

INTENDED USE

BD BBL™ Coagulase Plasma, Rabbit and BD BBL Coagulase Plasma, Rabbit with EDTA are used to qualitatively determine the pathogenicity of staphylococci using the direct tube method.

SUMMARY AND EXPLANATION

Identification of staphylococci is based on microscopic examination, colonial morphology and cultural and biochemical characteristics. Staphylococci associated with acute infection (*Staphylococcus aureus* in humans and *S. intermedius* and *S. hyicus* in animals) can clot plasma. The most widely used and generally accepted criterion for identification of these pathogenic organisms is based on the presence of the enzyme coagulase.¹ The ability of *Staphylococcus* to produce coagulase was first reported by Loeb² in 1903.

Coagulase binds plasma fibrinogen, causing the organisms to agglutinate or plasma to clot. Two different forms of coagulase can be produced, free and bound. Free coagulase is an extracellular enzyme produced when the organism is cultured in broth. Bound coagulase, also known as clumping factor, remains attached to the cell wall of the organism. The tube test can detect the presence of both bound and free coagulase. Isolates that do not produce clumping factor must be tested for the ability to produce extracellular coagulase (free coagulase).

BD BBL Coagulase Plasma, Rabbit and BD BBL Coagulase Plasma, Rabbit with EDTA are recommended for performing the direct tube test. The inoculum used for testing must be pure because a contaminant may produce false results after prolonged incubation. For the coagulase test, BD BBL Coagulase Plasma, Rabbit with EDTA is superior to citrated plasma because citrate-utilizing organisms such as *Pseudomonas* species, *Serratia marcescens*, *Enterococcus faecalis* and strains of *Streptococcus* will clot citrated plasma in 18 h.³

PRINCIPLES OF THE PROCEDURE

S. aureus produces two types of coagulase, free and bound. Free coagulase is an extracellular enzyme produced when the organism is cultured in broth. Bound coagulase, also known as the clumping factor, remains attached to the cell wall of the organism.

In the direct tube test, free coagulase liberated from the cell acts on prothrombin in the coagulase plasma to give a thrombin-like product. This product then acts on fibrinogen to form a fibrin clot.⁴

The tube test is performed by mixing an overnight broth culture or colonies from a non-inhibitory agar plate into a tube of rehydrated coagulase plasma. The tube is incubated at 37 °C. The formation of a clot in the plasma indicates coagulase production.

REAGENTS

Coagulase Plasma, Rabbit is lyophilized rabbit plasma with 0.85% sodium citrate and 0.85% sodium chloride, approximately.

Coagulase Plasma, Rabbit with EDTA is lyophilized rabbit plasma with 0.15% EDTA (ethylenediaminetetraacetic acid) and 0.85% sodium chloride, approximately.

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.

Storage

Store unopened lyophilized BD BBL Coagulase Plasma, Rabbit and BD BBL Coagulase Plasma, Rabbit with EDTA at 2–8 °C.

Store reconstituted plasma at 2–8 °C for up to 14 days, or aliquot and freeze promptly at -20 °C for up to 30 days. Do not thaw and refreeze.

Expiration date applies to product in its intact container when stored as directed. Do not use if the product is caked, discolored or shows other signs of deterioration. Examine reconstituted reagents for evidence of contamination, evaporation or other signs of deterioration, such as cloudiness or partial clotting.

SPECIMEN COLLECTION AND PREPARATION

Collect specimens or samples in sterile containers or with sterile swabs and transport immediately to the laboratory according to recommended guidelines.^{1,4-9}

Process each specimen using procedures appropriate for that sample.^{1,4-9}

Select well-isolated colonies. The test described below requires the use of a pure test culture.

Suspicious growth, such as black colonies on Vogel and Johnson Agar or Tellurite Glycine Agar, or golden, hemolytic colonies from BD Trypticase™ Soy Blood agar plates should be selected for testing.

Using a bacteriological loop, transfer a well-isolated colony from a pure culture into a tube of sterile Brain Heart Infusion Broth or BD Trypticase Soy Broth. Incubate for 18–24 h or until a dense growth is observed. Alternatively, several colonies (1 loopful) taken directly from a non-inhibitory agar plate such as BD Trypticase Soy Agar may be used as an inoculum instead of a broth culture.

PROCEDURE

Materials Provided: BD BBL Coagulase Plasma, Rabbit, BD BBL Coagulase Plasma, Rabbit with EDTA.

Materials Required But Not Provided: Bacteriological inoculating loop, Pipettes, Sterile purified water, Culture tubes, small (10 x 75 mm), Water bath or incubator (37 °C), BD Trypticase Soy Broth or Brain Heart Infusion (BHI) Broth.

Reagent Preparation

Rehydrate BD BBL Coagulase Plasma, Rabbit and BD BBL Coagulase Plasma, Rabbit with EDTA by adding sterile purified water to the vial as indicated below. Mix by gentle end-over-end rotation of the vial.

Product Size	Sterile Purified Water	Approximate Number of Tests
3 mL	3 mL	6
15 mL	15 mL	30

Test Procedure

1. Using a sterile 1 mL pipette, add 0.5 mL of rehydrated BD BBL Coagulase Plasma, Rabbit or BD BBL Coagulase Plasma, Rabbit with EDTA to a 10 x 75 mm test tube supported in a rack.
2. Using a sterile 1 mL serological pipette, add approximately 0.05 mL of the overnight broth culture of the test organism to the tube of plasma. Alternatively, using a sterile bacteriological loop, thoroughly emulsify several colonies (minimum 1 µL loopful) from a non-inhibitory agar plate in the tube of plasma.
3. Mix gently.
4. Incubate in a water bath or incubator at 37 °C for up to 6 h.
5. Examine the tubes periodically by gently tipping the tube. Avoid shaking or agitating the tube, which could cause breakdown of the clot and, consequently, doubtful or false negative test results. Any degree of clotting in the 6 h period is regarded as a positive result.
6. If no clot is visible after 6 hours, continue to incubate at 37 °C for up to 24 hours. Many weak enzyme-producing strains will coagulate the plasma only after 24 h of incubation.
7. Record results.

User Quality Control

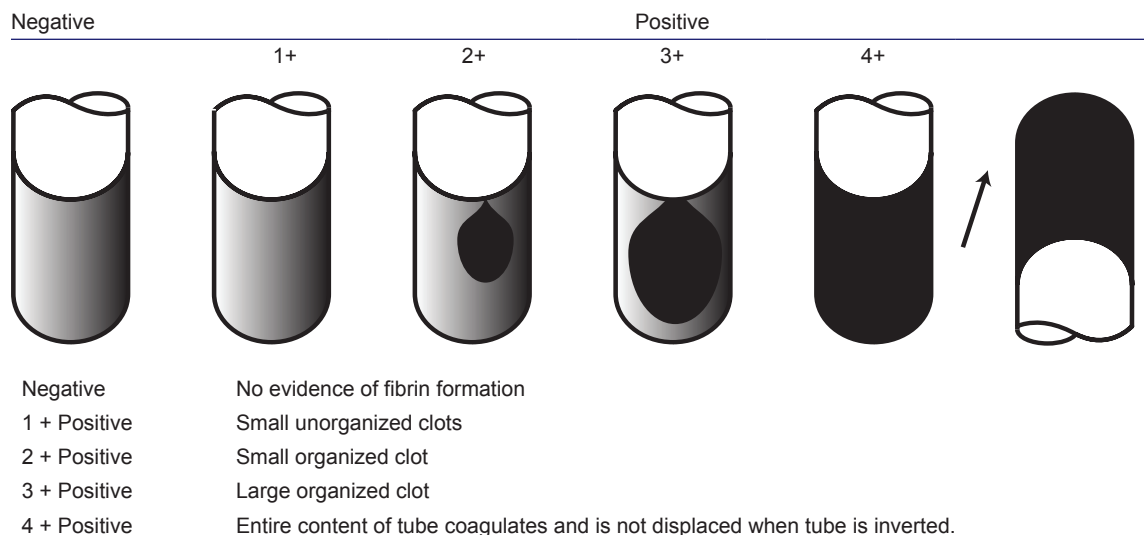
At the time of use, test both positive and negative control cultures to check performance of the coagulase plasma, techniques and methodology. The following cultures listed are the minimum that should be used for performance testing.

Organism	ATCC®	Reaction
<i>Staphylococcus aureus</i>	25923	Clot in tube
<i>Staphylococcus epidermidis</i>	12228	No clot in tube

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.

Results

Any degree of clotting in BD BBL Coagulase Plasma, Rabbit or BD BBL Coagulase Plasma, Rabbit with EDTA is considered a positive test. The following chart can be used as a guide in interpreting the reactions.



LIMITATIONS OF THE PROCEDURE

1. Some species of organisms utilize citrate in their metabolism and will yield false-positive reactions for coagulase activity. Normally, this does not cause problems since the coagulase test is performed almost exclusively on staphylococci. However, it is possible that bacteria that utilize citrate may contaminate *Staphylococcus* cultures on which the coagulase test is being performed. These contaminated cultures may, upon prolonged incubation, give false-positive results due to citrate utilization.⁴
2. Some strains of *S. aureus* produce staphylokinase, which may lyse clots. If the tubes are not read until 24 h of incubation, false-negative results may occur.¹
3. Do not use plasma if a heavy precipitate or clot has formed before inoculation.
4. For *Staphylococcus* species other than *S. aureus*, improved results may be obtained using agar plate cultures.

PERFORMANCE CHARACTERISTICS^{10,11}

The performance of BD Bacto™ Coagulase Plasma (now BD BBL Coagulase Plasma) was compared to four other tests for the identification of *Staphylococcus aureus* in a study by Ad Luijenkijk, van Belkum, Verbrugh and Kluytmans.¹⁰ The free-coagulase (tube) test was performed. In addition, the bound coagulase (agar) test and three commercial latex agglutination tests were used to identify isolates.

Of the 330 staphylococcal isolates tested, 300 were *S. aureus* and 30 were non-*S. aureus*. All of the tests produced negative results for the 30 non-*S. aureus* isolates for a specificity of 100%. The table below summarizes the sensitivity of each test system for the 300 *S. aureus* isolates.

	MSSA* (222 isolates)		MRSA** (78 isolates)		Total (300 isolates)	
Test	No. of false-negative results	Test Sensitivity (%)	No. of false-negative results	Test Sensitivity (%)	No. of false-negative results	Test Sensitivity (%)
Free Coagulase	0	100	6	92.3	6	98.0
Bound Coagulase	0	100	3	96.1	3	99.0
Latex Agglutination Test #1	0	100	0	100	0	100
Latex Agglutination Test #2	2	99.1	12	84.6	14	95.3
Latex Agglutination Test #3	0	100	0	100	0	100

*Methicillin-susceptible *S. aureus*.

**Methicillin-resistant *S. aureus*.

In a second study by McDonald and Chapin,¹¹ the performance of BD BBL Coagulase Plasma was compared in a 2-h tube coagulase test (TCT) to two commercial latex agglutination tests for identifying *S. aureus* directly from blood culture broths and pellets obtained from supernatants of BD BACTEC™ bottles. One hundred twelve (112) clinical blood culture isolates and 68 negative blood culture bottles seeded with a variety of gram-positive organisms were evaluated.

The table below gives the results of the coagulase test and the latex agglutination tests for both the seeded and clinical specimens.

Cultures and organism(s)	No. aerobic/ No. anaerobic (total)	No. of positive results					
		Direct			Pellet		
		Latex Test #1	Latex Test #2	TCT	Latex Test #1	Latex Test #2	TCT
Seeded							
<i>Staphylococcus aureus</i>	11/8 (19)	0	0	19	2	2	19
Coagulase-negative staphylococci	9/9 (18)	0	0	0	0	0	0
<i>Streptococcus pneumoniae</i>	5/5 (10)	0	0	0	0	0	0
<i>Enterococcus</i> spp.	6/5 (11)	5	5	0	5	5	0
<i>Streptococcus agalactiae</i>	3/5 (8)	0	0	0	0	0	0
<i>Streptococcus pyogenes</i>	1/1 (2)	0	0	0	0	0	0
Clinical							
Coagulase-negative staphylococci	70/3 (73)	0	0	0	0	0	0
<i>Staphylococcus aureus</i>	35/4 (39)	5	4	31	5	4	30

Among the 68 seeded blood culture bottles, the 2-h tube coagulase test using BD BBL Coagulase Plasma correctly identified 19 of 19 blood cultures seeded with *S. aureus*. There were no false positives with the 2-h tube coagulase test. Among the 112 clinical specimens tested, the 2-h tube coagulase test correctly identified 31 out of 39 *S. aureus* isolates directly in blood culture broth and 30 out of 39 *S. aureus* isolates in pelleted supernatants, for sensitivities of 79.5% and 76.9%, respectively. The specificity with both seeded and clinical isolates was 100% for the tube coagulase test.

AVAILABILITY

Cat. No. Description

240658	BD BBL™ Coagulase Plasma, Rabbit, 10 X 3.0 mL
240661	BD BBL™ Coagulase Plasma, Rabbit, 10 X 15.0 mL
240827	BD BBL™ Coagulase Plasma, Rabbit with EDTA, 10 X 3.0 mL
240826	BD BBL™ Coagulase Plasma, Rabbit with EDTA, 10 X 15.0 mL

REFERENCES

1. Kloos, W. E., and T. L. Bannerman. 1999. *Staphylococcus* and *Micrococcus*, p. 264-282. In Murray, P.R., E.J. Baron, M.A. Pfaller, F.C. Tenover and R.H. Tenover, Manual of clinical microbiology, 7th ed. American Society for Microbiology, Washington, D.C.
2. Loeb, L. 1903. The influence of certain bacteria on the coagulation of the blood. J. Med. Res. 10:407-419.
3. Bayliss, B.G. and E.R. Hall. 1965. Plasma coagulation by organisms other than *Staphylococcus aureus*. J. Bacteriol. 89:101-104.
4. Pezzlo, M. (ed.). 1994. Aerobic bacteriology, p. 1.0.0.-1.20.47. In H. D. Isenberg (ed.), Clinical microbiology procedures handbook, vol. 1. American Society for Microbiology, Washington, D.C.
5. Baron, E.J., L.R. Peterson and S.M. Finegold. 1994. Bailey & Scott's diagnostic microbiology, 9th ed. Mosby-Year Book, Inc., St Louis, MO.
6. Association of Official Analytical Chemists. 2000. Official methods of analysis of AOAC International, 17th ed. AOAC International, Arlington, VA.
7. Association of Official Analytical Chemists. 2001. FDA Bacteriological analytical manual online. <<http://www.cfsan.fda.gov/~ebam/bam-mm.html>>.
8. Downes, F.P. and K. Ito (ed.). 2001. Compendium of methods for the microbiological examination of foods, 4th ed. American Public Health Association, Washington, D.C.
9. Flowers, R.S., W. Andrews, C.W. Donnelly and E. Koenig. 1993. Pathogens in milk and milk products, p. 103-212. In R.T. Marshall (ed.), Standard methods for the examination of dairy products, 16th ed. American Public Health Association, Washington, D.C.
10. Luijendijk, A., A. van Belkum, H. Verbrugh and J. Kluytmans. 1996. Comparison of five tests for identification of *Staphylococcus aureus* from clinical samples. J. Clin. Microbiol. 34:2267-2269.
11. McDonald, C.L. and K. Chapin. 1995. Rapid Identification of *Staphylococcus aureus* from blood culture bottles by a classic 2-hour tube coagulase test. J. Clin. Microbiol. 33:50-52.

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
(06)	2019-09	Converted printed instructions for use to electronic format and added access information to obtain the document from BD.com/e-labeling .

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



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RRRR-MM-DD / RRRR-MM (MM = koniec miesiąca)
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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)
EEEE-HH-NN / EEEE-HH (HH = hónap utolsó napja)
AAAA-MM-GG / AAAA-MM (MM = fine mese)
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MMMM-MM-DD / MMMM-MM (MM = mėnesio pabaiga)
GGGG-MM-DD/GGGG-MM (MM = mėneša beigas)
JJJJ-MM-DD / JJJJ-MM (MM = einde maand)
AAAA-MM-DD / AAAA-MM (MM = slutten av månaden)
RRRR-MM-DD / RRRR-MM (MM = koniec miesiąca)
AAAA-MM-DD / AAAA-MM (MM = fim do mês)
AAAA-LL-ZZ / AAAA-LL (LL = sfârșitul lunii)
ГГГГ-ММ-ДД / ГГГГ-ММ (ММ = конец месяца)
RRRR-MM-DD / RRRR-MM (MM = koniec miesiąca)
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)
PPPP-MM-DD / PPPP-MM (MM = кінець місяця)
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Temperature limitation / Температурни ограничения / Teplotní omezení / Temperaturbegrænsning / Temperaturbegrenzung / Περιορισμοί θερμοκρασίας / Limitación de temperatura / Temperaturi piirang / Limites de température / Dozvoljena temperatura / Hőmérsékleti határ / Limiti di temperatura / Температураны шектеу / 온도 제한 / Laikymo temperatūra / Temperatūras ierobežojumi / Temperaturlimit / Temperaturbegrensning / Ograniczenie temperatury / Limites de temperatura / Limite de temperatură / Ограничение температуры / Ohraničenje teploty / Ograničenje temperature / Temperaturgräns / Sıcaklık sınırlaması / Обмеження температури / 温度限制



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CONTROL	Control / Контролно / Kontrola / Kontrol / Kontrolle / Μάρτυρας / Kontroll / Contrôle / Controllo / Бақылау / 컨트롤 / Kontrolé / Kontrolle / Controle / Controllo / Контроль / kontroll / 对照
CONTROL +	Positive control / Положителен контрол / Pozitivni kontrola / Positiv kontrol / Positive Kontrolle / Θετικός μάρτυρας / Control positivo / Positiivne kontroll / Contrôle positif / Pozitivna kontrola / Pozitív kontroll / Controllo positivo / Оң бақылау / 양성 컨트롤 / Teigiama kontrolė / Pozitívá kontrolé / Positieve controle / Kontrola dodatnia / Controllo positivo / Control pozitiv / Положительный контроль / Pozitif kontrol / Позитивний контроль / 阳性对照试剂
CONTROL -	Negative control / Отрицателен контрол / Negativní kontrola / Negativ kontrol / Negative Kontrolle / Αρνητικός μάρτυρας / Control negativo / Negatiivne kontroll / Contrôle négatif / Negativna kontrola / Negativ kontroll / Controllo negativo / Негативный бақылау / 음성 컨트롤 / Neigiama kontrolė / Negatívá kontrolé / Negatieve controle / Kontrola ujemna / Controllo negativo / Control negativ / Отрицательный контроль / Negatif kontrol / Негативний контроль / 阴性对照试剂
STERILE EO	Method of sterilization: ethylene oxide / Метод на стерилизация: етиленов оксид / Způsob sterilizace: etylenoxid / Steriliseringmetode: ethylenoxid / Sterilisationsmethode: Ethylenoxid / Μέθοδος αποστείρωσης: αιθυλενοξείδιο / Método de esterilización: óxido de etileno / Steriliseringmetode: etüleenoksiid / Méthode de stérilisation : oxyde d'éthylène / Metoda sterilizacije: etilen oksid / Sterilizálás módszere: etilén-oxid / Metoda di sterilizzazione: ossido di etilene / Sterilizacija edici – etilen totyгы / 소독 방법: 에틸렌옥사이드 / Sterilizavimo būdas: etileno oksidas / Sterilizēšanas metode: etilēnoksisds / Gesteriliseerd met behulp van ethyleenoxide / Steriliseringmetode: etylenoksid / Metoda sterylizacji: tienek etylu / Método de esterilização: óxido de etileno / Metodă de sterilizare: oxid de etilenă / Метод стерилизации: этиленоксид / Metodá sterilizácie: etylenoxid / 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: bestrålning / Sterilisationsmethode: Bestrahlung / Μέθοδος αποστείρωσης: ακτινοβολία / Método de esterilización: irradiación / Steriliseringmetode: kiirgus / Méthode de stérilisation : irradiation / Metoda sterilizacije: zračenje / Sterilizálás módszere: besugárzás / Metoda di sterilizzazione: irradiazione / Sterilizacija edici – сәуле тисы / 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 / Metodá sterilizácie: ožiarenie / Metoda sterilizacije: ozračevanje / Steriliseringmetod: strålning / Sterilizasyon yöntemi: ırradyasyon / 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 / Biológiai veszélyes / Rischio biologico / Биологический тауекелдер / 생물학적 위험 / Biologinis pavojus / Biologiskie riski / Biologisch risico / Biologisk risiko / Zagrożenia biologiczne / Perigo biológico / Riscuri biologice / Biologische опасность / Biologické riziko / Biološki rizici / Biologisk risk / Biyolojik Riskler / Біологічна небезпека / 生物学风险
	Caution, consult accompanying documents / Внимание, направете справка в придружаващите документи / Pozor! Pristudujte si příloženou dokumentaci! / Forsigtig, se ledsagende dokumenter / Achtung, Begleitdokumente beachten / Προσοχή, συμβουλευτείτε τα συνοδευτικά έγγραφα / Precaución, consultar la documentación adjunta / Ettevaatust! Lugeka 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 / Dămesio, žiūrėkite priedamus dokumentus / Piesardziba, skatit 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 / Vystraha, 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 temperaturgrænse / Temperaturobergrenze / Ανώτερο όριο θερμοκρασίας / Limite superior de temperatura / Ülemine temperatuuripiir / Limite supérieure de température / Gornja dozvoljena temperatura / Felső hőmérsékleti határ / Limite superiore di temperatura / Температураның рұқсат етілген жоғарғы шегі / 상한 온도 / Aukščiausia laikymo temperatūra / Ausgējā temperatūras robeža / Hoogste temperatuurlimiet / Øvre temperaturgrense / Górná 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 prostředí / Opbevarer 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 / Uchovávaťe v suchu / Držite na suvom mestu / Förvaras tørt / Kuru bir şekilde muhafaza edin / Бергerti від вологості / 请保持干燥
	Collection time / Време на събиране / Čas odběru / Opsamlingsstidspunkt / Entnahmeuhrzeit / Ώρα 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 föravtaging / Godzina pobrania / Hora de colheita / Ora colectării / Время сбора / Doba odboru / Vreme prikupljanja / Uppsamlingsstid / Toplama zamanı / Час забору / 采集时间
	Peel / Обелете / Otevfete zde / Abn / Abziehen / Αποκολλήστε / Desprender / Koorida / Décoller / Otvoriti skini / Húzza le / Staccare / Ўстиғи қабатын алып таста / 벗기 / Plęsti čia / Atfimt / Schillen / Trek av / Oderwać / Destacar / Se dezlipeste / Отклеить / Odrhните / Oljuštiti / Dra isär / Ayırma / Відкрити / 撕下
	Perforation / Перфорация / Perforace / Perforering / Διάτρηση / Perforación / Perforatsioon / Perforacija / Perforálás / Perforazione / Тесик тесу / 찢취선 / Perforacija / Perforácia / Perforatie / Perforacja / Perfuração / Perforare / Перфорация / Perforácia / Perforasyon / Перфорация / 穿孔
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	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 / Сапқын 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 награвать / Uchovávaťe mimo zdroja tepla / Držite dalje od toplote / Får ej utsättas för värme / Isidan uzak tutun / Бергerti від дії тепла / 请远离热源
	Cut / Срежете / Odstřihněte / Klip / Schneiden / Κόψτε / Cortar / Lõigata / Découper / Reži / Vágja ki / Tagliare / Keciңiz / 잘라내기 / Kirpti / Nogriez / Knippen / Kutt / Odciać / Cortar / Decupați / Отрезать / Odstřihněte / Iseći / Klipp / Kesme / Pozpizati / 剪下



Collection date / Дата на събиране / Datum odběru / Opsamlingsdato / Entnahmedatum / Ημερομηνία συλλογής / Fecha de recogida / Kogumiskuuupäev / Date de prélèvement / Dani prikupljanja / Mintavétel dátuma / Data di raccolta / Жинаған тізбекүні / 수집 날짜 / Paëmimo data / Savākšanas datums / Verzameldatum / Dato prøvetaking / 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/pårbaude / µL/teste / мкл/анализ / µL/检测



Keep away from light / Παзете от светлина / Nevystavujte světlu / Må ikke udsættes for lys / Vor Licht schützen / Κρατήστε το μακριά από το φως / Mantener alejado de la luz / Hoida eemal valgusest / Conserver à l'abri de la lumière / Držati dalje od svetla / Fény nem érheti / Tenere al riparo dalla luce / Қараңғыланған жерде ұста / 빛을 피해야 함 / Laikyti atokiau nuo šilumos šaltinių / Sargāt no gaismas / Niet blootstellen aan zonlicht / Må ikke utsettes for lys / Przechowywać z dala od źródła światła / Manter ao abrigo da luz / Feriți de lumină / Хранить в темноте / Uchovávajte mimo dosahu svetla / Držite dalje od svetlosti / Får ej utsättas för ljus / Işıktan uzak tutun / Беретти від дії світла / 请远离光线



Hydrogen gas generated / Образуван е водород газ / Možnost úniku plynného vodíku / Frembringer hydrogengas / Wasserstoffgas erzeugt / Δημιουργία αερίου υδρογόνου / Producción de gas de hidrógeno / Vesinikgaasi tekitatud / Produit de l'hydrogène gazeux / Sadržaji hydrogen vodik / Hidrogén gázt fejleszt / Produzione di gas idrogeno / Газтөктес сутері пайда болды / 수소 가스 생성됨 / Išskiria vandenilio dujas / Rodas ūdenradis / Waterstofgas gegenereerd / Hydrogengass generert / Powoduje powstawanie wodoru / Produção de gás de hidrogénio / Generare gaz de hidrogen / Выделение водорода / Vyrobené použitím vodíka / Osloбаda se vodonik / Genererad vätgas / 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 / Identificationnummer van de patiënt / Pasientens ID-nummer / Numer ID pacienta / Número da ID do doente / Număr ID pacient / Идентификационный номер пациента / Identifikačné číslo pacienta / ID broj pacijenta / Patientnummer / Hasta kimlik numarası / Идентификатор пациента / 患者标识号



Fragile, Handle with Care / Чупливо, Работете с необходимото внимание. / Křehké, Při manipulaci postupujte opatrně. / Forsigtig, kan gå i stykker. / Zerbrechlich, vorsichtig handhaben. / Εύθραστο. Χειριστείτε το με προσοχή. / Frágil. Manipular con cuidado. / Öm, kásitsege ettevaatlult. / Fragile. Manipuler avec précaution. / Lomljivo, rukujte pažljivo. / Törékeny! Óvatosan kezelendő. / Fragile, maneggiare con cura. / Сыныш, абайлап пайдаланыңыз. / 조심 깨지기 쉬운 처리 / Trapu, elkites atsargiai. / Trausls; rikoties uzmanīgi / Breekbaar, voorzichtig behandelen. / Ømtål, håndter forsigtig. / Krucha zawartość, przenosić ostrożnie. / Frágil, Manuseie 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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