



IVD Rx Only CE

8810061JAA(06)
2019-09
English

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

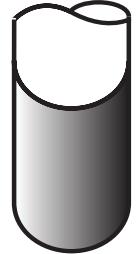
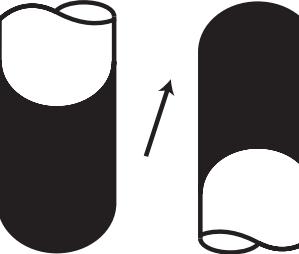
At the time of use, test both positive and negative control cultures to check performance of the coagulase plasma, techniques and methodology. The following cultures listed are the minimum that should be used for performance testing.

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.

Negative	Positive			
	1+	2+	3+	4+
				
	1+			
		2+		
			3+	
				4+
Negative	No evidence of fibrin formation			
1 + Positive	Small unorganized clots			
2 + Positive	Small organized clot			
3 + Positive	Large organized clot			
4 + Positive	Entire content of tube coagulates and is not displaced when tube is inverted.			

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.

Test	MSSA* (222 isolates)		MRSA** (78 isolates)		Total (300 isolates)	
	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. Yolken, 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



Manufacturer / Производител / Výrobce / Fabrikant / Hersteller / Κατασκευαστής / Fabricante / Tootja / Fabricant / Proizvodač / Gyártó / Fabbricante / Аткарушы / 제조업체 / Gamintojas / Ražotājs / Tilvirker / Producēt / Producător / Производитель / Výrobca / Proizvodač / Tillverkare / Uretici / Виробник / 生产厂商



Use by / Используйте до / Spotrebujte do / Brug før / Verwendbar bis / Xρήση έως / Usar antes de / Kasutada enne / Date de péremption / 사용 기한 / Upotrijebite do / Fehlhasználhatóság dátuma / Usare entro / Дейн пайдалануға / Naudokite iki / Izletot līdz / Houdbaar tot / Brukes for / Stosować do / Prazo de validade / A se utiliza pán la / Использовать до / Použíte do / Upotrebiti do / Använd före / Son kullanım tarihi / Використати до/line / 使用截止日期
YYYY-MM-DD / YYYY-MM (MM = end of month)
ГГГГ-ММ-ДД / ГГГГ-ММ (ММ = край на месец)
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 lopp)
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)
ЖОЮЮК-AA-KK / ЖОЮЮК-AA / (AA = айдан соңы)
YYYY-MM-DD/YYYY-MM (MM = 월 말)
ММММ-ММ-ДД / ММММ-ММ (MM = mēnesis pabaiga)
GGGG-MM-DD/GGGG-MM (MM = meneša 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 = fin do mês)
AAAA-LZ-ZZ / AAAA-LL (LL = sfârșitul lunii)
ГГГГ-ММ-ДД / ГГГГ-ММ (MM = 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 månaden)
YYYY-AA-GG / YYYY-AA (AA = ayin sonu)
PPPP-MM-DD / PPPP-MM (MM = кінець місяця)
YYYY-MM-DD / YYYY-MM (MM = 月末)



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



Authorized Representative in the European Community / Оторизиран представител в Европейската общност / Autorizovaný zástupce pro Evropském společenství / Autoriseret repræsentant i De Europæiske Fællesskaber / Autorisierte Vertreter in der Europäischen Gemeinschaft / Εξουσιοδοτημένος αντιπρόσωπος στην Ευρωπαϊκή Κοινότητα / Representante autorizado en la Comunidad Europea / Volitatud esindaja Euroopa Nõukogus / Reprézentant autorisé pour la Communauté européenne / Autorizuirani predstavnik u Europskoj uniji / Meghatalmazott képviselő az Európai Közösségen / Rappresentante autorizzato nella Comunità Europea / Europa қоюмындыстаңындағы үкіметтік екін / ユーリップ 공동체의 위원 대표 / Igaliatasis asttovas Europos Bendrijoje / Plinvarotais pārstāvis Eiropas Kopienā / Bevoegde vertegenwoordiger in de Europese Gemeenschap / Autorisert representant i EU / Autorizowane przedstawicielstwo we Wspólnocie Europejskiej / Representante autorizado na Comunidade Europeia / Représentant autorisé pour Comunitatea Europeană / Уполномоченный представитель в Европейском сообществе / Autorizovaný zástupca v Evropskom spoločenstve / Autorizovano predstavništvo v Evropskoj uniji / Auktoriserađ representant i Europeiska gemenskapen / Avrupa Topluluğu Yetkilii Temsilcisi / Упновраженији представник у краинах ЕС / 欧洲共同体授权代表



In Vitro Diagnostic Medical Device / Медицински уред за диагностика ин vitro / Lékařské zařízení určené pro diagnostiku in vitro / In vitro diagnostisk medicinsk anordning / Medizinisches In-vitro-Diagnostikum / In vitro διαγνωστική ιατρική συσκευή / Dispositivo médico para diagnóstico in vitro / In vitro diagnostika meditsinskaaparatur / Dispositif médical de diagnostic in vitro / Medicinska pomagala za In Vitro Dijagnostiku / In vitro diagnostikai orvosi eszköz / Dispositivo mediceale per diagnostica in vitro / Ιασανδής χαρχιζόμενης μεдициналық диагностика аспабы / In Vitro Diagnostic 의료 기기 / In vitro diagnostikos prietaisais / Medicīnas ierīces, ko lieto in vitro diagnostikā / Medisch hulpmiddel voor in-vitro diagnostiek / In vitro diagnostisk medisinsk utstyr / Urządzenie medyczne do diagnostyki in vitro / Dispositivo médico para diagnóstico in vitro / Dispositivo medical pentru diagnostic in vitro / Медицинский прибор для диагностики in vitro / Medicínska pomôcka na diagnostiku in vitro / Medicinski uredaj za in vitro diagnostiku / Medicinteknisk produkt för in vitro-diagnostik / In Vitro Diagnostik Tibbi Cihaz / Медичний пристрій для діагностики in vitro / 体外诊断医疗设备



Temperature limitation / Температурни ограничения / Teplotní omezení / Temperaturbegrensning / Temperaturbegrenzung / Περιορισμοί θερμοκρασίας / Limitación de temperatura / Temperatuuri piirang / Limites de température / Dozvoljena temperatura / Hőmérsékleti határ / Limiti di temperatura / Температурны шекту / 온도 제한 / Laikymo temperatūra / Temperatūras ierobežojumi / Temperaturlimit / Temperaturbegrenzung / Ограничение температуры / Limites de temperatura / Limite de temperatură / Ограничение температуры / Ohranenie teploty / Ograničenie temperature / Temperaturgräns / Sıcaklık sınırlaması / Обмеження температури / 温度限制



Batch Code (Lot) / Код на партидата / Kód (číslo) šárže / Batch-kode (lot) / Batch-Code (Charge) / Κωδικός παρτίδας (παρτίδα) / Código de lote (lote) / Partii kood / Numéro de lot / Lot (kod) / Tétel száma (Lot) / Codice batch (lotto) / Топтама коды / 배치 코드(로트) / Partijos numeris (LOT) / Partijas kods (laidiens) / Lot nummer / Batch-kode (parti) / Kod parti (seria) / Código do lote / Cod de serie (Lot) / Код партии (лот) / Kód série (šárža) / Kod serije / Partinummer (Lot) / Parti Kodu (Lot) / Kod partii / 批号 (亚批)



Contains sufficient for <n> tests / Съдържанието е достатъчно за <n> теста / Dostatečné množství pro <n> testů / Indeholder tilstrækkeligt til <n> tests / Ausreichend für <n> Tests / Περιέχει επαρκή ποσότητα για <n> εξτάσεις / Contenido suficiente para <n> pruebas / Kullaldane <n> testide jaoks / Contenu suffisant pour <n> tests / Sadržaj za <n> testova / <n> tesztelésre elégéndő / Contenuto sufficiente per <n> test / <n> тесттери үшін жеткілікті / <n> 테스트가 충분히 포함됨 / Pakankamas kiekis atitink <n> testu / Satur pietiekami <n> párbaudēm / Inhou voldoende voor <n> testen / Innholder tilstrekkelig til <n> tester / Zawiera ilość wystarczającą do <n> testów / Conteúdo suficiente para <n> testes / Continut suficient pentru <n> teste / Достаточно для <n> тестов(a) / Obsah vystačí na <n> testov / Sadržaj dovoljan za <n> testova / Innehåller tillräckligt för <n> analyser / <n> test için yeterli malzemeler / Вистачить для аналізів: <n> / 足够进行 <n> 次检测



Consult Instructions for Use / Направете справка в инструкциите за употреба / Prostudujte pokyny k použití / Se brugsanvisningen / Gebrauchsanweisung beachten / Συμβουλεύτε τις οδηγίες χρήσης / Consultar las instrucciones de uso / Luggedu kasutusjuhendit / Consulter la notice d'emploi / Koristi upute za upotrebu / Olvassa el a használati utasítást / Consultare le istruzioni per l'uso / Пайдалану нұсқаулығымен танысын алыңыз / 사용 지침 참조 / Skaitykite naudojimo instrukcijas / Skaitl lietošanas pamācību / Raadpleeg de gebruiksaanwijzing / Se i bruksanvisningen / Zobacz instrukcję użytkowania / Consultant as instruções de utilização / Consultați instrucțiunile de utilizare / См. руководство по эксплуатации / Poznij Pokyny na používanie / Pogledajte uputstvo za upotrebu / Se bruksanvisningen / Kullanım Talimatları'na başvurun / Див. инструкции з використання / 请参阅使用说明



Do not reuse / Не използвайте отново / Nepoužívejte opakovaneč / Ikke til genbrug / Nicht wiederverwenden / Μην επαναχρησιμοποιείτε / No reutilizar / Mitte kasutada korduvat / Ne pas réutiliser / Ne koristiti ponovo / Egyszer használatos / Non riutilizzare / Пайдаланбаңыз / 재사용 금지 / Tik vienkartiniam naudojimui / Nelietot atkārtoti / Niet opnieuw gebruiken / Kun til engangsbruk / Nie stosować powtórnie / Nār reutilize / Nu refolosiți / Не использовать повторно / Nepoužívajte opakovaneč / Ne upotrebljavajte ponovo / Får ej återanvändas / Tekrar kullanmayın / Не використовувати повторно / 请勿重复使用



Serial number / Серийн номер / Sériové číslo / Serienummer / Seriennummer / Σειριακός αριθμός / Nº de serie / Seeriaanumber / Numéro de série / Serijski broj / Sorozatszám / Numero di serie / Топтамалық номір / 일련 번호 / Serijos numeris / Sērijas numurs / Serie nummer / Numer seryjny / Número de serie / Număr de serie / Серийный номер / Seri numarası / Номер серии / 序列号



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 / Móvo už dôvodouptí obdobou IVD / Solo para la evaluación del rendimiento en diagnóstico in vitro / Ainult IVD seadme hindamiseks / Réservé à l'évaluation des performances IVD / Samo i znanstvene svrhe za In Vitro Dijagnostiku / Kizárolág in vitro diagnosztikához / Solo per valutazione delle prestazioni IVD / Жасанды жағдайда «пробирка шінде», диагностика тақ хұмысты бағалау үшін / IVD 성능 평가에 대해서만 사용 / Tik IVD prietais veikimo charakteristikoms tikrinti / Vienīgi IVD darbības novērtēšanai / Uitsluitend voor doeltreffendheidsonderzoek / Kun for evaluering av IVD-ytelse / Tylko do oceny wydajności IVD / Uso exclusivo para avaliação do IVD / Numai pentru evaluarea performanței IVD / Толькo для оценки качества диагностики in vitro / Určené či na diagnostiku in vitro / Samo za procenu učinka u in vitro dijagnostici / Endast för utvärdering av diagnostisk användning in vitro / Yalnızca IVD Performans değerlendirme için / Тільки для оцінювання якості дiагностики 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 / Límite inferior de temperatura / Alumine temperatuuri piir / Limite inférieure de température / Najniža dozvoljena temperatura / Alsó hőmérsékleti határ / Limite inferiore di temperatura / Температурният температура / Температурният температура / Žemiasiaus 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 / Sicaklık alt sınırı / Miňimalnaya temperatura / 温度下限

CONTROL Control / Контролно / Kontrola / Kontrol / Kontrolle / Μάρτυρας / Kontroll / Contrôle / Controllo / Қаңыбылау / 컨트롤 / Kontrolé / Kontrole / Controle / Controlo / Kontroll / Kontrolъ / Kontrolъ / 对照

CONTROL + Positive control / Положителен контрол / Positivní kontrola / Positiv kontrol / Positive Kontrolle / Θετικός μάρτυρας / Control positivo / Positiivne kontroll / Contrôle positif / Pozitívna kontrola / Pozitív kontroll / Controlo positivo / Οι δακτύλαια / 양성 컨트롤 / Teigamaa kontrolle / Pozitív kontrole / Positivee controle / Kontrola dodatnia / Controlo positivo / Control positív / Положительный контроль / Pozitif kontrol / Позитивный контроль / 阳性对照试剂

CONTROL - Negative control / Отрицателен контрол / Negativní kontrola / Negativ kontrol / Aruprtikóis yátritras / Control negativo / Negativne kontroll / Contrôle négatif / Negativa kontrola / Negativt kntroll / Controlla negativo / Негативный контроль / Neigama kontroll / Negativtare kontrole / Negatiive kontrole / Kontrola ujemna / Controlo negativo / Control negativ / Отрицательный контроль / Negatív kontroll / Негативный контроль / 阴性对照试剂

STERILE Method of sterilization: ethylene oxide / Метод на стерилизация: этиленов оксид / Způsob sterilizace: etylenoxid / Sterilisationsmethode: Ethylenoxid / Μέθοδος αποτελέσματος: αιθυλενόξειδο / Método de esterilización: óxido de etileno / Steriliseerimismeetod: etüleenoksids / Méthode de stérilisation : oxyde d'éthylène / Metoda sterilizacije: etilen oksid / Sterilizálás módszere: etilén-oxid / Metodo di sterilizzazione: ossido di etilene / Стерилизация једици - этилен топчива / 소독 방법: 에틸렌온사이드 / Sterilizávimo bódás: etileno oksidas / Sterilizēšanas metode: etēnoksiðs / Gesteriliseert met behulp van ethylenoxide / Steriliseringssmetode: etylenoksid / Metoda sterilizacji: etylen etylu / Método de esterilização: óxido de etileno / Metodā de sterilizare: oxid de etilena / Метод стерилизации: этиленовая стерильность / Metoda sterilizacije: etilenoksid / Metoda sterilizacije: etilen oksid / Steriliseringssmetod: etenonoxid / Sterilizasyon yöntemi: etilen oksit / Metoda steriliizacije: etilenoksim / 灭菌方法: 环氧乙烷

STERILE R Method of sterilization: irradiation / Метод на стерилизация: иридиация / Způsob sterilizace: záření / Steriliseringssmetode: bestrålning / Sterilisationsmethode: Bestrahlung / Μέθοδος απστεριγώσης: ακτινοβολία / Método de esterilización: irradiación / Steriliseerimismeetod: kirkus / Méthode de stérilisation : irradiation / Metoda sterilizacije: zračenje / Sterilizácijski módszerek: besúgrázás / Metodo di sterilizzazione: irradiazione / Стерилизация адци – сауне туcipy / 소독 방법: 방사 / Sterilizavimo bùdas: radiaciа / Sterilizēšanas metode: apstārošana / Gesteriliseerd met behulp van bestraling / Steriliseringssmetode: bestrålning / Metoda sterylizacji: napromienianie / Método de esterilização: irradiação / Metódа de sterilizacíe: iradiacíe / Метод стерилізації: іридація / Metoda sterilizacije: ozračavanje / Steriliseringssmetod: strålning / Sterilizasyon yöntemi: iradyasyon / Метод стерилізації: опроміненням / 灭菌方法: 辐射



Caution, consult accompanying documents / Внимание, направете справка в приложаващите документи / Pozor! Prostudujte si pripojenou dokumentaci!
/ Forsigtig, se ledsagende dokumenter / Achtung, Begleitdokumente beachten / Просохъ, съмбулсуете та сънодеснитка єнографа / Precaución, consultar la documentación adjunta / Ettevaatust! Lugeda kaasnevad dokumentatsiooni / Attention, consulter les documents joints / Upozorenje, koristi prateču dokumentaciju / Figueiem! Olvassa el a mellékelt tájékoztatót / Attenzione: consultare la documentazione allegata / Абайланаыз, тиистى құжаттармен тәнисцыңыз / 주의, 동봉된 설명서 참조 / Démésio, žiürékité pridedamus dokumentus / Piesardzība, skatīt pavaddokumentus / Voorzichtig, raadpleeg bijgevoegde documenten / Forsiktig, se vedlagt dokumentasjon / Naleží započaň zí s doložconymi dokumentami / Cuidado, consulte a documentação fornecida / Atenție, consultați documentele însoțitoare / Внимание: см. прилагаемую документацию / Výstraha, pozri sprievodné dokumenty / Pažnjal! Pologledajte priložena dokumenta / Obs! Se medföljande dokumentation / Dikkat, birlikte verilen belgelere başvurun / Уважа: див. супутната документација / 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 / Улемне температурнир / Limite supérieure de température / Gornja dozvoljena temperatura / Felső hőmérsékleti határ / Limite superiore di temperatura / Температурнаны рұсқа етігендегі жоғары шері / 상한 온도 / Aukščiausiai laikymo temperatūra / Augsējā temperatūras robeža / Hoogste temperatuurlimiet / Øvre temperaturgrense / Górnna granična temperatūra / Limite máxima de temperatura / Limită maximă de temperatură / Верхний предел температуры / Horní hranica teploty / Gornja granična temperatura / Øvre temperaturgrøns / Сүзгілік ғыст сині / Максимальна температура / 温度上限



Collection time / Время на събиране / Čas odberu / Opsamlingsstidspunkt / Enthnahmehrzeit / Ήora de recogida / Kogumisaeg / Heure de prélèvement / Sat prikupljanja / Mintavétel időpontja / Ora di raccolta / Жизнен узыты / 수집 시간 / Paémimo laikas / Savākšanas laiks / Verzameltijd / Tid pravetaking / Godzina pobrania / Hora de coleita / Ora colectării / Время сбора / Doba odberu / Vreme prikupljanja / Uppsamlingstid / Toplama zamanı / Час забора / 采集时间



Peel / Obenepre / Otvorete zde / Ábn / Abziehen / Αποκόλλησε / Desprender / Koorda / Décoller / Otvoriti skin / Húzza le / Staccare / Үстінгі қабатын алпың таста /



Do not use if package damaged / Не използвайте, ако опаковката е повредена / Ne porušitevajte, je-li obal poškozeny / Má ikke anvendes hvis emballagen er beskadiget / Inhal beschädigter Packungsnicht verwenden / Μη χρησιμοποιείτε εάν η συσκευή 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 koristite ako je oštećeno pakiranje / Ne használja, ha a csomagolás sérült / Non usare se la confezione è danneggiata / Egeret náket búzlygan bónca, pályandánba / 폐기지가 상온상 경우 사용 금지 / Jei pakuotu pažeista, neraduotu / 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 / Ne poružívajte, ak je obal poškodený / Ne koristite ako je pakovanje oštećeno / Anvärd ej om förpackningen är skadad / Ambalaž hasar görümsüse kullanılmayın / Не використовувати за пошкоджено упаковки / 如果包装破损, 请勿使用



Keep away from heat / Пазете от топлина / Nevystavujte přílišnému teplu / Má ikke utsættes for varme / Vor Wärme schützen / Κρατήστε το μακριά από τη θερμότητα / Mantener alejado de fuentes de calor / Hoida enam valgusest / Protéger de la chaleur / Držati dalje od izvora topline / Óvjá a melegítői / Tenere lontano dal calore / Салыңын жерде сакта / 열을 피해야 함 / Laikyti atokiam nuo šilumos šaltinių / Sargāt 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 cálidurá / Не нагревать / Uchovávajte mimo zdroja tepla / Držite dalje od toplote / Far ej utsättas för värme / Isidan uzak tutun / Берегти від дії тепла / 请远离热源



Cut / Срежете / Odstríhnéte / Klip / Schneiden / Kóψte / Cortar / Lõigata / Découper / Reži / Vágja ki / Tagliare / Kecisjéz / 잘라내기 / Kirpti / Nogriezt / Knippen / Kutt / Odciąć / Cortar / Decupať / Отрезать / Odstríhnite / Iseči / Klipp / Kesme / Rozřízati / 剪下



Collection date / Дата на събиране / Datum odběru / Opsamlingsdato / Entnahmedatum / Ημερομηνία συλλογής / Fecha de recogida / Kogumiskuupäev / Date de prélèvement / Dani prikupljanja / Mintavétele dátuma / Data di raccolta / Жынаган тәбекүні / 수집 날짜 / Paémimo data / Savākšanas datums / Verzameldatum / Dato prøvetaking / Data pobrania / Data de colheita / Data colectării / Дата сбора / Dátum 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/tirimas / 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 / Кратјотс то јакрија атпó то фиц / 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 / Қаралыланған жерде ұста / 빛을 피해야 함 / Laikyti atokiu nuo šilumos šaltiniu / 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 svjetlosti / Får ej utsättas för ljus / Ішкітан узак тұтун / Берегти від дін 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 tekkitatud / Produit de l'hydrogène gazeux / Sadrži hydrogen vodik / Hydrogén gáz fejeszt / Produzione di gas idrogeno / Газетеке сутері пайда болы / 수소 가스 생성됨 / İşksiria vandenilio dujas / Rodas Üdepradis / Waterstofgas gegenereerd / Hydrogengass generert / Powoduje powstawanie wodoru / Produção do gás de hidrogénio / Generare gaz de hidrogen / Выделение водорода / Vyrobené použitím vodíka / Oslobadá se vodoník / Genererad välgas / Açıga çıkan hidrojen gazi / Реакция з видленням 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 немірі / 환자 ID 번호 / Paciento identifikavimo numeris / Pacienta ID numurs / Identificatienummer van de patiënt / Pasientens ID-nummer / Numer ID pacienta / Número da ID do doente / Număr ID pacient / Идентификационный номер пациента / Identifikačné číslo pacienta / ID broj pacijenta / Patientnummer / Hasta kimlik numarası / Идентификатор пациента / 患者标识号



Fragile, Handle with Care / Чупливо, Работете с необходимото внимание. / Krehké. Při manipulaci postupujte opatrne. / Forsiktig, kan gå i stykker. / Zerbrechlich, vorsichtig handhaben. / Εύθραυστο. Χειριστέτε το με προσοχή. / Frágil. Manipular con cuidado. / Óm, kásitsege ettévaatlikult. / Fragile. Manipuler avec précaution. / Lomljivo, rukujte pažljivo. / Törékeny! Övatosan kezelendő. / Fragile, maneggiare con cura. / Сынъш, абылап пайдаланызыз. / 조심 깨지기 쉬운 처리 / Trapu, elkités atsargai. / Trauslis; rikkoties uzmanigi / Breekaar, voorzichtig behandelen. / Ømtålig, håndter forsiktig. / Krucha zawartość, przenosić ostrożnie. / Frágil, Manuseie com Cuidado. / Fragil, manipulați cu atenție. / Хрупкое! Обращаться с осторожностью. / Krehké, vyžaduje sa opatrná manipulácia. / Lomljivo - rukujte pažljivo. / Bräckligt. Hantera försiktigt. / Kolay Kirılır, Dikkatli Taşınır. / Тендітна, зерттатыс з обережності / 易碎, 小心轻放

Rx Only

This only applies to US: "Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner." / S'applique uniquement aux États-Unis: "Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner." / Vale solo per gli Stati Uniti: "Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner." / Gilt nur für die USA: "Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner." / Solo se aplica a los EE.UU.: "Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner."

bd.com/e-labeling
KEY-CODE: 8810061JAA

Europe, CH, GB, NO: +800 135 79 135	
International: +31 20 794 7071	
AR +800 135 79 135	LT 8800 30728
AU +800 135 79 135	MT +31 20 796 5693
BR 0800 591 1055	NZ +800 135 79 135
CA +1 855 805 8539	RO 0800 895 084
CO +800 135 79 135	RU +800 135 79 135
EE 0800 0100567	SG 800 101 3366
GR 00800 161 22015 7799	SK 0800 606 287
HR 0800 804 804	TR 00800 142 064 866
IL +800 135 79 135	US +1 855 236 0910
IS 800 8996	UY +800 135 79 135
LI +31 20 796 5692	VN 122 80297



Becton, Dickinson and Company
7 Loveton Circle
Sparks, MD 21152 USA

EC REP

Benex Limited
Pottery Road, Dun Laoghaire
Co. Dublin, Ireland

Australian Sponsor:

Becton Dickinson Pty Ltd.
4 Research Park Drive
Macquarie University Research Park
North Ryde, NSW 2113
Australia

ATCC® is a trademark of the American Type Culture Collection.

BD, the BD Logo, BACTEC, Bacto, BBL, and Trypticase are trademarks of Becton, Dickinson and Company or its affiliates.
© 2019 BD. All rights reserved.