BD BBL™ MGIT™ AST SIRE System

For the Antimycobacterial Susceptibility Testing of *Mycobacterium tuberculosis*

8809591JAA(05)
2019-09

INTENDED USE

The BD BBL™ MGIT™ AST SIRE System is a rapid manual qualitative procedure for susceptibility testing of *Mycobacterium tuberculosis*, from culture, to streptomycin, isoniazid, rifampin and ethambutol.

SUMMARY AND EXPLANATION

Antimycobacterial susceptibility testing is necessary for the proper treatment of patients with tuberculosis. The treatment of tuberculosis is commonly through a multiple drug regimen using the primary antimycobacterial drugs, streptomycin, isoniazid, rifampin and/or ethambutol. It is important that the antimycobacterial drugs utilized show appropriate activity against *Mycobacterium tuberculosis*, i.e., susceptibility.

Multidrug resistant *Mycobacterium tuberculosis* (MDR-TB) has recently become a serious public health problem.[1] Resistance to any of the four primary drugs, streptomycin (STR), isoniazid (INH), rifampin (RIF), and ethambutol (EMB), makes the disease more difficult and expensive to treat. The rapid detection of these strains is critical to the effective treatment of the patient.

Two methods have been widely used for antimycobacterial susceptibility testing. The first method, known as the Method of Proportion,[2] uses Middlebrook and Cohn 7H10 or 7H11 Agar. It compares colony counts on drug-containing and drug-free media. Resistance to a drug is detected when 1% or more of the population is resistant to the drug concentration under test. Results are generally available after 21 days of incubation. The second method is based on growth in liquid culture and generally takes from 3 to 14 days.

The BD BBL MGIT AST System provides the susceptibility result within 14 days and allows appropriate antibiotic therapy to be implemented sooner than with the Method of Proportion.

PRINCIPLES OF THE PROCEDURE

The BD BBL MGIT Mycobacteria Growth Indicator Tube is a tube containing a modified Middlebrook 7H9 Broth which, when supplemented with BD BBL MGIT OADC enrichment, supports the growth and detection of mycobacteria (see BD BBL MGIT Products package insert). The MGIT tube contains a fluorescent compound embedded in silicone on the bottom of a 16 x 100 mm round-bottom tube. The fluorescent compound is sensitive to the presence of oxygen dissolved in the broth. The initial concentration of dissolved oxygen quenches the emissions from the compound, and little fluorescence can be detected. Later, actively respiring microorganisms consume the oxygen and allow more fluorescence to be observed using a 365 nm UV transilluminator or longwave UV light.

The BD BBL MGIT AST System is a three to fourteen day qualitative test. The test is based on growth of the *Mycobacterium tuberculosis* strain in a drug-containing tube compared to a drug-free tube. MGIT tubes are observed daily from the third day after inoculation. The absence of fluorescence in the drug-containing tube two days beyond the appearance of fluorescence in the Growth Control tube is indicative of susceptibility of the organism to that drug. Fluorescence of a drug-containing tube on or within two days of fluorescence of the Growth Control tube is indicative of resistance of the organism to that drug.

REAGENTS

BD BBL MGIT AST SIRE Kit contains two each lyophilized vials of streptomycin, isoniazid, rifampin and ethambutol.

Approximate Formula* Per Vial Lyophilized Streptomycin: Streptomycin ..... 160 µg
Approximate Formula* Per Vial Lyophilized Isoniazid: Isoniazid ..... 20 µg
Approximate Formula* Per Vial Lyophilized Rifampin: Rifampin ..... 200 µg
Approximate Formula* Per Vial Lyophilized Ethambutol: Ethambutol ..... 700 µg

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

PRODUCT DETERIORATION

Some variation in the appearance of the lyophilized SIRE drugs may occur. This results from the lyophilization process and does not affect performance of the products.

Directions For Use: Reconstitute each BD BBL MGIT Streptomycin lyophilized vial with 4 mL of sterile distilled/deionized water to make a stock solution of 40 µg/mL.

Reconstitute each BD BBL MGIT Isoniazid lyophilized vial with 4 mL of sterile distilled/deionized water to make a stock solution of 5 µg/mL.

Reconstitute each BD BBL MGIT Rifampin lyophilized vial with 4 mL of sterile distilled/deionized water to make a stock solution of 50 µg/mL.

Reconstitute each BD BBL MGIT Ethambutol lyophilized vial with 4 mL of sterile distilled/deionized water to make a stock solution of 175 µg/mL.

Warnings and Precautions:

For *in vitro* Diagnostic Use.

Laboratory procedures involving mycobacteria require special equipment and technique to minimize biohazard.[3] Biosafety Level 2 practices and procedures, containment equipment and facilities are required for non-aerosol-producing manipulations of clinical specimens such as preparation of acid-fast smears. All aerosol-generating activities must be conducted in a Class I or II biological safety cabinet. Biosafety Level 3 practices, containment equipment and facilities are required for laboratory activities in the propagation and manipulation of cultures of *M. tuberculosis* and *M. bovis*. Animal studies also require special procedures.[4]

BD BBL MGIT AST SIRE – Catalog number 245119

BD BBL MGIT AST SIRE-Ethambutol, Lyophilized

Danger

H360 May damage fertility or the unborn child.

P201 Obtain special instructions before use. **P202** Do not handle until all safety precautions have been read and understood. **P280** Wear protective gloves/protective clothing/eye protection/face protection. **P308+P313** IF exposed or concerned: Get medical advice/attention. **P405** Store locked up. **P501** Dispose of contents/container in accordance with local/regional/national/international regulations.

BD BBL MGIT AST SIRE-Rifampin, Lyophilized

Warning

H302+H332 Harmful if swallowed or if inhaled

P261 Avoid breathing dust/fume/gas/mist/vapors/spray. **P264** Wash thoroughly after handling. **P270** Do not eat, drink or smoke when using this product. **P271** Use only outdoors or in a well-ventilated area. **P301+P312** IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. **P330** Rinse mouth. **P304+P340** IF INHALED: Remove person to fresh air and keep comfortable for breathing. **P312** Call a POISON CENTER or doctor/physician if you feel unwell. **P501** Dispose of contents/container in accordance with local/regional/national/international regulations.

Read and follow directions contained in all appropriate package inserts including the BD BBL MGIT Mycobacteria Growth Indicator Tube (see “Availability”).

Wear UV protective glasses when observing fluorescence and use only longwave illumination (365 nm). DO NOT USE SHORTWAVE UV LIGHT FOR VIEWING.

Prior to use, the user should examine the tubes for evidence of contamination or damage. Discard any tubes if they appear unsuitable or exhibit fluorescence prior to use. Dropped tubes should be examined carefully. If damage is seen, the tube should be discarded.

A nephelometer must be used for the preparation of isolate suspensions from solid media (e.g., Lowenstein-Jensen Medium).

Autoclave all inoculated MGIT tubes prior to disposal.

Storage Instructions: On receipt, store the lyophilized vials at 2–8 °C. Once reconstituted, the antibiotic solutions may be frozen and stored at -20 °C up to 6 months, not to exceed the original expiration date. Once thawed, use immediately. Discard unused portions.

SPECIMEN PREPARATION

All preparations detailed below are from cultures of *Mycobacterium tuberculosis*. The laboratory should confirm, by appropriate identification techniques, that the isolate to be tested is a pure culture.

Preparation of the Isolate from Solid Media:

1. Add 4 mL of BD BBL Middlebrook 7H9 Broth to a 16.5 x 128 mm sterile tube with cap containing 8–10 glass beads.
2. Scrape with a sterile loop as many colonies as possible from growth up to 14 days old, trying not to remove any solid medium. Suspend the colonies in the Middlebrook 7H9 Broth. The suspension should exceed in turbidity a 1.0 McFarland standard.
3. Vortex the suspension for 2–3 min to break up the larger clumps.
4. Let the suspension sit for 20 min without disturbing.
5. Transfer the supernatant fluid to another 16.5 x 128 mm sterile tube with cap (avoid transferring any of the sediment) and let sit for another 15 min.
6. Transfer the supernatant fluid (it should be smooth, free of any clumps) to a third 16.5 x 128 mm sterile tube.
7. Adjust the suspension to a 0.5 McFarland standard using a nephelometer.
8. Dilute 1.0 mL of the 0.5 McFarland-adjusted suspension in 4 mL of sterile saline (1:5 dilution). The inoculum is now ready. Proceed to “Inoculation Procedure for Susceptibility Test.”

Preparation from a Positive MGIT Tube:

1. For the preparation of the test inoculum, a positive MGIT tube should be used the day after it first becomes positive, up to and including three days following initial positivity. A tube which has been positive longer than four days should be subcultured to a fresh MGIT tube and used from one to three days following positivity in that MGIT tube. Vortex the MGIT tube for 10 s.
2. Pipette 1.0 mL of the suspension from the MGIT tube into 4 mL of sterile saline (1:5 dilution). The inoculum is now ready. Proceed to "Inoculation Procedure for Susceptibility Test."

PROCEDURE

Materials Provided: BD BBL MGIT AST SIRE Kit containing two each lyophilized vials of streptomycin, isoniazid, rifampin and ethambutol.

Materials Required But Not Provided: BD BBL MGIT Mycobacteria Growth Indicator Tubes, BD BBL MGIT OADC, ancillary culture media, reagents, quality control organisms and laboratory equipment as required for this procedure.

Negative Control: An unopened, uninoculated MGIT tube is used for the Negative Control.

Preparation of the Positive Control:

1. Empty broth from an uninoculated MGIT tube.
2. Label the tube as a Positive Control and record the date.
3. Prepare a 0.4% sodium sulfite solution (0.4 g in 100 mL sterile distilled or deionized water).
4. Add 5 mL of sodium sulfite solution to the empty MGIT tube. Replace the cap, tighten and allow to stand at room temperature for 1 h. Do not incubate.
5. Positive Control tubes can be used many times. Each Positive Control tube can be used for up to 4 weeks when stored at room temperature.

Inoculation Procedure for MGIT Susceptibility Test:

1. Label five MGIT tubes for each test isolate. Label one as MGIT GC (Growth Control), one as MGIT STR, one as MGIT INH, one as MGIT RIF, and the last as MGIT EMB.
2. Aseptically add 0.5 mL of BD BBL MGIT OADC to each tube.
3. Aseptically pipette, using a micropipette, 100 µL of 40 µg/mL MGIT STR solution to the appropriately labeled MGIT tube. Aseptically pipette 100 µL of 5 µg/mL MGIT INH solution to the appropriately labeled MGIT tube. Aseptically pipette 100 µL of 50 µg/mL MGIT RIF solution to the appropriately labeled MGIT tube. Aseptically pipette 100 µL of 175 µg/mL MGIT EMB solution to the appropriately labeled MGIT tube. No antibiotics should be added to the MGIT GC tube.

Drug	Concentration of Drug after Reconstitution	Volume Added to Mgit Tubes for Test	Final Concentration In MGIT Tubes
MGIT STR	40 µg/mL	100 µL	0.8* µg/mL
MGIT INH	5 µg/mL	100 µL	0.1* µg/mL
MGIT RIF	50 µg/mL	100 µL	1.0* µg/mL
MGIT EMB	175 µg/mL	100 µL	3.5* µg/mL

*Equivalent to CDC[3] recommended critical drug concentrations.

4. Inoculate using a pipette, 0.5 mL of the 1:5 organism suspension (see "Specimen Preparation") into each of the five MGIT tubes. Wipe the tubes with a tuberculocidal disinfectant. Tightly recap the tubes and mix well.
5. Incubate the labeled MGIT tubes at 37 °C.
6. Streak 0.1 mL of the 1:5 organism suspension to a BD BBL™ Trypticase™ Soy Agar with 5% Sheep Blood (TSA II) plate. Enclose in a plastic bag. Incubate at 35–37 °C.
7. Check the blood agar plate at 48 h for bacterial contamination.
8. If the blood agar plate shows no growth, then proceed to "Reading MGIT Tubes."
9. If the blood agar plate shows growth, discard MGIT tubes and repeat testing with pure culture.

Reading MGIT Tubes:

1. Remove the MGIT tubes from the incubator on the third day after inoculation and read with a 365 nm UV transilluminator or longwave UV light.

   NOTE: It is important to read the AST tube every day beginning on Day 3, until results can be interpreted.
2. Compare the MGIT GC tube to the Positive and Negative Control tubes. The Positive Control should strongly fluoresce (very bright orange color on the bottom of the tube and also an orange reflection on the meniscus). The Negative Control tube should have very little fluorescence.
3. If fluorescence of the MGIT GC tube looks more like the Positive Control than the Negative Control, it is positive for growth. Once the MGIT GC tube is positive, it is used to interpret the drug-containing tubes. The drug-containing tubes are interpreted on the same day the MGIT GC is positive and for up to two additional days, according to the "Interpretation of Test Results" section, not to exceed fourteen days.
4. If the GC tube has no fluorescence and looks more like the Negative Control, reincubate the tubes and continue to read daily until twelve days after inoculation of all tubes. If the GC result is equivocal (difficult to determine whether an orange fluorescence is present), then the tube should be considered negative and reincubated.
5. If the GC tube is not positive by the twelfth day of the test, the test is invalid.

Interpretation of Test Results: Interpret the MGIT result as Susceptible if the drug-containing tube does NOT fluoresce within two days of onset of fluorescence in the GC tube. Interpret the MGIT result as Resistant if the drug-containing tube fluoresces on or within two days of the day of onset of fluorescence in the GC tube. When interpreting resistance, finalize the result as soon as the MGIT GC and the drug-containing tubes fluoresce.

User Quality Control: Upon receipt of a new shipment or lot number of BD BBL MGIT AST SIRE Kit vials, it is suggested that the control organism shown below be inoculated into tubes with drugs (see "Inoculation Procedure for Susceptibility Test"). Upon observing the proper results, as shown below, the BD BBL MGIT AST SIRE drugs are ready for use in testing patient isolates. If the proper results are not observed, repeat the test. If, after repeating the test, the proper results are still not observed, do not use the media until you have contacted Technical Services at 1.800.638.8663 (United States only).

Strain	GC	MGIT STR	MGIT INH	MGIT RIF	MGIT EMB
M. tuberculosis ATCC® 27294	Fluorescence within 3–7 days	No fluorescence within 2 days of GC	No fluorescence within 2 days of GC	No fluorescence within 2 days of GC	No fluorescence within 2 days of GC

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.

LIMITATIONS OF THE PROCEDURE

Suspensions made from solid media must be allowed to settle for the prescribed times prior to standardization. Inoculum preparations made from solid media without the use of a nephelometer may give inaccurate results due to incorrect biomass.

The test is uninterpretable if the Growth Control does not fluoresce within twelve days of inoculation.

Use only pure cultures of *M. tuberculosis*. Cultures which are contaminated or which contain multiple strains of mycobacteria may give erroneous results.

PERFORMANCE CHARACTERISTICS

The performance of the BD BBL MGIT AST SIRE System was established in two clinical evaluations conducted at regional reference centers for mycobacterial susceptibility testing and university hospital-based laboratories in areas of high prevalence of *M. tuberculosis* resistance to isoniazid and/or rifampin. The BD BBL MGIT AST System was compared to the Method of Proportion. The clinical evaluation at four sites comparing INH and RIF results between the BD BBL MGIT AST System and Method of Proportion using 7H10 Media (INH at 0.2 µg/mL, RIF at 1.0 µg/mL) included 259 clinical isolates. The clinical evaluation comparing STR and EMB results between the BD BBL MGIT AST System and Method of Proportion included 138 clinical isolates: 103 isolates from two sites using 7H10 Media (STR at 2.0 µg/mL, EMB at 5.0 µg/mL), and 35 isolates from one site using LJ Media (STR at 4.0 µg/mL, EMB at 1.0 µg/mL).

Data was analyzed and interpreted qualitatively for category agreement (S/S or R/R), and overall (site combined) percent agreements were as follows: STR = 94.9%, INH = 93.1%, RIF = 98.5%, and EMB = 93.5%.[5]

Tables 1 and 2 show comparative performance between the BD BBL MGIT AST SIRE System and the Method of Proportion.

Table 1

Number of Isolates with Indicated Susceptibility Results					
Drug	**MGIT and MOP R**	**MOP S MGIT R**	**MOP R MGIT S**	**MGIT and MOP S**	**Total Isolates Tested**
STR	24	5	2	107	138
INH	70	13	5	171	259
RIF	61	1	3	194	259
EMB	12	5	4	117	138

S = Susceptible R = Resistant

Reproducibility of BD BBL MGIT AST SIRE System test results were compared to expected results for a panel of 5 ATCC strains and 16 qualified strains which included several strains resistant to each of the drugs. The reproducibility results were: 97% for STR, 94% for INH, 98% for RIF, and 94% for EMB. Individual site reproducibility results ranged from 92% to 100% for combined drug results.

Table 2

Performance Characteristics (%)					
Drug	**Sensitivity**	**Specificity**	**Predictive Value of Susceptibility**	**Predictive Value of Resistance**	**Category Agreement**
STR	92.3	95.5	98.2	82.8	94.9
INH	93.3	92.9	97.2	84.3	93.1
RIF	95.3	99.5	98.5	98.4	98.5
EMB	75.0	95.9	96.7	70.0	93.5

AVAILABILITY

Cat. No.	Description
245119	BD BBL™ MGIT™ AST SIRE Kit, carton of 8 lyophilized vials.
245111	BD BBL™ MGIT™ Mycobacteria Growth Indicator Tubes, 4 mL, carton of 25 tubes.
245113	BD BBL™ MGIT™ Mycobacteria Growth Indicator Tubes, 4 mL, carton of 100 tubes.
245116	BD BBL™ MGIT™ OADC, 15 mL, carton of 6 vials.
221818	BD BBL™ MGIT™ Normal Saline, 5 mL, carton of 10.
221819	BD BBL™ MGIT™ Normal Saline, 5 mL, carton of 100.
295939	BD BBL™ MGIT™ Middlebrook 7H9 Broth, 8 mL, carton of 10.
297345	BD BBL™ MGIT™ Water, 5 mL, carton of 100.

REFERENCES

1. Barenfanger, J. 1993. Making your lab safe against multi-drug resistant *Mycobacterium tuberculosis*. Clin. Microbiol. Newsl. *15*: 76–80.
2. Clinical and Laboratory Standards Institute (CLSI). Susceptibility Testing of Mycobacteria, Nocardiae, and Other Aerobic Actinomycetes; Approved Standard-Second Edition. CLSI document M24-A2. Clinical and Laboratory Standards Institute, Wayne, PA, USA
3. Kent, P.T., and G.P. Kubica. 1985. Public health mycobacteriology: a guide for the level III laboratory. USDHHS. Centers for Disease Control, Atlanta.
4. U.S. Public Health Service, Centers for Disease Control and Prevention, and National Institutes of Health. 1999. Biosafety in microbiological and biomedical laboratories, 4th ed. HHS Publication No. (CDC) 93-8395. U.S. Government Printing Office, Washington, D.C.
5. Data on file, BD Diagnostic Systems.

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

Change History

Revision	Date	Change Summary
(05)	2019-09	Converted printed instructions for use to electronic format and added access information to obtain the document from BD.com/e-labeling. Per Safety Data Sheet for catalog number 245119 added Health Hazard Pictogram, signal word “Danger”, all hazard & precautionary codes and statements for BD BBL MGIT AST SIRE-Ethambutol, Lyophilized. Existing Precautionary codes and statements updated for BD BBL MGIT AST SIRE-Rifampin, Lyophilized.

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

Manufacturer / Производител / Výrobce / Fabrikant / Hersteller / Κατασκευαστής / Fabricante / Tootja / Fabricant / Proizvođač / Gyártó / Fabbricante / Атқарушы / 제조업체 / Gamintojas / Ražotājs / Tilvirker / Producent / Producător / Производитель / Výrobca / Proizvođač / Tillverkare / Üretici / Виробник / 生产厂商

Use by / Използвайте до / Spotřebujte do / Brug før / Verwendbar bis / Χρήση έως / Usar antes de / Kasutada enne / Date de péremption / 사용 기한 / Upotrijebiti do / Felhasználhatóság dátuma / Usare entro / Дейін пайдалануға / Naudokite iki / Izlietot līdz / Houdbaar tot / Brukes for / Stosować do / Prazo de validade / A se utiliza până la / Использовать до / Použite do / Upotrebiti do / Använd före / Son kullanma 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 = края на месеца)
RRRR-MM-DD / RRRR-MM (MM = konec měsíce)
ÅÅÅÅ-MM-DD / ÅÅÅÅ-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)
ЖЖЖЖ-АА-КК / ЖЖЖЖ-АА / (АА = айдың соңы)
YYYY-MM-DD/YYYY-MM(MM = 월말)
MMMM-MM-DD / MMMM-MM (MM = mėnesio pabaiga)
GGGG-MM-DD/GGGG-MM (MM = mēneša beigas)
JJJJ-MM-DD / JJJJ-MM (MM = einde maand)
ÅÅÅÅ-MM-DD / ÅÅÅÅ-MM (MM = slutten av måneden)
RRRR-MM-DD / RRRR-MM (MM = koniec miesiąca)
AAAA-MM-DD / AAAA-MM (MM = fim do mês)
AAAA-LL-ZZ / AAAA-LL (LL = sfârşitul lunii)
ГГГГ-ММ-ДД / ГГГГ-ММ (ММ = конец месяца)
RRRR-MM-DD / RRRR-MM (MM = koniec mesiaca)
GGGG-MM-DD / GGGG-MM (MM = kraj meseca)
ÅÅÅÅ-MM-DD / ÅÅÅÅ-MM (MM = slutet av månaden)
YYYY-AA-GG / YYYY-AA (AA = ayın sonu)
PPPP-MM-ДД / 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 / Katalógusszám / Numero di catalogo / Каталог нөмірі / 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 / Autorisierter Vertreter in der Europäischen Gemeinschaft / Εξουσιοδοτημένος αντιπρόσωπος στην Ευρωπαϊκή Κοινότητα / Representante autorizado en la Comunidad Europea / Volitatud esindaja Euroopa Nõukogus / Représentant autorisé pour la Communauté européenne / Autorizuirani predstavnik u Europskoj uniji / Meghatalmazott képviselő az Európai Közösségben / Rappresentante autorizzato nella Comunità Europea / Европа қауымдастығындағы уәкілетті өкіл /유럽 공동체의 위임 대표 / Įgaliotasis atstovas Europos Bendrijoje / Pilnvarotais pārstāvis Eiropas Kopienā / Bevoegde vertegenwoordiger in de Europese Gemeenschap / Autorisert representant i EU / Autoryzowane przedstawicielstwo we Wspólnocie Europejskiej / Representante autorizado na Comunidade Europeia / Reprezentantul autorizat pentru Comunitatea Europeană / Уполномоченный представитель в Европейском сообществе / Autorizovaný zástupca v Európskom spoločenstve / Autorizovano predstavništvo u Evropskoj uniji / Auktoriserad representant i Europeiska gemenskapen / Avrupa Topluluğu Yetkili Temsilcisi / Уповноважений представник у країнах ЄС / 欧洲共同体授权代表

In Vitro Diagnostic Medical Device / Медицински уред за диагностика ин витро / 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 meditsiiniaparatuur / Dispositif médical de diagnostic in vitro / Medicinska pomagala za In Vitro Dijagnostiku / In vitro diagnosztikai orvosi eszköz / Dispositivo medicale per diagnostica in vitro / Жасанды жағдайда жүргізетін медициналық диагностика аспабы / In Vitro Diagnostic 의료 기기 / In vitro diagnostikos prietaisas / 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 / Dispozitiv medical pentru diagnostic in vitro / Медицинский прибор для диагностики in vitro / Medicínska pomôcka na diagnostiku in vitro / Medicinski uređaj za in vitro dijagnostiku / Medicinteknisk produkt för in vitro-diagnostik / İn Vitro Diyagnostik Tıbbi Cihaz / Медичний пристрій для діагностики in vitro / 体外诊断医疗设备

Temperature limitation / Температурни ограничения / Teplotní omezení / Temperaturbegrænsning / Temperaturbegrenzung / Περιορισμοί θερμοκρασίας / Limitación de temperatura / Temperatuuri piirang / Limites de température / Dozvoljena temperatura / Hőmérsékleti határ / Limiti di temperatura / Температураны шектеу /온도 제한 / Laikymo temperatūra / Temperatūras ierobežojumi / Temperatuurlimiet / Temperaturbegrensning / Ograniczenie temperatury / Limites de temperatura / Limite de temperatură / Ограничение температуры / Ohraničenie teploty / Ograničenje temperature / Temperaturgräns / Sıcaklık sınırlaması / Обмеження температури / 温度限制

Batch Code (Lot) / Код на партидата / Kód (číslo) šarže / 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 partii (seria) / Código do lote / Cod de serie (Lot) / Код партии (лот) / Kód série (šarža) / Kod serije / Partinummer (Lot) / Parti Kodu (Lot) / Код партії / 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> εξετάσεις / Contenido suficiente para <n> pruebas / Küllaldane <n> testide jaoks / Contenu suffisant pour <n> tests / Sadržaj za <n> testova / <n> teszthez elegendő / Contenuto sufficiente per <n> test / <n> тесттері үшін жеткілікті / <n> 테스트가 충분히 포함됨 / Pakankamas kiekis atlikti <n> testų / Satur pietiekami <n> pārbaudēm / Inhoud voldoende voor “n” testen / Innholder tilstrekkelig til <n> tester / Zawiera ilość wystarczającą do <n> testów / Conteúdo suficiente para <n> testes / Conţinut suficient pentru <n> teste / Достаточно для <n> тестов(а) / Obsah vystačí na <n> testov / Sadržaj dovoljan za <n> testova / Innehåller tillräckligt för <n> analyser / <n> test için yeterli malzeme içerir / Вистачить для аналізів: <n> / 足够进行 <n> 次检测

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

Do not reuse / Не използвайте отново / Nepoužívejte opakovaně / Ikke til genbrug / Nicht wiederverwenden / Μην επαναχρησιμοποιείτε / No reutilizar / Mitte kasutada korduvalt / 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 / Não reutilize / Nu refolosiţi / Не использовать повторно / Nepoužívajte opakovane / Ne upotrebljavajte ponovo / Får ej återanvändas / Tekrar kullanmayın / Не використовувати повторно / 请勿重复使用

Serial number / Сериен номер / Sériové číslo / Serienummer / Seriennummer / Σειριακός αριθμός / Nº de serie / Seerianumber / Numéro de série / Serijski broj / Sorozatszám / Numero di serie / Топтамалық нөмірі / 일련 번호 / Serijos numeris / Sērijas numurs / Serie nummer / Numer seryjny /Número de série / Număr de serie / Серийный номер / Seri numarası / Номер серії / 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 / Μόνο για αξιολόγηση απόδοσης IVD / Sólo para la evaluación del rendimiento en diagnóstico in vitro / Ainult IVD seadme hindamiseks / Réservé à l'évaluation des performances IVD / Samo u znanstvene svrhe za In Vitro Dijagnostiku / Kizárólag in vitro diagnosztikához / Solo per valutazione delle prestazioni IVD / Жасанды 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-ytelse / Tylko do oceny wydajności IVD / Uso exclusivo para avaliação de IVD / Numai pentru evaluarea performanţei 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 / Тільки для оцінювання якості діагностики 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 temperatuuripiir / Limite inférieure de température / Najniža dozvoljena temperatura / Alsó hőmérsékleti határ / Limite inferiore di temperatura / Температураның төменгі руқсат шеri / 하한 온도 / Žemiausia laikymo temperatūra / Temperatūras zemākā robeža / Laagste temperatuurlimiet / Nedre temperaturgrense / Dolna granica temperatury / Limite mínimo de temperatura / Limită minimă de temperatură / Нижний предел температуры / Spodná hranica teploty / Donja granica temperature / Nedre temperaturgräns / Sıcaklık alt sınırı / Мінімальна температура / 温度下限

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

CONTROL + Positive control / Положителен контрол / Pozitivní 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 / Pozitīvā kontrole / Positieve controle / Kontrola dodatnia / Controlo 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 / Negatív kontroll / Controllo negativo / Негативтік бақылау / 음성 컨트롤 / Neigiama kontrolė / Negatīvā kontrole / Negatieve controle / Kontrola ujemna / Controlo 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 / Steriliseringsmetode: ethylenoxid / Sterilisationsmethode: Ethylenoxid / Μέθοδος αποστείρωσης: αιθυλενοξείδιο / Método de esterilización: óxido de etileno / Steriliseerimismeetod: etüleenoksiid / Méthode de stérilisation : oxyde d'éthylène / Metoda sterilizacije: etilen oksid / Sterilizálás módszere: etilén-oxid / Metodo di sterilizzazione: ossido di etilene / Стерилизация әдici – этилен тотығы / 소독 방법: 에틸렌옥사이드 / Sterilizavimo būdas: etileno oksidas / Sterilizēšanas metode: etilēnoksīds / Gesteriliseerd met behulp van ethyleenoxide / Steriliseringsmetode: 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 / Steriliseringsmetod: etenoxid / Sterilizasyon yöntemi: etilen oksit / Метод стерилізації: етиленоксидом / 灭菌方法：环氧乙烷

STERILE R Method of sterilization: irradiation / Метод на стерилизация: ирадиация / Způsob sterilizace: záření / Steriliseringsmetode: bestråling / Sterilisationsmethode: Bestrahlung / Μέθοδος αποστείρωσης: ακτινοβολία / Método de esterilización: irradiación / Steriliseerimismeetod: kiirgus / Méthode de stérilisation : irradiation / Metoda sterilizacije: zračenje / Sterilizálás módszere: besugárzás / Metodo di sterilizzazione: irradiazione / Стерилизация әдici – сәуле түсіру / 소독 방법: 방사 / Sterilizavimo būdas: radiacija / Sterilizēšanas metode: apstarošana / Gesteriliseerd met behulp van bestraling / Steriliseringsmetode: bestråling / Metoda sterylizacji: napromienianie / Método de esterilização: irradiação / Metodă de sterilizare: iradiere / Метод стерилизации: облучение / Metóda sterilizácie: ožiarenie / Metoda sterilizacije: ozračavanje / Steriliseringsmetod: strålning / Sterilizasyon yöntemi: irradyasyon / Метод стерилізації: опроміненням / 灭菌方法：辐射

Biological Risks / Биологични рискове / Biologická rizika / Biologisk fare / Biogefährdung / Βιολογικοί κίνδυνοι / Riesgos biológicos / Bioloogilised riskid / Risques biologiques / Biološki rizik / Biológiailag veszélyes / Rischio biologico / Биологиялық тәуекелдер / 생물학적 위험 / Biologinis pavojus / Bioloģiskie riski / Biologisch risico / Biologisk risiko / Zagrożenia biologiczne / Perigo biológico / Riscuri biologice / Биологическая 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! Prostudujte si přiloženou dokumentaci! / Forsigtig, se ledsagende dokumenter / Achtung, Begleitdokumente beachten / Προσοχή, συμβουλευτείτε τα συνοδευτικά έγγραφα / Precaución, consultar la documentación adjunta / Ettevaatust! Lugeda kaasnevat dokumentatsiooni / Attention, consulter les documents joints / Upozorenje, koristi prateću dokumentaciju / Figyelem! Olvassa el a mellékelt tájékoztatót / Attenzione: consultare la documentazione allegata / Абайлаңыз, тиісті құжаттармен танысыңыз / 주의, 동봉된 설명서 참조 / Dėmesio, žiūrėkite pridedamus dokumentus / Piesardzība, skatīt pavaddokumentus / Voorzichtig, raadpleeg bijgevoegde documenten / Forsiktig, se vedlagt dokumentasjon / Należy zapoznać się z dołączonymi dokumentami / Cuidado, consulte a documentação fornecida / Atenţie, consultaţi documentele însoţitoare / Внимание: см. прилагаемую документацию / Výstraha, pozri sprievodné dokumenty / Pažnja! Pogledajte priložena dokumenta / Obs! Se medföljande dokumentation / Dikkat, birlikte verilen belgelere başvurun / Увага: див. супутню документацію / 小心，请参阅附带文档。

Upper limit of temperature / Горен лимит на температурата / Horní hranice teploty / Øvre temperaturgrænse / Temperaturobergrenze / Ανώτερο όριο θερμοκρασίας / Límite superior de temperatura / Ülemine temperatuuripiir / Limite supérieure de température / Gornja dozvoljena temperatura / Felső hőmérsékleti határ / Limite superiore di temperatura / Температураның руқсат етілген жоғарғы шеri / 상한 온도 / Aukščiausia laikymo temperatūra / Augšējā temperatūras robeža / Hoogste temperatuurlimiet / Øvre temperaturgrense / Górna granica temperatury / Limite máximo de temperatura / Limită maximă de temperatură / Верхний предел температуры / Horná hranica teploty / Gornja granica temperature / Övre temperaturgräns / Sıcaklık üst sınırı / Максимальна температура / 温度上限

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

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

Peel / Обелете / Otevřete zde / Åbn / Abziehen / Αποκολλήστε / Desprender / Koorida / Décoller / Otvoriti skini / Húzza le / Staccare / Ұстіңгі қабатын алып таста / 벗기기 / Plėšti čia / Atlīmēt / Schillen / Trekk av / Oderwać / Destacar / Se dezlipeşte / Отклеить / Odtrhnite / Oljuštiti / Dra isär / Ayırma / Відклеїти / 撕下

Perforation / Перфорация / Perforace / Perforering / Διάτρηση / Perforación / Perforatsioon / Perforacija / Perforálás / Perforazione / Тесік тесу / 절취선 / Perforacija / Perforācija / Perforatie / Perforacja / Perfuração / Perforare / Перфорация / Perforácia / Perforasyon / Перфорація / 穿孔

Do not use if package damaged / Не използвайте, ако опаковката е повредена / Nepoužívejte, je-li obal poškozený / Må 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 használja, ha a csomagolás sérült / Non usare se la confezione è danneggiata / Ерер пакет бұзылған болса, пайдаланба / 패키지가 손상된 경우 사용 금지 / Jei pakuotė pažeista, nenaudoti / Nelietot, ja iepakojums bojāts / Niet gebruiken indien de verpakking beschadigd is / Må ikke brukes hvis pakke er skadet / Nie używać, jeśli opakowanie jest uszkodzone / Não usar se a embalagem estiver danificada / A nu se folosi dacă pachetul este deteriorat / Не использовать при повреждении упаковки / Nepoužívajte, ak je obal poškodený / Ne koristite ako je pakovanje oštećeno / Använd ej om förpackningen är skadad / Ambalaj hasar görmüşse kullanmayın / Не використовувати за пошкодженої упаковки / 如果包装破损，请勿使用

Keep away from heat / Пазете от топлина / Nevystavujte přílišnému teplu / Må ikke udsættes for varme / Vor Wärme schützen / Κρατήστε το μακριά από τη θερμότητα / Mantener alejado de fuentes de calor / Hoida eemal valgusest / Protéger de la chaleur / Držati dalje od izvora topline / Óvja a melegtől / Tenere lontano dal calore / Салқын жерде сақта / 열을 피해야 함 / Laikyti atokiau nuo šilumos šaltinių / Sargāt no karstuma / Beschermen tegen warmte / Må ikke utsettes for varme / Przechowywać z dala od źródeł ciepła / Manter ao abrigo do calor / A se feri de căldură / Не нагревать / Uchovávajte mimo zdroja tepla / Držite dalje od toplote / Får ej utsättas för värme / Isıdan uzak tutun / Берегти від дії тепла / 请远离热源

Cut / Срежете / Odstřihněte / Klip / Schneiden / Κόψτε / Cortar / Lõigata / Découper / Reži / Vágja ki / Tagliare / Кесіңіз / 잘라내기 / Kirpti / Nogriezt / Knippen / Kutt / Odciąć / Cortar / Decupaţi / Отрезать / Odstrihnite / Iseći / Klipp / Kesme / Розрізати / 剪下

Collection date / Дата на събиране / Datum odběru / Opsamlingsdato / Entnahmedatum / Ημερομηνία συλλογής / Fecha de recogida / Kogumiskuupäev / Date de prélèvement / Dani prikupljanja / Mintavétel dátuma / Data di raccolta / Жинаған тізбекүні / 수집 날짜 / Paėmimo data / Savākšanas datums / Verzameldatum / Dato 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/tyrimas / µL/pārbaude / µL/teste / мкл/аналіз / 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 źródeł światła / Manter ao abrigo da luz / Ferit de lumină / Хранить в темноте / Uchovávajte mimo dosahu svetla / Držite dalje od svetlosti / Får ej utsättas för ljus / Işıktan 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 / Sadrži hydrogen vodik / Hidrogén gázt fejleszt / Produzione di gas idrogeno / Газтектес сутеги 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 / Oslobađa 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 pacjenta / Número da ID do doente / Număr ID pacient / Идентификационный номер пациента / Identifikačné číslo pacienta / ID broj pacijenta / Patientnummer / Hasta kimlik numarası / Ідентифікатор пацієнта / 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. / Εύθραυστο. Χειριστείτε το με προσοχή. / Frágil. Manipular con cuidado. / Õrn, käsitsege ettevaatlikult. / Fragile. Manipuler avec précaution. / Lomljivo, rukujte pažljivo. / Törékeny! Óvatosan kezelendő. / Fragile, maneggiare con cura. / Сынғыш, абайлап пайдаланыңыз. / 조심 깨지기 쉬운 처리 / Trapu, elkitės atsargiai. / Trausls; rīkoties uzmanīgi / Breekbaar, voorzichtig behandelen. / Ømtålig, håndter forsiktig. / Krucha zawartość, przenosić ostrożnie. / Frágil, Manuseie com Cuidado. / Fragil, manipulaţi cu atenţie. / Хрупкое! Обращаться с осторожностью. / Krehké, vyžaduje sa opatrná manipulácia. / Lomljivo - rukujte pažljivo. / Bräckligt. Hantera försiktigt. / Kolay Kırılır, Dikkatli Taşıyın. / Тендітна, звертатися з обережністю / 易碎，小心轻放

bd.com/e-labeling
KEY-CODE: 8809591JAA

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