BD BACTEC™ MGIT™ 960 SIRE Kits

For the Antimycobacterial Susceptibility Testing of *Mycobacterium tuberculosis*

R_X Only CE IVD

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INTENDED USE

The BD BACTEC™ MGIT™ 960 SIRE Kit is a rapid qualitative procedure for susceptibility testing of *Mycobacterium tuberculosis*, from culture, to streptomycin (STR), isoniazid (INH), rifampin (RIF) and ethambutol (EMB). The BD BACTEC MGIT 960 STR 4.0 Kit and the BD BACTEC MGIT 960 INH 0.4 Kit are for testing at higher drug concentrations.

The BD BACTEC MGIT 960 susceptibility test kits are used with the BD BACTEC MGIT 960 and BD BACTEC MGIT 320 Systems.

SUMMARY AND EXPLANATION

Antimycobacterial susceptibility testing is valuable in the proper treatment of patients with tuberculosis. The treatment of tuberculosis is commonly through a multiple drug regimen that includes the antimycobacterial drugs streptomycin, isoniazid, rifampin and ethambutol. It is important that the antimycobacterial drugs prescribed show appropriate activity against *Mycobacterium tuberculosis*, i.e., susceptibility of the isolate to the drug.

Multi-drug resistant *Mycobacterium tuberculosis* (MDR-TB) has recently become a serious public health problem.[1] Resistance to any of the 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 resistant isolates is critical to effective patient management.

A widely used method for antimycobacterial susceptibility testing, known as the Method of Proportion,[2] uses Middlebrook and Cohn 7H10 Agar. It compares colony counts on drug-containing and drug-free media. Resistance to a drug is detected when 1% or more of the bacterial population is resistant to the drug concentration under test. Results are generally available after 21 days of incubation.

Historically, the Method of Proportion (MOP) procedure has included susceptibility testing of *M. tuberculosis* using two concentrations of antimicrobials. The Clinical and Laboratory Standards Institute (CLSI) continues to recommend that the MOP test procedure include two concentrations of the primary drugs for testing except rifampin. The recommended low concentrations for the MOP procedure are the critical concentrations for these drugs. The critical concentration is defined as the drug concentration that allows the interpretation of a result as either resistant or susceptible. An isolate is determined resistant if 1% or more of the test population grows in the presence of the critical concentration of the drug. The high drug concentration is used to profile the degree of resistance within the population. This result provides information to the physician to assist in determining whether a modification to the therapy regimen is necessary.

The BD BACTEC MGIT 960 SIRE test provides the susceptibility results to be reported earlier, in most cases, than the MOP procedure.

The BD BACTEC MGIT 960 SIRE test was developed with critical concentrations for streptomycin, isoniazid, rifampin and ethambutol that are slightly lower than the critical concentrations used in the MOP in order to avoid false susceptibility. This is most apparent for streptomycin where many isolates are close to the recommended critical concentration as performed by the MOP. For this reason, a second, higher drug concentration was developed for streptomycin and isoniazid. A susceptible result at the critical concentration can be reported and no other testing is necessary. Isolates that are resistant at the critical concentration of streptomycin, isoniazid and/or ethambutol, should be tested at a higher drug concentration either in the BD BACTEC MGIT system or using an alternate method. In this case, a final result of resistant at the critical concentration may be reported, with notification that an additional test at a higher concentration is being performed.

Testing of resistant isolates at a higher concentration is important to identify those that exhibit low-level resistance, i.e., resistant at the critical concentration and susceptible at the high concentration. The high concentrations in the BD BACTEC MGIT system were designed to be lower than the concentrations used in the MOP. This design of the BD BACTEC MGIT system is such that a resistant result, especially for streptomycin, may not always correlate to a resistant result at the high concentration in MOP. In the event that a streptomycin result is obtained that is resistant at the high concentration, an alternate method of testing at this concentration should be performed.

PRINCIPLES OF THE PROCEDURE

The BD BBL™ MGIT 7 mL Mycobacteria Growth Indicator Tube is a tube containing a modified Middlebrook 7H9 Broth which supports the growth and detection of mycobacteria (see BD BBL MGIT 7 mL 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 emission from the compound, and little fluorescence can be detected. Later, actively growing and respiring microorganisms consume the oxygen that allows the compound to fluoresce.

The BD BACTEC MGIT 960 SIRE Kit is a 4–13 day qualitative test. The test is based on growth of the *M. tuberculosis* isolate in a drug-containing tube compared to a drug-free tube (Growth Control). The BD BACTEC MGIT instrument monitors tubes for increased fluorescence. Analysis of fluorescence in the drug-containing tube compared to the fluorescence of the Growth Control tube is used by the instrument to determine susceptibility results.

The BD BACTEC MGIT instrument automatically interprets these results, and reports a susceptible or resistant result.

REAGENTS

BD BACTEC MGIT 960 SIRE Kit contains one each lyophilized vials of streptomycin, isoniazid, rifampin and ethambutol and eight vials of SIRE Supplement.

Approximate Formula* Per Vial Lyophilized drug: Streptomycin ..... 332 µg
Approximate Formula* Per Vial Lyophilized drug: Isoniazid 33.2µg
Approximate Formula* Per Vial Lyophilized drug: Rifampin ..... 332 µg
Approximate Formula* Per Vial Lyophilized drug: Ethambutol ..... 1,660 µg

BD BACTEC MGIT 960 IR Kit contains one each lyophilized vials of isoniazid and rifampin and four vials of SIRE Supplement.

Approximate Formula* Per Vial Lyophilized drug: Isoniazid 33.2µg
Approximate Formula* Per Vial Lyophilized drug: Rifampin ..... 332 µg

BD BACTEC MGIT 960 STR 4.0 Kit contains one vial lyophilized streptomycin and two vials of SIRE Supplement.

Approximate Formula* Per Vial Lyophilized drug: Streptomycin ..... 664 µg

BD BACTEC MGIT 960 INH 0.4 Kit contains one vial lyophilized isoniazid and two vials of SIRE Supplement.

Approximate Formula* Per Vial Lyophilized drug: Isoniazid 66.4µg

BD BACTEC MGIT 960 SIRE Supplement contains 20 mL Middlebrook OADC enrichment

Approximate Formula* Per L Purified Water

Bovine albumin	50.0 g	Catalase	0.03 g
Dextrose	20.0 g	Oleic Acid	0.6 g

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

Storage and reconstitution of reagents: BD BACTEC MGIT 960 SIRE Drug vials – On receipt, store the lyophilized drug vials at 2–8 °C. Once reconstituted, the antibiotic solutions may be frozen and stored at -20 °C or colder up to six months, not to exceed the original expiration date. Once thawed, use immediately. Discard unused portions.

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.

BD BACTEC MGIT SIRE Supplement – On receipt, store in dark at 2–8 °C. Avoid freezing or overheating. Open and use prior to the expiration date. Minimize exposure to light.

Directions For Use:

Reconstitute each BD BACTEC MGIT 960 SIRE Kit Streptomycin lyophilized drug vial with **4 mL** of sterile distilled/deionized water to make a stock solution of 83 µg/mL.

Reconstitute each BD BACTEC MGIT 960 SIRE Kit Isoniazid lyophilized drug vial with **4 mL** of sterile distilled/deionized water to make a stock solution of 8.3 µg/mL.

Reconstitute each BD BACTEC MGIT 960 SIRE Kit Rifampin lyophilized drug vial with **4 mL** of sterile distilled/deionized water to make a stock solution of 83 µg/mL.

Reconstitute each BD BACTEC MGIT 960 SIRE Kit Ethambutol lyophilized drug vial with **4 mL** of sterile distilled/deionized water to make a stock solution of 415 µg/mL.

NOTE: The following are reconstituted with a different volume. Failure to use the appropriate volume of sterile distilled water for reconstitution of the higher drug concentrations will invalidate those test results.

Reconstitute each BD BACTEC MGIT 960 STR 4.0 Kit Streptomycin lyophilized drug vial with **2 mL** of sterile distilled/deionized water to make a stock solution of 332 µg/mL.

Reconstitute each BD BACTEC MGIT 960 INH 0.4 Kit Isoniazid lyophilized drug vial with **2 mL** of sterile distilled/deionized water to make a stock solution of 33.2 µg/mL.

Warnings and Precautions

For *in vitro* Diagnostic Use.

POTENTIALLY INFECTIOUS TEST SPECIMEN: Pathogenic microorganisms, including hepatitis viruses and Human Immunodeficiency Virus, may be present in clinical specimens. "Standard Precautions"[3-6] and institutional guidelines should be followed in handling all items contaminated with blood and other body fluids.

BD BACTEC MGIT 960 SIRE – Catalog number 245123

BD BACTEC MGIT 960 Rifampin

Danger

H301 Toxic if swallowed. **H332** Harmful 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+P310** IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. **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. **P321** Specific treatment (see on this label). **P405** Store locked up. **P501** Dispose of contents/container in accordance with local/regional/national/international regulations.

BD BACTEC MGIT 960 Ethambutol

Danger

H360 May damage fertility or the unborn child.

P280 Wear protective gloves/protective clothing/eye protection/face protection. **P201** Obtain special instructions before use. **P202** Do not handle until all safety precautions have been read and understood. **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 BACTEC MGIT 960 IR – Catalog number 245157

BD BACTEC MGIT 960 IR Rifampin

Danger

H301 Toxic if swallowed. **H332** Harmful 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+P310** IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. **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. **P405** Store locked up. **P501** Dispose of contents/container in accordance with local/regional/national/international regulations.

Working with *M. tuberculosis* growth in culture requires Biosafety Level (BSL) 3 practices, containment equipment and facilities.

Read and follow directions contained in all appropriate package inserts including the BD BBL MGIT 7 mL Mycobacteria Growth Indicator Tube.

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

In the event of tube breakage: 1) Close the instrument drawers; 2) Turn off the instrument; 3) Vacate the area immediately; 4) Consult your facility/CDC guidelines. An inoculated leaking or broken tube may produce an aerosol of mycobacteria; appropriate handling should be observed.

Autoclave all inoculated BD MGIT tubes prior to disposal.

INOCULUM PREPARATION

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

Inoculum can be prepared from solid media or from a positive BD BACTEC MGIT 7 mL tube. In addition, cultures grown in liquid and on solid media can be used to prepare a seed BD MGIT tube, which can then be used to prepare the inoculum. Each of these options is described below.

Preparation of the Inoculum from Solid Media:

NOTE: It is important to prepare the inoculum according to the following instructions to obtain the appropriate organism concentration for the susceptibility test.

1. Add 4 mL of BD BBL Middlebrook 7H9 Broth (or BD BBL MGIT 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 no more than 14 days old, trying not to remove any solid medium. Suspend the colonies in the Middlebrook 7H9 Broth.
3. Vortex the suspension for 2–3 min to break up the larger clumps. The suspension should exceed a 1.0 McFarland standard in turbidity.
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. NOTE: The organism suspension should be greater than a 0.5 McFarland Standard at this step.
7. Adjust the suspension to a 0.5 McFarland standard by visual comparison to a 0.5 McFarland turbidity standard. Do not adjust below a 0.5 McFarland Standard.
8. Dilute 1 mL of the adjusted suspension in 4 mL of sterile saline (1:5 dilution). Proceed to “Inoculation Procedure for Susceptibility Test.”

Preparation of the Inoculum from a Positive BD BACTEC MGIT 7 mL Tube:

NOTE: It is important to prepare the inoculum using the following time references to obtain the appropriate organism concentration for the susceptibility test.

1. The first day of an instrument positive BD MGIT tube is considered Day 0.
2. For the preparation of the test inoculum, a positive 7 mL BD MGIT tube should be used the day **after** it first becomes positive on the BD BACTEC MGIT instrument (Day 1), up to and including the fifth day (Day 5) after instrument positivity. A tube which has been positive longer than five days should be subcultured to a fresh 7 mL BD MGIT tube containing BD BACTEC MGIT Growth Supplement and tested on the BD BACTEC MGIT instrument until positive, and used from one to five days following positivity. See “Preparation of a Seed BD MGIT Tube from Liquid Media.”
3. If the tube is a Day 1 or Day 2 positive, use the BD MGIT broth suspension for the inoculation procedures. Mix well. Proceed to “Inoculation Procedure for Susceptibility Test.”
4. If the tube is a Day 3, Day 4, or Day 5 positive, mix well then dilute 1 mL of the positive broth in 4 mL of sterile saline (1:5 dilution). Mix tube thoroughly. Use the diluted suspension for the inoculation procedures. Proceed to “Inoculation Procedure for Susceptibility Test.”

Preparation of a Seed BD MGIT Tube from Liquid Media

1. Mix the tube by inversion or vortexing.
2. Make a 1:100 dilution by adding 0.1 mL of the culture into 10 mL of BD BBL Middlebrook 7H9 Broth or BD BBL MGIT Broth. Mix well.
3. Add 0.5 mL of this suspension into a 7 mL BD MGIT tube supplemented with 0.8 mL of BD BACTEC MGIT Growth Supplement.
4. Cap tightly and gently mix by inverting 2–3 times.
5. Enter the tube into a BD BACTEC MGIT instrument and test until positive.

   NOTE: Time to positivity **must** be ≥ 4 days for use as AST inoculum. If tube becomes positive in < 4 days, return to step 1 and prepare a new seed tube.
6. This tube may now be used from one to five days following positivity. Proceed to “Preparation of the Inoculum from a Positive BD BACTEC MGIT 7 mL Tube” above.

Preparation of a Seed BD MGIT Tube from Solid Media

1. Using a sterile loop, scrape growth from a slant and add to a 7 mL BD MGIT tube supplemented with 0.8 mL of BD BACTEC MGIT Growth Supplement.
2. Cap tightly and gently mix by inverting 2–3 times.
3. Enter the tube into a BD BACTEC MGIT instrument and test until positive.

   NOTE: Time to positivity **must** be ≥ 4 days for use as AST inoculum. If tube becomes positive in < 4 days, return to step 1 and prepare a new seed tube.
4. This tube may now be used from one to five days following positivity. Proceed to “Preparation of the Inoculum from a Positive BD BACTEC MGIT 7 mL Tube” above.

PROCEDURE

Materials Provided: BD BACTEC MGIT 960 SIRE Kit containing one vial each lyophilized drug and eight vials of SIRE Supplement (approximately 40 tests per drug per kit). BD BACTEC MGIT 960 STR 4.0 Kit containing one vial each lyophilized drug and two vials of SIRE Supplement (approximately 20 tests per kit) and BD BACTEC MGIT 960 INH 0.4 Kit containing one vial each lyophilized drug and two vials of SIRE Supplement (approximately 20 tests per kit).

Materials Required But Not Provided: BD BBL MGIT 7 mL Mycobacteria Growth Indicator Tubes, ancillary culture media, reagents, quality control organisms and laboratory equipment as required for this procedure.

Inoculation Procedure for BD BACTEC MGIT 960 SIRE Kit Susceptibility Test:

1. Label five 7 mL BD MGIT tubes for each test isolate. Label one as GC (Growth Control), one as STR, one as INH, one as RIF and one as EMB. Place the tubes in the correct sequence in the appropriate size AST Set Carrier (see BD BACTEC MGIT Instrument User's Manual).
2. Aseptically add 0.8 mL of BD BACTEC MGIT SIRE Supplement to each tube. NOTE: It is important to use the supplement supplied with the kit.
3. Aseptically pipet, using a micropipet, 100 µL of 83 µg/mL MGIT STR solution to the appropriately labeled BD MGIT tube. Aseptically pipet 100 µL of 8.3 µg/mL MGIT INH solution to the appropriately labeled BD MGIT tube. Aseptically pipet 100 µL of 83 µg/mL MGIT RIF solution to the appropriately labeled BD MGIT tube. Aseptically pipet 100 µL of 415 µg/mL MGIT EMB solution to the appropriately labeled BD MGIT tube. It is important to add the correct drug to the corresponding tube. No antibiotics should be added to the BD MGIT GC tube.

Drug	Concentration of Drug after Reconstitution*	Volume Added to BD MGIT Tubes for Test	Final Concentration in BD MGIT Tubes
MGIT STR	83 µg/mL	100 µL	1.0 µg/mL
MGIT INH	8.3 µg/mL	100 µL	0.1 µg/mL
MGIT RIF	83 µg/mL	100 µL	1.0 µg/mL
MGIT EMB	415 µg/mL	100 µL	5.0 µg/mL

* These drugs must be reconstituted using **4 mL** sterile/deionized water to achieve concentrations indicated.

4. **Growth Control tube preparation and inoculation:** Aseptically pipet 0.1 mL of the organism suspension (see "**INOCULUM PREPARATION**") into 10 mL of sterile saline to prepare the 1:100 Growth Control suspension. Mix the Growth Control suspension thoroughly. Inoculate **0.5** mL of the 1:100 Growth Control suspension into the BD MGIT tube labeled "GC."
5. **Drug-containing tube inoculation:** Aseptically pipet 0.5 mL of the organism suspension (see "**INOCULUM PREPARATION**") into each of the FOUR remaining drug tubes (STR, INH, RIF, EMB).
6. Tightly recap the tubes. Mix tubes thoroughly by gentle inversion three to four times.
7. Enter the AST set into the BD BACTEC MGIT instrument using the AST set entry feature (refer to the BD BACTEC MGIT Instrument User's Manual). Ensure that the order of the tubes in the AST Set Carrier conforms to the set carrier definitions selected when performing the AST set entry feature.
8. Streak 0.1 mL of the organism suspension to a BD Trypticase™ Soy Agar with 5% Sheep Blood (TSA II) plate. Enclose in a plastic bag. Incubate at 35–37 °C.
9. Check the blood agar plate at 48 h for bacterial contamination. If the blood agar plate shows no growth, then allow AST testing to proceed. If the blood agar plate shows growth, discard the AST set (refer to the BD BACTEC MGIT Instrument User's Manual) and repeat testing with pure culture.

Inoculation Procedure for BD BACTEC MGIT 960 STR 4.0 and INH 0.4 Kits Susceptibility Test:

It is recommended if resistance occurs at the critical concentration, a susceptibility profile test be performed which, at a minimum, tests the high concentration of the drug to which the isolate was originally resistant.

Isolate Source: The isolate used for this testing must have been prepared as described in "**INOCULUM PREPARATION**." A seed tube may be prepared from the drug-free Growth Control tube from the previously tested AST set of the isolate, by inoculating 0.5 mL to a fresh BD MGIT 7 mL tube containing BD BACTEC MGIT Growth Supplement. Once the seed tube is instrument positive, proceed as described in "**INOCULUM PREPARATION**: Preparation of the Inoculum from a Positive BD MGIT tube."

1. Label enough BD MGIT 7 mL tubes for the test isolate to have a MGIT GC (Growth Control) and a MGIT drug tube for each antimicrobic tested. Place the tubes in the correct sequence in the appropriate size AST Set Carrier (see BD BACTEC MGIT Instrument User's Manual).
2. Aseptically add 0.8 mL of BD BACTEC MGIT SIRE Supplement to each tube. NOTE: It is important to use the supplement supplied with the kit.
3. Aseptically pipet, using a micropipet, 100 µL of the drug solution to the appropriately labeled BD MGIT tube. It is important to add the correct drug to the corresponding tube. No antibiotics should be added to the BD MGIT GC tube.

Drug	Concentration of Drug after Reconstitution*	Volume Added to BD MGIT Tubes for Test	Final Concentration in BD MGIT Tubes
MGIT STR 4.0	332 µg/mL	100 µL	4.0 µg/mL
MGIT INH 0.4	33.2 µg/mL	100 µL	0.4 µg/mL

* These drugs must be reconstituted using **2 mL** sterile/deionized water to achieve concentrations indicated.

4. **Growth Control tube preparation and inoculation:** Aseptically pipet 0.1 mL of the organism suspension (see "**INOCULUM PREPARATION**") into 10 mL of sterile saline to prepare the 1:100 Growth Control suspension. Mix the Growth Control suspension thoroughly. Inoculate **0.5** mL of the 1:100 Growth Control suspension into the BD MGIT tube labeled "GC."
5. **Drug-containing tube inoculation:** Aseptically pipet 0.5 mL of the organism suspension (see "**INOCULUM PREPARATION**") into each of the drug tubes.
6. Tightly recap the tubes. Mix tubes thoroughly by gentle inversion three to four times.
7. Enter the AST set into the BD BACTEC MGIT instrument using the AST set entry feature (refer to the BD BACTEC MGIT Instrument User's Manual). Ensure that the order of the tubes in the AST Set Carrier conforms to the set carrier definitions selected when performing the AST set entry feature.

8. Streak 0.1 mL of the organism suspension to a BD Trypticase Soy Agar with 5% Sheep Blood (TSA II) plate. Enclose in a plastic bag. Incubate at 35–37 °C.
9. Check the blood agar plate at 48 h for bacterial contamination. If the blood agar plate shows no growth, then allow AST testing to proceed. If the blood agar plate shows growth, discard the AST set (refer to the BD BACTEC MGIT Instrument User's Manual) and repeat testing with pure culture.

NOTE: The susceptibility test may be configured in a variety of formats. For example, a five tube carrier set containing only the critical concentrations can be configured into the system. A variety of other tube carrier sets can be configured depending on the optional profile tests being run (refer to BD BACTEC MGIT Instrument User's Manual).

User Quality Control: Upon receipt of a new shipment or lot number of BD BACTEC MGIT 960 SIRE Kit vials, it is recommended that the control organism shown below be tested. The control organism should be a pure culture and the culture should be prepared according to the "**INOCULUM PREPARATION**" instructions.

The quality control (QC) AST Set should be prepared according to the "Inoculation Procedure for Susceptibility Test" instructions for the drug kits being tested. Important considerations when preparing the QC AST Set are the proper reconstitution of the lyophilized drugs and the proper dilution of the QC organism for the Growth Control and drug tubes.

It is important to add the appropriate drug to the corresponding labeled tube. The use of the pan-sensitive QC organism will not detect incorrect drug pipetted into AST Set tubes.

Observation of the proper results, as shown below, within 4–13 days indicates that the BD BACTEC MGIT 960 SIRE Kits 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 product until you have contacted BD Technical Service and Support at 1.800.638.8663 (United States only).

Strain	GC	MGIT STR	MGIT INH	MGIT RIF	MGIT EMB
M. tuberculosis ATCC® 27294	Positive	Susceptible	Susceptible	Susceptible	Susceptible

Strain	GC	MGIT STR 4.0	MGIT INH 0.4
M. tuberculosis ATCC 27294	Positive	Susceptible	Susceptible

The same control organism should be run as batch QC once each week when susceptibility testing is performed. If the batch QC fails, do not report patient results for the drug(s) that failed for that testing period. Repeat the QC for the drug(s) and patient isolates affected by the initial QC failure. If the repeat QC does not perform as expected, do not report patient results. Do not use the product until you have contacted BD Technical Service and Support at 1.800.638.8663 (United States only).

During the external evaluation of the BD BACTEC MGIT 960 SIRE Kits, the most common causes of QC failure were contaminated QC cultures, over/under inoculated AST Sets, drug not added to appropriate tubes and instrument error conditions.

RESULTS

The BD BACTEC MGIT instrument will monitor AST Sets until a susceptible or resistant determination is made. Once the set testing is completed, the results are reported by the BD BACTEC MGIT instrument (refer to the BD BACTEC MGIT Instrument User's Manual). The BD BACTEC MGIT instrument will report an AST Set result as an Error(X), no susceptibility interpretation, when certain conditions occur that may affect the test results. Conditions that may result in an Error(X) result are described in Section 7-Troubleshooting of the BD BACTEC MGIT Instrument User's Manual.

When reporting results, it is important to include the test method, drug name and concentration, whether the result is obtained with the BD BACTEC MGIT System or an alternate method. The Pulmonary and/or Infectious Disease specialist in TB control should be consulted concerning the appropriate therapeutic regimen and dosages.

In the event of unexpected resistant results, verify identification of isolate tested as *M. tuberculosis*. Ensure that only a pure culture was used (rule-out presence of mixed mycobacteria, etc.) Mono-resistance to ethambutol is uncommon and should be verified.[2,7]

BD BACTEC MGIT 960 SIRE critical concentration result reporting

Drug (concentration)	MGIT System Result	Recommended Report	Action
STR (1.0 µg/mL)	Susceptible (SIRE)	Isolate tested with BD BACTEC MGIT System [drug/concentration] and result is susceptible.	No report.
INH (0.1 µg/mL) RIF (1.0 µg/mL)	Resistant (SIR)	Isolate tested with BD BACTEC MGIT System [drug/concentration] and result is resistant. Results of testing [drug] at a higher concentration to follow (if tested).	Recommend testing at higher concentration (STR and/or INH).
EMB (5.0 µg/mL)	Resistant (E)	**If resistant to more than ethambutol (EMB)** Isolate tested with BD BACTEC MGIT System [Ethambutol 5.0 µg/mL] and result is resistant. Consult laboratory for testing EMB at a higher concentration. **If mono-resistant to ethambutol (EMB)** Isolate tested with BD BACTEC MGIT System [Ethambutol 5.0 µg/mL] and result is resistant. Mono-resistance to ethambutol is uncommon. Consult laboratory for confirmation.	Recommend testing EMB at higher concentration using alternate method. Recommend testing EMB at both critical concentration and higher concentration with an alternate method.
	Error (X)	No report.	Repeat test.

BD BACTEC MGIT 960 STR 4.0 and INH 0.4 result reporting

Drug (concentration)	MGIT System Result	Recommended Report	Action
STR (4.0 µg/mL)	Susceptible	Isolate tested with BD BACTEC MGIT System streptomycin 4.0 µg/mL and result is susceptible. This isolate, with a resistant result at 1.0 µg/mL and a susceptible result at 4.0 µg/mL, indicates low-level resistance to streptomycin.	No action.
	Resistant	Isolate tested with BD BACTEC MGIT System streptomycin 4.0 µg/mL and result is resistant. Consult laboratory for confirmation.	Isolate should be tested by an alternate method to verify result.
	Error (X)	No report.	Repeat test.
INH (0.4 µg/mL)	Susceptible	Isolate tested with BD BACTEC MGIT System isoniazid 0.4 µg/mL and result is susceptible. This isolate, with a resistant result at 0.1 µg/mL and a susceptible result at 0.4 µg/mL, indicates low-level resistance to isoniazid.	No action.
	Resistant	Isolate tested with BD BACTEC MGIT System isoniazid 0.4 µg/mL and result is resistant.	No action.
	Error (X)	No report.	Repeat test.

LIMITATIONS OF THE PROCEDURE

The BD BACTEC MGIT System susceptibility test does not interpret the degree of susceptibility of the isolate being tested. Results are reported as either S, susceptible, or R, resistant, for the drug and concentration tested.

The BD BACTEC MGIT 960 SIRE test was developed with critical concentrations for streptomycin, isoniazid, rifampin and ethambutol that are slightly lower than the critical concentrations used in the MOP in order to avoid false susceptibility. Testing of the higher concentrations, as recommended, will enhance the ability to detect isolates with low-level resistance.

The BD BACTEC MGIT System susceptibility tests can only be performed using a BD BACTEC MGIT instrument. The AST Sets cannot be read manually.

Use only pure cultures of *M. tuberculosis*. Cultures that are contaminated or that may contain multiple species of mycobacteria may give erroneous results and should not be tested. Direct testing from clinical specimens is not recommended.

Suspensions made from solid media must be allowed to settle for the prescribed times prior to standardization. Inoculum preparations made from solid media should be visually compared to a 0.5 McFarland turbidity standard; failure to do so may give inaccurate results or cause an AST Set error.

Failure to use the 1:5 dilution of the organism suspension, when indicated, to inoculate the drug containing tubes may give inaccurate results.

Failure to use a 1:100 dilution of the organism suspension for the inoculation of the Growth Control tube may give inaccurate results or cause an AST Set error.

Failure to reconstitute the drugs with the appropriate volume of sterile distilled/deionized water may give inaccurate results.

Thorough mixing of inoculated tubes is important. Failure to mix the tubes adequately can lead to false resistant results.

Failure to load the tubes of the AST Set into the AST Set Carrier in the proper sequence may give inaccurate results. Failure to select the appropriate set carrier drug definition may result in invalid or inaccurate results.

Failure to load the AST Set into the instrument correctly will result in an anonymous condition that must be resolved within eight hours. If condition is not resolved within eight hours, the AST Set must be discarded and set up again.

Failure to use the SIRE Supplement in the AST Set may give inaccurate results. DO NOT add BD BACTEC MGIT Growth Supplement to the AST Set.

EXPECTED VALUES

A total of 106 clinical isolates of *M. tuberculosis* were tested with the BD BACTEC MGIT 960 SIRE susceptibility test at four geographically diverse sites. The testing included both fresh clinical and stock isolates from both liquid and solid culture sources. A total of 200 susceptibility tests (liquid and solid) were performed at the critical concentrations of streptomycin (STR), isoniazid (INH) and rifampin (RIF) and a total of 223 susceptibility tests (liquid and solid) were performed at the critical concentration of ethambutol (EMB) during separate testing. The overall average time-to-result for the BD BACTEC MGIT 960 SIRE susceptibility test is seven to eight days with a range from four to fourteen days. The data are shown in Figure 1 at end of insert.

PERFORMANCE CHARACTERISTICS

ANALYTICAL STUDIES

Liquid and Solid Media AST Inoculum Ranges:

Liquid media – The recommended procedure for preparing an AST Set from a positive BD MGIT 7 mL tube uses a direct inoculum on Day 1 and Day 2 post-positivity and a dilute (1:5) inoculum on Day 3 to Day 5 post-positivity. Internal studies show that inocula prepared from a Day 1 to Day 5 positive BD MGIT 7 mL tube range between 0.8×10^5 to 3.2×10^5 CFU/mL.

Solid media – The recommended procedure for preparing an AST Set from growth on solid media (up to 14 days) uses a 1:5 dilution of an organism suspension equivalent to a 0.5 McFarland Standard. Internal studies show that inocula prepared from solid medium culture range between 1.4×10^5 to 2.4×10^6 CFU/mL.

Lot Reproducibility:

Lot reproducibility was evaluated using twenty-five *M. tuberculosis* isolates (to include five ATCC strains). Each BD BACTEC MGIT 960 SIRE test at the critical drug concentration was performed in triplicate for a total of seventy-five results per drug. Each replicate represented a separate test condition differentiated by lot of SIRE drug and SIRE Supplement used (three lots each).

Those isolates that were determined resistant to streptomycin, isoniazid or ethambutol in the initial test were then tested with the high drug concentration, except the ATCC strains. In addition to the resistant isolates tested, two sensitive isolates to STR (critical concentration), two sensitive isolates to INH (critical concentration) and two sensitive isolates to EMB (critical concentration) were included in the susceptibility profile test. Observed results were compared to the expected results.

The overall reproducibility for each drug at the critical concentration is 96% for STR, 100% for INH, 100% for RIF and 100% for EMB. The overall reproducibility for each drug at the high concentration is 96% for STR 4.0 and 100% for INH 0.4.

CDC Challenge Panel Testing:

The performance of the BD BACTEC MGIT 960 SIRE susceptibility test was evaluated using a panel of challenge isolates obtained from the Centers for Disease Control and Prevention (CDC), GA, USA. The panel consisted of thirty isolates of *M. tuberculosis* with known susceptibility patterns (using MOP). The panel was tested twice with the BD BACTEC MGIT 960 SIRE susceptibility test and both results were in agreement. The BD BACTEC MGIT 960 SIRE results were compared to the CDC expected results.

The overall agreement with CDC expected results for each drug at the critical concentration is 93% for STR, 100% for INH, 100% for RIF and 100% for EMB. The overall agreement with CDC expected results for each drug at the high concentration is 100% for STR 4.0 and 100% for INH 0.4.

CLINICAL EVALUATION

The BD BACTEC MGIT 960 SIRE susceptibility test was evaluated at four geographically diverse clinical sites, composed of regional reference centers and university hospital-based laboratories, including one foreign site. The BD BACTEC MGIT 960 SIRE susceptibility test was compared to the Method of Proportion (MOP)[2] susceptibility test method. The initial evaluation included the drugs streptomycin, isoniazid and rifampin. A separate evaluation was performed for the drug ethambutol.

Reproducibility Testing:

The reproducibility of the BD BACTEC MGIT 960 SIRE test was evaluated at the clinical sites using a panel of ten qualified isolates, including several isolates resistant to each of the drugs. The BD BACTEC MGIT 960 SIRE test results were compared to the expected results. The overall reproducibility for each drug at the critical concentration is 98.9% for STR, 99.7% for INH, 99.2% for RIF and 97.5% for EMB. Individual site reproducibility ranged from 89.9% to 100% for the combined critical concentration drug results. The overall reproducibility for each drug at the high concentration is 99.7% for STR 4.0 and 95.6% for INH 0.4. Individual site reproducibility ranged from 92.2% to 100% for the combined high concentration drug results.

CDC Challenge Panel Testing:

The performance of the BD BACTEC MGIT 960 SIRE susceptibility test was evaluated using a panel of challenge isolates obtained from the Centers for Disease Control and Prevention (CDC), GA, USA. The panel consisted of thirty isolates of *M. tuberculosis* with known susceptibility patterns (using MOP) tested by each clinical site.

Table 1 shows the agreement of the BD BACTEC MGIT 960 SIRE susceptibility test for each drug compared to the CDC expected results.

Table 1: CDC Challenge Panel – BD BACTEC MGIT 960 Clinical Site Testing

MGIT 960	Number tested	Number Correct	% Correct
STR 1.0	120	111	92.5
INH 0.1	120	119	99.2
RIF 1.0	120	120	100
EMB 5.0	119	111	93.3
STR 4.0	29*	29	100
INH 0.4	87*	82	94.3

* Only isolates resistant at critical concentrations tested at STR 4.0 and INH 0.4.

Clinical Isolate Testing:

A total of 106 clinical isolates of *M. tuberculosis* were tested with the BD BACTEC MGIT 960 SIRE susceptibility test and the MOP susceptibility test. This included testing of both fresh clinical and stock isolates from both liquid and solid culture sources. This generated a total of 195 test results for the initial susceptibility test performed for streptomycin, isoniazid and rifampin (critical concentration). A separate evaluation of ethambutol was performed from frozen aliquots of the original clinical and stock isolates as well as prospective clinical isolates from both liquid and solid culture sources. This generated a total of 223 test results for the ethambutol test at the critical concentration.

Table 2 presents the results from clinical isolate testing for each drug (critical concentration) from liquid source cultures. Table 3 presents the results from clinical isolate testing for each drug (critical concentration) from solid source cultures.

Table 2: Clinical Isolate Results – BD BACTEC MGIT 960 AST Compared to Method of Proportion from Liquid Source Cultures

	Method of Proportion			MGIT 960 AST System				
					Susceptible Results		Resistant Result	
DRUG	Concentration	S	R	Concentration	# Agreement	% Agreement (95% CI)	# Agreement	% Agreement (95% CI)
STR	2.0 µg/mL	69	27	1.0 µg/mL	62	90 (80–96)	26	96 (81–100)
INH	0.2 µg/mL	59	37	0.1 µg/mL	57	97 (88–100)	36	97 (86–100)
RIF	1.0 µg/mL	72	24	1.0 µg/mL	71	99 (93–100)	24	100 (95–100)
EMB	5.0 µg/mL	91	20	5.0 µg/mL	88	97 (91–99)	17	85 (62–97)

All isolates with discordant MGIT results were tested by MOP at two independent sites. Of the seven discordant STR resistant (R-960, S-MOP) isolates, three had resistant results from both sites and one had susceptible results from both sites. The remaining three had resistant results from one site and susceptible results from the other site. The discordant STR susceptible (S-960, R-MOP) isolate had susceptible results from both sites. The two discordant INH resistant (R-960, S-MOP) isolates had susceptible results from both sites. The discordant INH susceptible (S-960, R-MOP) isolate had susceptible results from both sites. The discordant RIF resistant (R-960, S-MOP) isolate had resistant results from both sites. The three discordant EMB resistant (R-960, S-MOP) isolates had susceptible results from both sites. Of the three discordant EMB susceptible (S-960, R-MOP) isolates, two had susceptible results from both sites and one had a resistant result from one site and a susceptible result from the other site.

Table 3: Clinical Isolate Results – BD BACTEC MGIT 960 AST Compared to Method of Proportion from Solid Source Cultures

	Method of Proportion			MGIT 960 AST System				
					Susceptible Results		Resistant Result	
DRUG	Concentration	S	R	Concentration	# Agreement	% Agreement (95% CI)	# Agreement	% Agreement (95% CI)
STR	2.0 µg/mL	70	29	1.0 µg/mL	65	93 (84–98)	28	97 (82–100)
INH	0.2 µg/mL	63	36	0.1 µg/mL	62	98 (92–100)	35	97 (86–100)
RIF	1.0 µg/mL	70	29	1.0 µg/mL	70	100 (95–100)	26	90 (73–98)
EMB	5.0 µg/mL	87	25	5.0 µg/mL	86	99 (94–100)	20	80 (59–93)

All isolates with discordant MGIT results were tested by MOP at two independent sites. Of the five discordant STR resistant (R-960, S-MOP) isolates, two had resistant results from both sites and one had susceptible results from both sites. The remaining two had resistant results from one site and susceptible results from the other site. The discordant STR susceptible (S-960, R-MOP) isolate had resistant results from both sites. The discordant INH resistant (R-960, S-MOP) isolate had susceptible results from both sites. The discordant INH susceptible (S-960, R-MOP) isolate had resistant results from both sites. The three discordant RIF susceptible (S-960, R-MOP) isolates had susceptible results from both sites. The one discordant EMB resistant (R-960, S-MOP) isolate had resistant results from both sites. Of the five discordant EMB susceptible (S-960, R-MOP) isolates, four had susceptible results from both sites. The remaining isolate had a resistant result from one site and a susceptible result from the other site.

Table 4 presents the results from clinical isolate testing for streptomycin and isoniazid (high concentration) from liquid source cultures. Table 5 presents the results from clinical isolate testing for streptomycin and isoniazid (high concentration) from solid source cultures.

Table 4: Clinical Isolate Results – BD BACTEC MGIT 960 AST Compared to Method of Proportion from Liquid Source Cultures

	Method of Proportion			MGIT 960 AST System				
					Susceptible Results		Resistant Result	
DRUG	Concentration	S	R	Concentration	# Agreement	% Agreement (95% CI)	# Agreement	% Agreement (95% CI)
STR	10.0 µg/mL	77	19	4.0 µg/mL	73*	95 (87–99)	17	90 (67–99)
INH	1.0 µg/mL	65	31	0.4 µg/mL	65*	100 (95–100)	29	94 (74–99)

* Assumes MGIT high drug S result for all isolates with MGIT low drug S result.

All isolates with discordant MGIT results were tested by MOP at two independent sites. The four discordant STR resistant (R-960, S-MOP) isolates had susceptible results from both sites. Of the two discordant STR susceptible (S-960, R-MOP) isolates, one had susceptible results from both sites and one had resistant results from both sites. Of the two discordant INH susceptible (S-960, R-MOP) isolates, one had susceptible results from both sites and one had resistant results from both sites.

Table 5: Clinical Isolate Results – BD BACTEC MGIT 960 AST Compared to Method of Proportion from Solid Source Cultures

	Method of Proportion			MGIT 960 AST System				
					Susceptible Results		Resistant Result	
DRUG	Concentration	S	R	Concentration	# Agreement	% Agreement (95% CI)	# Agreement	% Agreement (95% CI)
STR	10.0 µg/mL	78	21	4.0 µg/mL	73*	94 (86–98)	17	81 (58–95)
INH	1.0 µg/mL	68	31	0.4 µg/mL	68*	100 (95–100)	30	87 (83–100)

* Assumes MGIT high drug S result for all isolates with MGIT low drug S result.

All isolates with discordant MGIT results were tested by MOP at two independent sites. The five discordant STR resistant (R-960, S-MOP) isolates had susceptible results from both sites. Of the four discordant STR susceptible (S-960, R-MOP) isolates, three had susceptible results from both sites and one had resistant results from both sites. The discordant INH susceptible (S-960, R-MOP) isolate had resistant results from both sites.

AVAILABILITY

Cat. No.	Description
245123	BD BACTEC™ MGIT™ 960 SIRE Kit, carton of 4 lyophilized drug vials, and 8 SIRE Supplements.
245125	BD BACTEC™ MGIT™ 960 STR 4.0 Kit, carton of 1 lyophilized drug vial and 2 SIRE Supplements.
245157	BD BACTEC™ MGIT™ 960 IR Kit, carton of 2 lyophilized drug vials, and 4 SIRE Supplements.
245126	BD BACTEC™ MGIT™ 960 INH 0.4 Kit, carton of 1 lyophilized drug vial and 2 SIRE Supplements.

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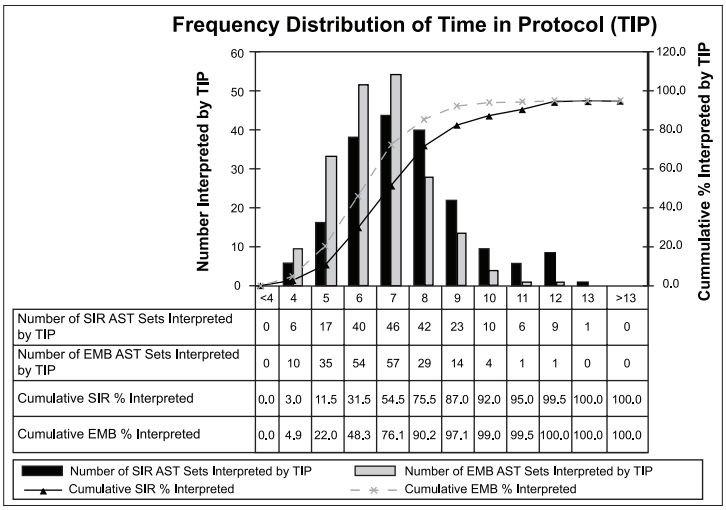
7. Ridderhof, J. 2001. Multicenter evaluation of 3.75 µg/mL ethambutol (EMB) in BD BACTEC vials for susceptibility testing of *Mycobacterium tuberculosis*. Abstract C-244, American Society for Microbiology Abstracts 2001.

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

Figure 1: Distribution of BD BACTEC MGIT 960 AST Time in Protocol



	<4	4	5	6	7	8	9	10	11	12	13	>13
Number of SIR AST Sets Interpreted by TIP	0	6	17	40	46	42	23	10	6	9	1	0
Number of EMB AST Sets Interpreted by TIP	0	10	35	54	57	29	14	4	1	1	0	0
Cumulative SIR % Interpreted	0.0	3.0	11.5	31.5	54.5	75.5	87.0	92.0	95.0	99.5	100.0	100.0
Cumulative EMB % Interpreted	0.0	4.9	22.0	48.3	76.1	90.2	97.1	99.0	99.5	100.0	100.0	100.0

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 245123 existing precautionary codes and statements updated for BD BACTEC MGIT 960 Rifampin; added health hazard pictogram, signal word “Danger”, all hazard & precautionary codes and statements for BD BACTEC MGIT 960 Ethambutol. Per Safety Data Sheet for catalog number 245157 existing hazard & precautionary codes and statements updated for BD BACTEC MGIT 960 Rifampin.

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

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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

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

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

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

Method of sterilization: ethylene oxide / Метод на стерилизация: етиленов оксид / Způsob sterilizace: etylenoxid / Steriliseringsmetode: ethylenoxid / 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

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 түсipy / 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

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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

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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 / 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

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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 / Feriți 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 сутегі 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

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