



BD Legionella Agar (NEN)

Legionella Agar (NEN) without Antibiotics with Pimaricin

BCYE Agar without Cysteine with Pimaricin

Prepared Plated Media

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English

INTENDED USE

BD Legionella Agar (NEN) (= "BCYE + ab") and BD Legionella Agar (NEN) without Antibiotics with Pimaricin (= "BCYE") are media for the detection and presumptive identification of *Legionella* species from water, according to the Dutch standard NEN 6265 (the information given above in quotation marks is the designation of the media as described in this standard). BD BCYE Agar without Cysteine with Pimaricin (= "BCYE-Cys") is a control medium to detect the presence of bacteria other than *Legionella* which may also appear on the other two media.

BD does not assume responsibility if the product is used for applications, microorganisms, or procedures not recommended in the Instructions for Use.

PRINCIPLES OF THE PROCEDURE

Legionella pneumophila has been determined to be the agent of Legionnaires' disease.¹⁻⁵ Additionally, more than 30 other *Legionella* species have been described which may or may not be involved in human disease.⁴ Although *Legionella* is not extremely fastidious, it needs cysteine and ferric ions for growth. The most frequently used isolation media are all based on BCYE α agar which contains charcoal as a scavenger of radicals and peroxides.

The Dutch Standard (NEN 6265) describes the use of three different media for the isolation and confirmation of *Legionella* from water.⁶ According to this standard, water is tested for the presence of *Legionella* by inoculating all three media with the sample. While Legionella Agar (NEN) and Legionella Agar (NEN) without Antibiotics with Cysteine are used for the isolation of the *Legionella* bacteria in the sample, BCYE Agar without Cysteine with Pimaricin (which, due to the absence of cysteine, does not allow any of significant growth of *Legionella*) is used as a control medium to detect the presence of bacteria other than *Legionella* which may also appear on the other two media.

BCYE Agar without Cysteine with Pimaricin is also used later during subculturing to confirm an isolate from Legionella Agar (NEN) and Legionella Agar (NEN) without Antibiotics with Pimaricin as *Legionella*. If an isolate fails to grow on BCYE Agar without Cysteine with Pimaricin and grows only on Legionella Agar (NEN) and Legionella Agar (NEN) without antibiotics with Pimaricin, the isolation of *Legionella* is confirmed. The combined use of the three media according to the NEN Standard 6265 allows a presumptive diagnosis for *Legionella* species. For details, consult the NEN Standard 6265.⁶

For all three media, the medium described by Edelstein, BCYE α (Buffered Charcoal Yeast Extract α -Ketoglutarate) Agar, is the base medium. Since *Legionella* is sensitive to sodium, potassium hydroxide is used to adjust the pH.

The three media contain pimaricin to reduce the growth of contaminating fungi. The use of pimaricin (=natamycin) of an antifungal agent in media for *Legionella* has been described.⁷ However, the authors used much higher concentrations than those mentioned in the NEN standard.⁶

BD Legionella Agar (NEN) and BD Legionella Agar (NEN) without Antibiotics with Pimaricin contain all necessary ingredients for the growth of *Legionella*, including cysteine. In BD Legionella Agar (NEN), polymyxin and ceftazolin render the medium partially selective against contaminating bacteria.

BD BCYE Agar Without Cysteine with Pimaricin contains all the ingredients except cysteine, one of the two factors needed for recovery of *Legionella*. This medium does not allow growth of *Legionella*.

REAGENTS

Approximate Formulas* Per Liter Purified Water

Ingredient	BD Legionella Agar (NEN)	BD Legionella Agar (NEN) Without Antibiotics with Pimaricin	BD BCYE Agar Without Cysteine with Pimaricin
Yeast Extract	10.0 g	10.0 g	10.0 g
Ferric Pyrophosphate	0.25 g	0.25 g	0.25 g
ACES Buffer	10.0 g	10.0 g	10.0 g
Charcoal, activated	2.0 g	2.0 g	2.0 g
Alpha-Ketoglutarate	1.0 g	1.0 g	1.0 g
Agar	15.0 g	15.0 g	15.0 g
Pimaricin	0.067 g	0.067 g	0.067 g
L-Cysteine	0.4 g	0.4 g	-
Polymyxin B	80000 IU	-	-
Cefazolin Sodium Salt	8.8 mg	-	-

pH 6.8 ± 0.2

*Adjusted and/or supplemented as required to meet performance criteria.

WARNINGS AND PRECAUTIONS

For laboratory use only.

Do not use plates if they show evidence of microbial contamination, discoloration, drying, cracking, or other signs of deterioration.

Biological and Chemical Safety of the Product

This section may also contain information on specific biological and/or chemical hazards, indicated by the appropriate symbols, together with the appropriate R (risk)- and S (safety)-phrases.⁸

Biohazard Originating from Specimens and Microorganisms Cultivated on Microbiological Media

Observe established precautions against microbiological hazards. Specimens and cultures of microorganisms must be handled according to local biohazard guidelines and legislation. According to the European Directive 2000/54/EC, most bacterial and fungal pathogens are included in risk group 2. Risk group 3 has been created to include *Salmonella* Typhi, enterohemorrhagic *Escherichia coli* (EHEC; also referred to as STEC = Shiga toxin-producing *E. coli*), *Shigella dysenteriae* (type 1) and several other bacteria and fungi. Other bacterial and fungal pathogens included in risk group 3 are: all *Brucella* spp.; *Mycobacterium tuberculosis*; *M. bovis*; *M. africanum*; *M. ulcerans*; and *Histoplasma capsulatum*. For details, consult Annex III of Directive 2000/54/EC.⁹

Product Disposal

After use and prior to discarding, specimen containers and all contaminated material, including the used culture media and contaminated culture containers, must be autoclaved for 20 to 30 min at 121 °C or higher (if large volumes of disposed materials must be sterilized), or incinerated by validated procedures.

STORAGE

On receipt, store plates in the dark at 2–8 °C, in their original sleeve wrapping until just prior to use. Avoid freezing and overheating. The plates may be inoculated up to the expiration date and incubated for the recommended incubation times.

USER QUALITY CONTROL

Inoculate samples of the medium with <100 cfu per plate of the *Legionella* strains and 10² to 10³ cfu per plate of *E. coli* and *Staphylococcus aureus*. Include BCYE Agar (257321) or other media suitable for *Legionella* as a growth reference. Incubate plates at 36 ± 1 °C in a moist aerobic atmosphere and inspect *E. coli* and *S. aureus* after 2 to 3 days and *Legionella* strains after at least 7 days.

Species	Strains	BD Legionella Agar (NEN)	BD Legionella Agar (NEN) Without Antibiotics with Pimaricin	BD BCYE Agar Without Cysteine with Pimaricin
<i>Legionella pneumophila</i>	ATCC® 33152	Growth good to excellent; colonies white-gray to blue-gray	Growth good to excellent; colonies white-gray to blue-gray	No growth to trace growth; pin-point colonies
<i>Legionella bozemanii</i>	ATCC 33217	Growth good to excellent; colonies white-gray to blue-gray	Growth good to excellent; colonies white-gray to blue-gray	No growth to trace growth; pin-point colonies
<i>Legionella anisa</i>	DSM 17627	Growth good to excellent; colonies white-gray to blue-gray	Growth good to excellent; colonies white-gray to blue-gray	No growth to moderate growth; pin-point colonies
<i>Escherichia coli</i>	ATCC 25922	Inhibition partial to complete	Growth good to excellent	Growth good to excellent
<i>Staphylococcus aureus</i>	ATCC 25923	Inhibition partial to complete	Growth good to excellent	Growth good to excellent

Note: Although the three media described here contain pimaricin as an antifungal agent, the inhibition of molds on this medium is rather weak.

Always use fresh test strain suspensions, prepared from overnight cultures in appropriate liquid media (e.g., Tryptic or BD Trypticase™ Soy Broth for aerobes, and Schaedler Broth with hemin and vitamin K for anaerobes). Alternatively, fresh suspensions prepared from overnight cultures on plated media can be used. Incubation times of precultures must be extended if the test strain grows slowly. For **testing the nutritive capacity of a plated medium** according to the CLSI standard M22, dilute the inoculum suspension to provide 1 to 2×10^4 cfu per plate.¹⁰ A tenfold lighter inoculum should be used if this does not provide isolated colonies. According to DIN EN 12322, the growth-promoting properties are tested with 100 to 1,000 cfu or a sufficient amount of cfu to provide isolated colonies by an appropriate streaking plate technique.¹¹ If the strains are inoculated by a quantitative plating technique, 50 to 500 cfu per plate are usually appropriate to obtain a countable number of colonies. For **testing the inhibitory capacity of a selective plated medium**, according to CLSI M22, 1 to 2×10^5 cfu per plate must be used for inoculation, and about 10^4 or more cfu according to DIN EN 12322.^{10,11} Very high inocula of unwanted strains may “overload” the medium, leading to “breakthrough” growth. For comparison, always include a growth reference medium which should be a nonselective medium that provides optimal growth of all test strains. For aerobic strains, Columbia Agar with 5% Sheep Blood, for fastidious strains (like *Neisseria gonorrhoeae*) Chocolate Agar, for anaerobes Schaedler Agar with Vitamin K and 5% Sheep Blood, and for fungi Sabouraud Glucose Agar are suitable for this purpose. If tested quantitatively, growth of “desired” strains on the test medium should be at least 70% of that on the reference medium. On selective media, growth of “undesired” strains must be partially to completely inhibited. The degree of inhibition depends on the medium and the strains, but growth is usually reduced by a factor of 10^3 to 10^4 (or more) as compared to the growth on the nonselective growth reference medium. For **testing the growth performance of media in vials**, comparable methods are used. Smaller tubes and vials should be inoculated with 10^5 cfu according to the CLSI M22-A2 standard.¹⁰ Vials or bottles with fill volumes above 10 mL should first be aliquoted in 5 or 10 mL amounts in sterile tubes and tested in the same way.

PROCEDURE

Materials Provided

BD BCYE Agar without Cysteine with Pimaricin, BD Legionella Agar (NEN), and BD Legionella Agar (NEN) without Antibiotics with Pimaricin, provided in 90 mm BD Stacker™ plates.

Materials Not Provided

Ancillary culture media, reagents, inoculating loops, spreaders, pipettors, incubators, and laboratory equipment as required.

Test Procedure

Follow the procedure outlined in NEN 6265: 2007. A summary of the test procedure is given above in section **PRINCIPLES OF THE PROCEDURE**. Incubate plates at 36 ± 1 °C for at least 7 days up to 10 days for the primary isolation, and for up to 5 days for subcultures before discarding.

Results

After incubation, BCYE Agar without Cysteine with Pimaricin plates inoculated with a presumptive *Legionella* strain will show no growth or very weak growth as compared to Legionella Agar (NEN) and Legionella Agar (NEN) without Antibiotics with Pimaricin. Normal to strong growth on BCYE Agar without Cysteine with Pimaricin indicates that the isolate is not a *Legionella* strain but a contaminating organism from the sample. Refer to NEN 6265 for details. Isolates confirmed as *Legionella* based on growth on the media containing cysteine must be confirmed as *Legionella* with serological or other appropriate procedures.

PERFORMANCE CHARACTERISTICS AND LIMITATIONS OF THE PROCEDURE

BD BCYE Agar without Cysteine with Pimaricin is not an isolation medium for *Legionella*. *Legionella oakridgensis* and *L. spiritensis* require cysteine for primary isolation but may grow in the absence of cysteine thereafter; hence they may grow on BD BCYE Agar without Cysteine with Pimaricin, especially after an extended incubation period.

BD Legionella Agar (NEN) without Antibiotics with Pimaricin should not be used as the only medium for isolation of *Legionella* since it is nonselective and allows growth of contaminating organisms.

BD Legionella Agar (NEN), although it is a selective medium, occasionally allows the growth of contaminating organisms. Isolates from this medium must be confirmed as *Legionella* with serological or other appropriate procedures.

BD Legionella Agar (NEN) contains a cephalosporin (cefazolin). Some *Legionella* species, e.g., *L. micdadei*, are sensitive to cephalosporins and may not grow on this medium.

Although the three media described here contain pimaricin as an antifungal, the inhibition of molds on this medium is rather weak.

Use of these media for the isolation and detection of *Legionella* species from clinical specimens has not been documented.

AVAILABILITY

Cat. No.	Description	Number of plates per package
254549	BD Legionella Agar (NEN)	120
254550	BD Legionella Agar (NEN) without Antibiotics with Pimaricin	120
254552	BD BCYE Agar without Cysteine with Pimaricin	120

REFERENCES






1. McDade, J.E., C.C. Shepard, D.W. Fraser, T.R. Tsai, M.A. Redus, W.R. Dowdle, and the Laboratory Investigation Team. 1977. Legionnaires' disease: isolation of a bacterium and demonstration of its role in other respiratory disease. *N. Engl. J. Med.* 297:1197–1203.
2. Feeley, J.C., G.W. Gorman, R.E. Weaver, D.C. Mackel, and H.W. Smith. 1978. Primary isolation media for Legionnaires' disease bacterium. *J. Clin. Microbiol.* 8:320–325.
3. Edelstein, P.H. 1981. Improved semiselective medium for isolation of *Legionella pneumophila* from potable water. *J. Clin. Microbiol.* 14: 298–303.
4. Winn, W.C. 1995. *Legionella*, p. 533-544. *In*: P.R. Murray, E.J. Baron, M.A. Pfaller, F.C. Tenover, and R.H. Tenover (ed.), *Manual of clinical microbiology*, 6th ed. American Society for Microbiology, Washington, D.C. USA.
5. Dennis, P.J.L. 1988. Isolation of legionellae from environmental specimens. *In*: *A Laboratory Manual for Legionella*. Harrison, T.G. and A.G. Taylor (eds.). John Wiley & Sons Ltd., Chichester, UK.
6. Nederlandse Norm NEN 6265:2007. Water–Detection and enumeration of *Legionella*. Nederlands Normalisatie-instituut. 2007.
7. Edelstein, P.H. and M.A.C. Edelstein. 1996. Natamycin as a selective antifungal agent in media for growth of *Legionella* spp. *J. Clin. Microbiol.* 34: 185–187.
8. Directive 67/548/EEC of the European Parliament and of the Council of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances. *Official Journal P* 196, 16.08.1967, p. 0001–0098.
9. Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16(1) of Directive 98/391/EEC). *Official Journal L* 262, 17.10.2000, p. 0021–0045.
10. Clinical and Laboratory Standards Institute. Standard M22. Quality assurance for commercially prepared microbiological culture media. Wayne, Pennsylvania USA. Search for latest version at clsi.org.
11. DIN EN 12322. 1999. Culture media for microbiology–performance criteria for culture media. Beuth Verlag Berlin.

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Change History

Revision	Date	Change Summary
01	2020-07	Document number changed, version reset to revision 01 for BD branding updates. Updated access information to obtain the document from bd.com/e-labeling .

Some symbols listed below may not apply to this product.

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 RRRR-MM-DD / RRRR-MM (MM = konec měsíce)
 AAAA-MM-DD / AAAA-MM (MM = slutning af måned)
 JJJJ-MM-TT / JJJJ-MM (MM = Monatsende)
 EEEE-MM-HH / EEEE-MM (MM = τέλος του μήνα)
 AAAA-MM-DD / AAAA-MM (MM = fin del mes)
 AAAA-KK-PP / AAAA-KK (KK = kuu lõpp)
 AAAA-MM-JJ / AAAA-MM (MM = fin du mois)
 GGGG-MM-DD / GGGG-MM (MM = kraj mjeseca)
 ÉÉÉÉ-HH-NN / ÉÉÉÉ-HH (HH = hónap utolsó napja)
 AAAA-MM-GG / AAAA-MM (MM = fine mese)
 ЖӨЖӨЖ-АА-КК / ЖӨЖӨЖ-АА / (АА = айдың соңы)
 YYYY-MM-DD/YYYY-MM (MM = 월말)
 MMMM-MM-DD / MMMM-MM (MM = mēnesio pabaiga)
 GGGG-MM-DD/GGGG-MM (MM = mēneša beigas)
 JJJJ-MM-DD / JJJJ-MM (MM = einde maand)
 AAAA-MM-DD / AAAA-MM (MM = slutten av måneden)
 RRRR-MM-DD / RRRR-MM (MM = koniec miesiąca)
 AAAA-MM-DD / AAAA-MM (MM = fim do mês)
 AAAA-LL-ZZ / AAAA-LL (LL = sfârșitul lunii)
 ГТТТ-ММ-ДД / ГТТТ-ММ (ММ = конец месяца)
 RRRR-MM-DD / RRRR-MM (MM = koniec mesiacu)
 GGGG-MM-DD / GGGG-MM (MM = kraj meseca)
 AAAA-MM-DD / AAAA-MM (MM = slutet av månaden)
 YYYY-AA-GG / YYYY-AA (AA = ayın sonu)
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For IVD Performance evaluation only / Само за оценка качеството на работа на IVD / Pouze pro vyhodnocení výkonu IVD / Kun til evaluering af IVD ydelse / Nur für IVD- Leistungsbewertungszwecke / Μόνο για αξιολόγηση απόδοσης IVD / Sólo para la evaluación del rendimiento en diagnóstico in vitro / Ainult IVD seadme hindamiseks / Réserve à l'évaluation des performances IVD / Samo u znanstvene svrhe za In Vitro Dijagnostiku / Kizárólag in vitro diagnosztikához / Solo per valutazione delle prestazioni IVD / Жасаңды жағдайда «пробирка ішінде» диагностикада тек жұмысты бағалау үшін / IVD 성능 평가에 대해서만 사용 / Tik IVD prietaisų veikimo charakteristikoms tikrinti / Vienīgi IVD darbības novērtēšanai / Uitsluitend voor doeltreffendheidsonderzoek / Kun for evaluering av IVD-ydelse / Tytko do oceny wydajności IVD / Uso exclusivo para avaliação de IVD / Numai pentru evaluarea performanței IVD / Только для оценки качества диагностики in vitro / Určené iba na diagnostiku in vitro / Samo za procenu učinka u in vitro dijagnostici / Endast för utvärdering av diagnostisk användning in vitro / Yalnızca IVD Performans değerlendirmesi için / Только для оценивания качества диагностики in vitro / 仅限 IVD 性能评估
For US: "For Investigational Use Only"



Lower limit of temperature / Долен лимит на температурата / Dolní hranice teploty / Nedre temperaturgrænse / Temperaturuntergrenze / Κατώτερο όριο θερμοκρασίας / Limite inferior de temperatura / Alumine temperaturipiiri / 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 temperaturgrænse / Dolna granica temperatury / Limite minimo de temperatura / Limitā minimā de temperatūra / Нижняя предел температуры / Spodná hranica teploty / Donja granica temperature / Nedre temperaturgräns / Sicaklık alt sınırı / Мінімальна температура / 温度下限

CONTROL

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

CONTROL +

Positive control / Положительный контроль / Pozitivní kontrola / Pozitív kontrol / Positive Kontrolle / Θετικός μάρτυρας / Control positivo / Positiivne kontroll / Contrôle positif / Pozitívna kontrola / Pozitív kontroll / Controllo positivo / Оң бақылау / 양성 컨트롤 / Teigijama kontrolé / Pozitívá kontrolé / Positiieve controle / Kontrola dodatnia / Controllo positivo / Control pozitiv / Положительный контроль / Pozitif kontrol / Позитивный контроль / 阳性对照试剂

CONTROL -

Negative control / Отрицательный контроль / Negativní kontrola / Negatív kontrol / Negative Kontrolle / Αρνητικός μάρτυρας / Control negativo / Negatiivne kontroll / Contrôle négatif / Negatívna kontrola / Negatív kontroll / Controllo negativo / Негативтік бақылау / 음성 컨트롤 / Neigijama kontrolé / Negatívá kontrolé / Negatiieve controle / Kontrola ujemna / Controllo negativo / Control negativ / Отрицательный контроль / Negatif kontrol / Негативный контроль / 阴性对照试剂

STERILE EO

Method of sterilization: ethylene oxide / Метод на стерилизация: этиленов оксид / Způsob sterilizace: etylenoxid / Steriliseringmetode: etylenoxid / Steriliseringsmetode: etylenoxid / Μέθοδος αποστείρωσης: αιθυλενοξείδιο / Método de esterilización: óxido de etileno / Steriliseerimismetode: etüleenoksiid / Méthode de stérilisation : oxyde d'éthylène / Metoda sterilizacije: etilen oksid / Sterilizálás módszere: etilén-oxid / Metoda di sterilizzazione: ossido di etilene / Стерилизация адісі – 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 / Metóda sterilizácie: etylénoxid / Metoda sterilizacije: etilen oksid / Steriliseringmetod: etenoxid / Sterilizasyon yöntemi: etilen oksit / Метод стерилизації: этиленоксидом / 灭菌方法: 环氧乙烷

STERILE R

Method of sterilization: irradiation / Метод на стерилизация: ирадиация / Způsob sterilizace: záření / Steriliseringmetode: bestråling / Sterilisationsmethode: Bestrahlung / Μέθοδος αποστείρωσης: ακτινοβολία / Método de esterilización: irradiación / Steriliseerimismetode: kiirgus / Méthode de stérilisation : irradiation / Metoda sterilizacije: zračenje / Sterilizálás módszere: besugárzás / Metoda di sterilizzazione: irradiazione / Стерилизация адісі – сәулелік тәуекелдер / Sterilizavimo būdas: radiacija / Sterilizēšanas metode: apstarošana / Gesteriliseerd met behulp van bestraling / Steriliseringmetode: bestråling / Metoda sterylizacji: napromienianie / Método de esterilização: irradiação / Metodă de sterilizare: irradiație / Metóda sterilizácie: ožiarenie / Metoda sterilizacije: ozračavanje / Steriliseringmetod: strålning / Sterilizasyon yöntemi: ışınyasyon / Метод стерилизації: опроміненням / 灭菌方法: 辐射



Biological Risks / Биологични рискове / Biologická rizika / Biologisk fare / Biogefährdung / Βιολογικοί κίνδυνοι / Riesgos biológicos / Biologilised riskid / Risques biologiques / Biološki rizik / Biológiallag veszélyes / Rischio biologico / Биологиялык тәуекелдер / 생물학적 위험 / Biologiskie riski / Biologisch risico / Biologisk risiko / Zagrożenia biologiczne / Perigo biológico / Riscuri biologice / Биологическая опасность / Biologické riziko / Biološki rizici / Biologisk risk / Biyojlojik 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 / Ettevaatus! Lugeeda kaasnevat dokumentatsiooni / Attention, consulter les documents joints / Upozorenje, koristite prateću dokumentaciju / Figyelem! Olvassa el a mellékeltájékoztatót / Attenzione: consultare la documentazione allegata / Абайлаңыз, тиісті құжаттармен танысыңыз / 주의, 동봉된 설명서 참조 / Dmesio, žiūrėkite pridėdamus dokumentus / Piesardzība, skatīt pavaddokumentus / Voorzichtig, gaadpleeg bijgevoegde documenten / Forsiktig, se vedlagt dokumentasjon / Należy zapoznać się z dołączonymi dokumentami / Cuidado, consulte a documentação fornecida / Atenție, consultați documentele însoțitoare / Внимание: см. прилагаемую документацию / Vystraha, pozri sprievodné dokumenty / Pažňaj! Pogledajte priložena dokumenta / Obs! Se medföljande dokumentation / Dikkat, birlikte verilen belgeleere 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 temperaturgrænse / Temperaturobergrenze / Ανώτερο όριο θερμοκρασίας / Limite superior de temperatura / Ülemine temperaturipiiri / 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 temperaturgrænse / Górná granica temperatury / Limite máximo de temperatura / Limitā maksimā de temperatūra / Верхний предел температуры / Horná hranica teploty / Gornja granica temperature / Øvre temperaturgräns / Sicaklık üst sınırı / Максимальна температура / 温度上限



Keep dry / Пазете сухо / Skladujte v suchém prostredí / Orbevaras tørt / Trocoklagern / Φυλάξτε το στεγνό / Mantener seco / Hoida kuivaks / Conserver au sec / Držati na suhom / Száraz helyen tartandó / Tenere all'asciutto / Құрғақ күйінде ұста / 건조 상태 유지 / Laikykite sausiai / Uzglabāt sausu / Droog houden / Houdes tørt / Przechowywać w stanie suchym / Manter seco / A se feri de umezeală / Не допускать попадания влаги / Uchovávať v suchu / Držite na suvom mestu / Förvaras torrt / Kuru bir şekilde muhafaza edin / Беретти від вологи / 请保持干燥



Collection time / Време на събиране / Čas odběru / Opsamlingsstidspunkt / Entnahmehzeit / 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 odboru / Vreme prikupljanja / Uppsamlingsstid / Toplama zamanı / Час забору / 采集时间



Peel / Обелете / Otevřete zde / Abn / Abziehen / Αποκολλήστε / Desprender / Koorida / Décoller / Otvoriti skini / Húzza le / Staccare / Ўстіңгі қабатын алып таста / 벗 기기 / Plești ăia / Atfimt / Schillen / Trekk av / Oderwać / Destacar / Se dezlipeste / Отклеить / Odrhňte / Oljuštiti / Dra isår / Айрма / Відклеїти / 撕下



Perforation / Перфорация / Perforace / Perforering / Διότρηση / Perforación / Perforatsioon / Perforacija / Perforálás / Perforazione / Tecik тесу / 절취선 / Perforacija / Perforăcija / Perforatie / Perforacja / Perfuração / Perfore / Перфорация / Perforácia / Perforasyon / Перфорация / 穿孔



Do not use if package damaged / Не използвайте, ако опаковката е повредена / Nepoužívejte, je-li obal poškozený / Má ikke anvendes hvis emballagen er beskadiget / Inhal beschädigter Packungnicht verwenden / Μη χρησιμοποιείτε εάν η συσκευασία έχει υποστεί ζημιά. / No usar si el paquete está dañado / Mitte kasutada, kui pakend on kahjustatud / Ne pas l'utiliser si l'emballage est endommagé / Ne koristiti ako je oštećeno pakiranje / Ne használni, ha a csomagolás sérült / Non usare se la confezione è danneggiata / Егер пакет бұзылған болса, пайдаланба / 패키지가 손상된 경우 사용 금지 / Jei pakuotė pažeista, nenaudoti / Nelietot, ja iepakojums bojāts / Niet gebruiken indien de verpakking beschadigd is / Má ikke brukes hvis pakke er skadet / Nie używać, jeśli opakowanie jest uszkodzone / Não usar se a embalagem estiver danificada / A nu se folosi dacă pachetul este deteriorat / Не использовать при повреждении упаковки / Nepoužívejte, ak je obal poškozený / Ne koristite ako je pakovanje oštećeno / Ανvänd 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 / Nevstavujte přitišnému teplu / Má ikke udsættes for varme / Vor Wärme schützen / Κρατήστε το μακριά από τη θερμότητα / Mantener alejado de fuentes de calor / Hoida eemal valgusesst / Protéger de la chaleur / Držati dalje od izvora topline / Óvja a melegtől / Tenere lontano dal calore / Сақын жерде сақта / 열을 피해야 함 / Laikyti atokiau nuo šilumos šaltinių / Sargati no karstuma / Beschermen tegen warmte / Má 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 / Кесіңіз / 잘라내기 / Kirpti / Nogriez / Knippen / Kutt / Odciać / Cortar / Decupați / Отрезать / Odstřihněte / Iseći / Klipp / Kesme / Pozřizati / 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 / Жынаған тизбекуні / 수집 날짜 / Paėmimo data / Savākšanas datums / Verzameldatum / Dato prøvetaking / Data pobrania / Data de colheita / Data colectării / Дата сбора / Datum odboru / 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/pärbaude / µL/teste / мкл/анализ / µL/检测



Keep away from light / Пазете 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 svjetla / 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 źródła światła / Manter ao abrigo da luz / Feriti de lumină / Хранити в темноте / Uchovávať mimo dosahu svetla / Držite dalje od svetlosti / Får ej utsättas för ljus / İşiktan uzak tutun / Берегти 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 / Sadrží hydrogen vodík / Hidrogén gázt fejleszt / Produzione di gas idrogeno / Газтөктес сутері пайда болды / 수소 가스 생성됨 / Išskiria vandenilio dujas / Rodas ūdeņradis / 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 vätgas / 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 / Идентифікатор пацієнта / 患者标识号



Fragile, Handle with Care / Чупливо, Роботете с необходимото внимание. / Křehké. Při manipulaci postupujte opatrně. / Forsigtigt, kan gå i stykker. / Zerbrechlich, vorsichtighandhaben. / Ευφραστο. Χειριστείτε το με προσοχή. / Frágil. Manipular con cuidado. / Örn, kásitsege ettevaatlilikult. / Fragile. Manipuler avec précaution. / Lomljivo, rukujte pažljivo. / Төрөкөнү! Оватосан kezelendő. / Fragile, maneggiare con cura. / Сынғыш, абайлап пайдаланыңыз. / 조심 깨지기 쉬운 처리 / Трапу, elkités atsargiai. / Trausls; rūkotiis uzmanīgi / Breekbaar, voorzichtig behandelen. / Ømtålig, håndter forsigtigt. / 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 Kirılır, Dikkatli Taşımın. / Тендітна, звертатися з обережністю / 易碎，小心轻放



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