality Control procedures. It is recommended that the user refer to pertinent CLSI guidance and CLIA regulations for appropriate Quality Control practices.

Test isolate for autoagglutination

1. From the test culture on chocolate agar, transfer a loopful of growth to a drop (approximately 35 µL) of sterile 0.85% saline on a clean slide and emulsify the organism.
 2. Rotate the slide for 1 min, then observe for agglutination.
 3. If agglutination (autoagglutination) occurs, the culture is rough and cannot be tested. Subculture to chocolate agar, incubate and test the organism again as described in steps 1 and 2.
- If no agglutination occurs, proceed with testing the organism as described (see Procedural Steps).

Procedural Steps

Culture isolates are tested with BD Difco Haemophilus Influenzae Antiserum Poly for presumptive identification followed by testing with monospecific antisera.

1. Put 1 drop of the BD Difco Haemophilus Influenzae Antiserum to be tested on an agglutination slide.
2. Transfer a loopful of growth of the test organism to the drop of antiserum and mix thoroughly.
3. Rotate the slide for 1 min and read for agglutination.

RESULTS

1. Read and record results as follows:
 - 4+ 100% agglutination (background clear to slightly hazy)
 - 3+ 75% agglutination (background slightly cloudy)
 - 2+ 50% agglutination (background moderately cloudy)
 - 1+ 25% agglutination (background cloudy)
 - No agglutination
2. The positive control should produce a 3+ or greater agglutination.
3. The negative control should show no agglutination.
4. For testing isolates, a 3+ or greater agglutination within 1 min is a positive result.

Positive agglutination using BD Difco Haemophilus Influenza Antiserum Poly and one of the individual typing sera combined with adequate biochemical results confirms the serotype of *H. influenzae* present.

LIMITATIONS OF THE PROCEDURE

1. Correct interpretation of serologic reactions depends upon culture purity and morphological characteristics and biochemical reactions that are consistent with identification of the microorganism as *H. influenzae*.
2. Serologic methods alone cannot identify the isolate as *H. influenzae*.

- Excessive heat from external sources (hot bacteriological loop, burner flame, light source, etc.) may prevent a smooth suspension of the microorganism or cause evaporation or precipitation of the test mixture. False-positive reactions may occur.
- Rough culture isolates do occur and will agglutinate spontaneously causing agglutination of negative controls (autoagglutination). Smooth colonies must be selected and tested in serologic procedures.
- H. influenzae* has antigenic similarities with several unrelated bacteria. Cross-reactions can occur between *H. influenzae* and strains of *S. pneumoniae*, *Escherichia coli* and several species of *Staphylococcus*, *Streptococcus* and *Bacillus*.
- BD Difco Haemophilus Influenzae Antisera have been tested using undiluted cultures taken from agar media. These antisera have not been tested using antigen suspensions in saline or other diluents. If the user applies variations in the recommended steps (see PROCEDURE), each lot of antiserum must be tested with known control cultures to verify expected reactions under the modified procedure.
- Unencapsulated *H. influenzae* may cross react and should not be interpreted as a positive reaction.⁶ Therefore, unencapsulated *H. influenzae* should not undergo serological typing.

PERFORMANCE CHARACTERISTICS⁴

The performance of BD Difco Haemophilus Influenzae Antiserum Type b, manufactured by BD Difco Laboratories, was compared in a slide agglutination test to four other tests for serotyping isolates of *Haemophilus influenzae* in a study by Himmelreich, Barenkamp and Storch.⁴ Slide agglutination using another commercial antiserum, coagglutination, latex agglutination and counterimmunoelectrophoresis with multiple antisera were also used to serotype isolates. Eighty (80) reference strains were used in this study. Of these isolates, 39 were *Haemophilus influenzae* type b.⁴

The table below lists the number of correctly identified isolates obtained for each test system.

Strain	BD Difco Haemophilus Influenzae Antiserum Type b Slide Agglutination Test	Commercial Slide Agglutination Test	Commercial Latex Agglutination Test	Commercial Coagglutination Test	Counter Immuno-electrophoresis
<i>H. influenzae</i> type b	39/39	39/39	39/39	39/39	9/39
<i>H. influenzae</i> not type b	37/37*	37/37*	37/37**	41/41	41/41
Organisms not tested	4	4	4	—	—

* 4 samples out of the 41 *H. influenzae* not type b autoagglutinated and could not be tested by the slide agglutination method.

**4 samples out of the 41 *H. influenzae* not type b gave nonspecific reactions, agglutination of the isolate with both the *H. influenzae* type b and control latex preparations.

AVAILABILITY

Cat. No. Description

222371 BD Difco™ Haemophilus Influenzae Antiserum Poly, 1 mL
 222501 BD Difco™ Haemophilus Influenzae Antiserum Type a, 1 mL
 222361 BD Difco™ Haemophilus Influenzae Antiserum Type b, 1 mL
 227891 BD Difco™ Haemophilus Influenzae Antiserum Type c, 1 mL
 227901 BD Difco™ Haemophilus Influenzae Antiserum Type d, 1 mL
 227911 BD Difco™ Haemophilus Influenzae Antiserum Type e, 1 mL
 227921 BD Difco™ Haemophilus Influenzae Antiserum Type f, 1 mL

REFERENCES

- Insel, R. and P. Anderson. 1986. *Haemophilus influenzae* type b: assays for the capsular polysaccharide and for antipolysaccharide antibody, p. 379–384. In N.R. Rose, H. Friedman, and J.L. Fahey (ed.), Manual of clinical laboratory immunology, 3rd ed. American Society for Microbiology, Washington, D.C.
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- The World Health Organization. Laboratory Methods for the Diagnosis of Meningitis Caused by *Neisseria meningitidis*, *Streptococcus pneumoniae*, and *Haemophilus influenzae*. WHO Manual, Second Edition. 2011. Retrieved from <http://www.cdc.gov/meningitis/lab-manual/full-manual.pdf>.
- LaClaire LL, Tondella MLC, Beall DS, et al. (2003) Identification of *Haemophilus influenzae* Serotypes by Standard Slide Agglutination Serotyping and PCR-Based Capsule Typing. J Clin Microbiol. 41 (1): 393–396.

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

Change History

Revision	Date	Change Summary
(05)	2020-05	Converted printed instructions for use to electronic format and added access information to obtain the document from bd.com/e-labeling. Updated Precautionary statements, P270 and P330 added to existing statements per current Safety Data Sheet for Catalog Number 222361. Updated Specimen Collection and Preparation, added descriptions for colony morphology of encapsulated and non-encapsulated strains. Added Limitation of the Procedure #7. Added References #5 and #6.

US Customers only: For symbol glossary, refer to bd.com/symbols-glossary



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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 måned)

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

ΕΕΕΕ-ΜΜ-ΗΗ / ΕΕΕΕ-ΜΜ (ΜΜ = τέλος του μήνα)

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

AAAA-KK-PP / AAAA-KK (KK = кyu lōpp)

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)

ЖҰЖЖ-АА-КК / ЖҰЖЖ-АА / (АА = айдың соңы)

YYYY-MM-DD/YYYY-MM(MM = 월)

MMMM-MM-DD / MMMM-MM (MM = mensesio pabaiga)

GGGG-MM-DD/GGGG-MM (MM = mēneša beigas)

JJJJ-MM-DD / JJJJ-MM (MM = einde maand)

ÅÅÅÅ-MM-DD / ÅÅÅÅ-MM (MM = slutten av månede)

RRRR-MM-DD / RRRR-MM (MM = koniec mie

AAAA-MM-DD / AAAA-MM (MM = fim do mês)

AAAA-LL-ZZ / AAAA-LL (LL = sfârșitul lunii)

ГГГГ-ММ-ДД / ГГГГ-ММ (ММ = конец месяца)

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

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

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

YYYY-AA-GG / YYYY-AA (AA = ayın sonu)

RRRR-ММ-ДД / RRRR-ММ (ММ = кінець місяця)

YYYY-MM-DD / YYYY-MM (MM = 月末)

REF

Catalog number / Каталоген номер / Katalogové číslo / Katalognummer / Αριθμός καταλόγου / Número de catálogo / Katalognummer / Numéro catalogue / Kataloški broj / Katalógusszám / Numero di catalogo / Katalog nemiri / 카탈로그 번호 / Katalogo / numeris / Kataloga numurs / Catalogus nummer / Numer katalogowy / Număr de catalog / Номер по каталог / Katalogové číslo / Kataloški broj / Kataloga numeras / Номер за каталогом / 目錄號

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IVD

In Vitro Diagnostisk Medical Device / Медицинский уред за диагностика ин витро / Lékařské zařízení určené pro diagnostiku in vitro / In vitro diagnostisk medicinsk anordning / Medicinsches In-vitro-Diagnostikum / In vitro diyagnostiklik itirqli oskurek / Dispositivo médico para diagnóstico in vitro / In vitro diagnostika meditsinaparatuur / Dispositif médical de diagnostic in vitro / Medicinska pomagala za In Vitro Dijagnostiku / In vitro dijagnostizatski orvosi eszköz / Dispositivo medicale pro diagnostica in vitro / Жасанды жағдайда жүзеге асырылатын медициналық диагностика аспабы / In Vitro Diagnostisk 의료 기기 / In vitro diagnostikos prietaisai / Medicinas ierices, ko lieto in vitro diagnostika / Medisch hulpmiddel voor in-vitro diagnostiek / In vitro diagnostisk medisinsk udstyr / 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 pomoćna na diagnostiku in vitro / Medicinski uređaj za in vitro dijagnostiku / Medicinteknisk produkt för in vitro-diagnostik / In Vitro Diagnostisk 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 / Temperatuuri piirang / Limites de température / Dovoljena temperatura / Hőmérsékleti határ / Limiti di temperatura / Температураны шекте / 온도제한 / Laikymo temperatūra / Temperatūros ierobojėjumi / Temperatuurlimiet / Temperaturbegrensning / Ograniczenie temperatury / Limites de temperatura / Limite de temperatură / Ограничение температуры / Ohraničenie teploty / Ograničenje temperature / Temperaturgräns / Sıcaklık sınırlaması / Обмеження температури / 温度限制

LOT

Batch Code (Lot) / Код на партидата / Kód (číslo) šarže / Batch-code (lot) / Batch-Code (Charge) / Κωδικός παρτίδας (παρτίδα) / Código de lote (lote) / Partii kood / Numéro de lot / Lot (kod) / Tétel száma (Lot) / Codice batch (lotti) / Топтама коды / 배치 코드(로트) / Partijas numeris (LOT) / Partijas kods (laidiens) / Lot nummer / Batch-code (part) / Kod partii (seria) / Código do lote / Cod de serie (Lot) / Код партии (лот) / Kód série (šarža) / Kod serije / Partnummer (Lot) / Parti Kodu (Lot) / Код партії (партия) (亚批)



Contains sufficient for <n> tests / Съдържащи 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> تستی یافد جەمئییەتی / <n> 테스트가 충분히 포함됨 / Pakannams kiekis atlikti <n> testu / Satur pietiekami <n> pārbaudēm / Inhoud voldoende voor <n> testen / Innholder tilstrekkelig til <n> tester / Zawiera ilość wystarczającą do <n> testów / Conținuto suficiente pentru <n> teste / Conținut suficiente pentru <n> teste / Достаточна до <n> тестов(а) / Obsah vystačí na <n> testov / Sadržaj dovoljan za <n> testova / Innehåller tillräckligt för <n> analyser / <n> test için yeterli malzeme içerir / Вистачить для аналізів: <n> / 足够进行 <n> 次检测



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Lower limit of temperature / Долен лимит на температурата / Dolní hranice teploty / Nedre temperaturgrænse / Temperaturuntergrenze / Κατώτερο όριο θερμοκρασίας / Limite inferior de temperatura / Alumine temperatuuripiir / Limite inférieure de température / Najniža dozvoljena temperatura / Alsó hőmérsékleti határ / Limite inferiore di temperatura / Температураның төменгі рұқсат шегі / 하한 온도 / Žemiausia laikymo temperatūra / Temperatūras zemākā robeža / Laagste temperatuurlimiet / Nedre temperaturgrense / Dolna granica temperatury / Limite minimo de temperatura / Limită minimă de temperatură / Нижний предел температуры / Spodná hranica teploty / Donja granica temperature / Nedre temperaturgräns / Sıcaklık alt sınırı / Минимальна температура / 温度下限



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



Positive control / Положительный контрол / Pozitívni kontrola / Positiv kontrol / Positive Kontrolle / Θετικός μάρτυρας / Control positivo / Positiivne kontroll / Contrôle positif / Pozitívna kontrola / Pozitív kontroll / Controllo positivo / Оң бақылау / 양성 컨트롤 / Teigiama kontrolė / Pozitívna kontrol / Positieve controle / Kontrola dodatnia / Controllo positivo / Control pozitiv / Положительный контроль / Pozitif kontrol / Позитивный контроль / 阳性对照试剂



Negative control / Отрицательный контрол / Negatívni kontrola / Negativ kontrol / Negative Kontrolle / Αρνητικός μάρτυρας / Control negativo / Negativne kontroll / Contrôle négatif / Negatívna kontrola / Negatív kontroll / Controllo negativo / Негативтік бақылау / 음성 컨트롤 / Neigiama kontrolė / Negatívna kontrol / Negatieve controle / Kontrola ujemna / Controllo negativo / Control negativ / Отрицательный контроль / Negatif kontrol / Негативный контроль / 阴性对照试剂



Method of sterilization: ethylene oxide / Метод на стерилизация: етиленов оксид / Způsob sterilizace: etylenoxid / Steriliseringmetode: ethylenoxid / Sterilisierungsmethode: 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: etilēnoksis / Gesteriliseerd met behulp van ethylenoxide / Steriliseringsmetode: etylenoksid / Metoda sterylizacji: tlenek etylu / Método de esterilização: óxido de etileno / Metodă de sterilizare: oxid de etilenă / Метод стерилизации: этиленоксид / Metodă sterilizácie: etylénoxid / Metoda sterilizacije: etilen oksid / Steriliseringsmetod: etenoxid / Sterilizasyon yöntemi: etilen oksit / Метод стерилизації: этиленоксидом / 灭菌方法: 环氧乙烷



Method of sterilization: irradiation / Метод на стерилизация: ирадиация / Způsob sterilizace: záření / Steriliseringmetode: bestrålning / Sterilisierungsmethode: Bestrahlung / Μέθοδος αποστείρωσης: ακτινοβολία / Método de esterilización: irradiación / Steriliseerimismeetod: kiirgus / Méthode de stérilisation : irradiation / Metoda sterilizacije: zračenje / Sterilizálás módszere: besugárzás / Metodo di sterilizzazione: irradiazione / Стерилизация әдісі – сәуле түсіру / 소독 방법: 방사 / Sterilizavimo būdas: radiacija / Sterilizēšanas metode: apstarošana / Gesteriliseerd met behulp van bestraling / Steriliseringmetode: bestrålning / Metoda sterylizacji: napromienianie / Método de esterilização: irradiação / Metodă de sterilizare: iradiere / Метод стерилизации: облучение / Metodă sterilizácie: ožarovanie / Metoda sterilizacije: ozračevanje / Steriliseringsmetod: strålning / Sterilizasyon yöntemi: ırradyasyon / Метод стерилизації: опромінення / 灭菌方法: 辐射



Biological Risks / Биологични рискове / Biologická rizika / Biologisk fare / Biogefährdung / Βιολογικοί κίνδυνοι / Riesgos biológicos / Bioloogilised riskid / Risques biologiques / Biološki rizik / Biológiallag veszélyes / Rischio biologico / Биологиялық тәуекелдер / 생물학적 위험 / Biologinis pavojus / Biologiskie riski / Biologisch risico / Biologisk risiko / Zagrożenia biologiczne / Perigo biológico / Riscuri biologice / Биологическая опасность / Biologické riziko / Biološki rizici / Biologisk risk / Bioloogijk 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 / Ettevaatust! Lugeda kaasnevat dokumentatsiooni / Attention, consulter les documents joints / Urozorenje, koristi prateću dokumentaciju / Figyelem! Olvassa el a mellékelt tájékoztatót / Attenzione: consultare la documentazione allegata / Абайлаңыз, тиісті құжаттармен танысыңыз / 주의, 동봉된 설명서 참조 / Dêmesio, žiūrėkite pridėdamus dokumentus / Piesardzība, skatīt pavaddokumentus / 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 / Výstraha, pozri sprievodné dokumenty / Pažnja! Pogledajte priložena dokumenta / Obs! Se medföljande dokumentation / Dikkat, birlikte verilen belgelere başvurun / Увага: див. супутню документацію / 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 рұқсат етілген жоғарғы шегі / 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 / Sıcaklık üst sınırı / Максимальна температура / 温度上限



Keep dry / Пазете сухо / Skladujte v suchém prostredí / Opbevares tørt / Trocklagern / 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 sausiai / Uzglabāt sausu / Droog houden / Holdes tørt / Przechowywać w stanie suchym / Manter seco / A se feri de umezeală / Не допускать попадания влаги / Uchovávať v suchu / Držite na suvom mestu / Förvaras tørt / Kuru bir şekilde muhafaza edin / Бергити від вологості / 请保持干燥



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



Peel / Обелете / Otevfete zde / Abn / Abziehen / Αποκολλήστε / Desprender / Koorida / Décoller / Otvoriti skini / Húzza le / Staccare / Үстіңгі қабатын алып таста / 벗기다 / Plēsti cia / Attīmēt / Schillen / Trekk av / Oderwać / Destacar / Se deslzeipie / Отклеить / Odtrhnite / Oluštiti / Dra isår / Ayırma / Відклеїти / 撕下



Perforation / Перфорация / Perforace / Perforering / Διάρθρωση / Perforación / Perforatsioon / Perforacija / Perforálás / Perforazione / Тесик тесу / 절취선 / Perforacija / Perforácia / Perforatie / Perforacia / Perfuração / Perforare / Перфорация / Perforácia / Perforasyon / Перфорация / 穿孔



Do not use if package damaged / Не използвайте, ако опаковката е повредена / Ne používejte, je-li obal poškozený / Må ikke anvendes hvis emballagen er beskadiget / Inhal beschädigter Packung nicht 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 / Ереп пакет бұзылған болса, пайдаланба / 패키지가 손상된 경우 사용 금지 / Jei pakuotė pažeista, nenaudoti / 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 / Ne používať, 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 přílišnému 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 / Салқын жерде сақта / 열을 피해야 함 / Laikyti atokiau nuo šilumos šaltinių / Sargāt 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 / Uchovávať mimo zdroja tepla / Držite dalje od toplote / Får ej utsättas för värme / Isidan uzak tutun / Беретти від дії тепла / 请远离热源



Cut / Срежете / Odstřihněte / Klip / Schneiden / Κόψτε / Cortar / Lõigata / Découper / Reži / Vágja ki / Tagliare / Keciňz / 잘라내기 / Kirpti / Nogriez / Knippen / Kutt / Odciać / Cortar / Decupați / Отрезать / Odstrihnite / Iseći / Klipp / Kesme / Розрізати / 剪下



Collection date / Дата на събиране / Datum odběru / Opsamlingsdato / Entnahmedatum / 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 praveťaking / Data pobrania / Data de colheita / Data colectării / Дата сбора / Datum odberu / Datum prikupljanja / Uppsamlingsdatum / Toplama tarihi / Дата забору / 采集日期



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/检测



Keep away from light / Пазете от светлина / Nevystavujte svėtlui / 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 / Isidan uzak tutun / Беретти від дії світла / 请远离光线



Hydrogen gas generated / Образован е водород газ / Možnost úniku plyného vodíku / Frembringer hydrogengas / Wasserstoffgas erzeugt / Δημιουργία αερίου υδρογόνου / Producción de gas de hidrógeno / Vesinikgaasi tekitatud / Produit de l'hydrogène gazeux / Hidrogén gázt fejleszt / Produzione di gas idrogeno / Газтөктес сутери 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 / Vyrobené použitím vodíka / Oslobada se vodonik / Genererad vätegas / Açığa çıkan hidrojen gazı / Реакция 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 numarasi / Идентификатор пациента / 患者标识号



Fragile, Handle with Care / Чупливо, Роботете 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. / Öm, käsitsege ettevaatlikult. / Fragile. Manipuler avec précaution. / Lomljivo, rukujte pažljivo. / Törékeny! Óvatosan kezelendő. / Fragile, maneggiare con cura. / Сынығыш, абайлап пайдаланыңыз. / 조심 깨지기 쉬운 처리 / Trapu, elkitesz atsargiai. / Trausls; rīkoties uzmanīgi / Breekbaar, voorzichtig behandelen. / Ømtåligh, håndter forsigtig. / Krucha zawartość, przenosić ostrożnie. / Frágil, Manusele com Cuidado. / Frágil, 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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