BD BACTEC™ MGIT™ 960 SIRE Kit

For the Antimycobacterial Susceptibility Testing of *Mycobacterium tuberculosis*

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INTENDED USE

The BD BACTEC™ MGIT™ 960 SIRE Kit is used as a rapid qualitative procedure for susceptibility testing of *Mycobacterium tuberculosis*, from culture, to streptomycin, isoniazid, rifampin and ethambutol using the BD BACTEC MGIT 960 and BD BACTEC MGIT 320 Systems.

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 which includes the antimycobacterial drugs streptomycin, isoniazid, rifampin and/or ethambutol. It is important that the antimycobacterial drugs prescribed show appropriate activity against *Mycobacterium tuberculosis*, i.e., susceptibility of the isolate to the drug.

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 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. The second method, known as the BD BACTEC 460TB radiometric susceptibility method,[3] generally takes from 4 to 12 days. It is based on the production of radioactive ^{14}C-labeled carbon dioxide by the growing mycobacteria, manifested by a growth index increase in the system.

Historically, the Method of Proportion (MOP) procedure has included susceptibility testing of *Mycobacterium 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 generally considered to be the critical concentrations for these drugs. The critical concentration is defined as the drug concentration which inhibits the wild type sub-population while allowing sufficient growth of the mutant resistant sub-population in order to determine resistance at the critical proportion of 1%. The high drug concentration is not considered to be the critical concentration. However, resistance at the high concentration is evidence that resistance is generally distributed among the population of the test *M. tuberculosis* strain. Some clinicians use the susceptibility test results at the high concentrations to profile the degree of resistance of the test strain.

The BD BACTEC MGIT 960 SIRE test provides the susceptibility result in approximately the same time frame as the BD BACTEC 460TB system. In addition, this method is non-radiometric and allows appropriate antibiotic susceptibility results to be reported earlier, in most cases, than with the MOP procedure.

The BD BACTEC MGIT system has been developed to allow susceptibility testing at the critical concentration for streptomycin, isoniazid, rifampin and ethambutol, and at a higher concentration for streptomycin, isoniazid, and ethambutol. These concentrations correlate with the two concentrations used in the MOP procedure. A susceptible result at the critical concentration can be reported and no other tests are necessary. However, any strain determined to be resistant with the BD BACTEC MGIT 960 SIRE kit to streptomycin, isoniazid, and ethambutol at the critical concentration may be, at a minimum, tested at the high concentration. In this case, a final result of resistant at the critical concentration may be reported, with notification that an additional test at the high concentration is being 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 BD 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 respiring microorganisms consume the oxygen which 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 *Mycobacterium 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 using predefined algorithms (which compare growth in the drug containing tube to that in the Growth Control tube) and the susceptible or resistant result is reported by the instrument.

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 (STR)..... 332 µg
Approximate Formula* Per Vial Lyophilized drug: Isoniazid (INH) ..... 33.2 µg
Approximate Formula* Per Vial Lyophilized drug: Rifampin (RIF)..... 332 µg
Approximate Formula* Per Vial Lyophilized drug: Ethambutol (EMB)..... 1,660 µg

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

Approximate Formula* Per Vial Lyophilized drug: Isoniazid..... 66.4 µg

BD BACTEC MGIT EMB 7.5 Kit contains one vial lyophilized ethambutol and two vials of SIRE Supplement.

Approximate Formula* Per Vial Lyophilized drug: Ethambutol..... 1,245 µg

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.

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.

Reconstitute each BD BACTEC MGIT 960 EMB 7.5 Kit ethambutol lyophilized drug vial with **2 mL** of sterile distilled/deionized water to make a stock solution of 622.5 µg/mL.

WARNINGS:

For *in vitro* Diagnostic Use.

POTENTIALLY INFECTIOUS TEST SPECIMEN: Observe "Universal Precautions"[4] and institutional guidelines when handling and disposing of infectious materials.

BD BACTEC MGIT 960 – Catalog number 245127

BD BACTEC MGIT 960 Ethambutol

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.

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 BACTEC 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 or if BD MGIT tubes exhibit fluorescence prior to use.

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.

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 (or BD BACTEC 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. 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 by visual comparison to a 0.5 McFarland turbidity standard.
8. Dilute 1 mL of the adjusted suspension in 4 mL of sterile saline (1:5 dilution).

Preparation from a Positive BD BACTEC MGIT Tube:

1. 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.
2. If the tube is a Day 1 or Day 2 positive, proceed to “Inoculation Procedure for Susceptibility Test.”
3. If the tube is a Day 3, Day 4, or Day 5 positive, then dilute 1 mL of the positive broth in 4 mL of sterile saline (1:5 dilution). Use the diluted suspension for the inoculation procedures. Proceed to “Inoculation Procedure for Susceptibility Test.”

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 lyophilized drug and two vials of SIRE Supplement (approximately 20 tests per kit), BD BACTEC MGIT 960 INH 0.4 Kit containing one vial lyophilized drug and two vials of SIRE Supplement (approximately 20 tests per kit), and BD BACTEC MGIT 960 EMB 7.5 Kit containing one vial lyophilized drug and two vials of SIRE Supplement (approximately 20 tests per kit).

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

IMPORTANT PROCEDURAL NOTE:

Be sure to tightly recap the BD MGIT tubes after all additions are made. Mix tubes thoroughly by gentle inversion three to four times.

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

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 the last 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 correct supplement.
3. Aseptically pipet, using a micropipet, 100 µL of 83 µg/mL BD BACTEC MGIT STR solution to the appropriately labeled BD MGIT tube. Aseptically pipet 100 µL of 8.3 µg/mL BD BACTEC MGIT INH solution to the appropriately labeled BD MGIT tube. Aseptically pipet 100 µL of 83 µg/mL BD BACTEC MGIT RIF solution to the appropriately labeled BD MGIT tube. Aseptically pipet 100 µL of 415 µg/mL BD BACTEC MGIT EMB solution to the appropriately labeled BD MGIT tube. No drug solutions 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
BD BACTEC MGIT STR	83 µg/mL	100 µL	1.0* µg/mL
BD BACTEC MGIT INH	8.3 µg/mL	100 µL	0.1* µg/mL
BD BACTEC MGIT RIF	83 µg/mL	100 µL	1.0* µg/mL
BD BACTEC MGIT EMB	415 µg/mL	100 µL	5.0* µg/mL

*Equivalent to CDC[4] recommended critical drug concentrations.

** 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 "Specimen 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 "Specimen Preparation") into each of the FOUR remaining drug tubes (STR, INH, RIF, EMB).
6. Tightly recap the tubes and mix well.
7. Enter the AST set into the BD BACTEC MGIT 960 SIRE Kit 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, INH 0.4 and EMB 7.5 Kits Susceptibility Test:

If resistance occurs at the critical concentration, an optional profile test may be performed which, at minimum, tests the high concentration of the drug to which it was originally resistant:

Isolate Source – The isolate used for this testing must have been prepared as described in "Specimen Preparation." A seed tube may be prepared from the drug free Growth Control tube from the previously tested AST set of the isolate, from which 0.5 mL may be inoculated 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 "Specimen Preparation: Preparation from a Positive BD MGIT tube."

1. Label enough BD MGIT 7 mL tubes for the test isolate to have a BD MGIT GC (Growth Control) and a BD MGIT drug tube for each antimicrobic tested.
2. Aseptically add 0.8 mL of BD BACTEC MGIT SIRE Supplement to each tube. NOTE: it is important to use the correct supplement.
3. Aseptically pipet, using a micropipet, 100 µL of the drug solution to the appropriately labeled BD MGIT 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
BD BACTEC MGIT STR 4.0	332 µg/mL	100 µL	4.0* µg/mL
BD BACTEC MGIT INH 0.4	33.2 µg/mL	100 µL	0.4* µg/mL
BD BACTEC MGIT EMB 7.5	622.5 µg/mL	100 µL	7.5* µg/mL

* Equivalent to MOP high drug concentrations.[4]

** 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 "Specimen 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 "Specimen Preparation") into each of the drug tubes.
6. Tightly recap the tubes and mix well.
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 suggested that the control organism shown below be tested (see "Inoculation Procedure for Susceptibility Test"). Observation of the proper results, as shown below, within 4–13 days indicates that the BD BACTEC MGIT 960 SIRE Kit is 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 Technical Services at 1.800.638.8663 (United States only).

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 Technical Services at 1.800.638.8663 (United States only).

Strains	GC	BD BACTEC MGIT STR	BD BACTEC MGIT INH	BD BACTEC MGIT RIF	BD BACTEC MGIT EMB
M. tuberculosis ATCC® 27294	Positive	Susceptible	Susceptible	Susceptible	Susceptible

Strains	GC	BD BACTEC MGIT STR 4.0	BD BACTEC MGIT INH 0.4	BD BACTEC MGIT EMB 7.5
M. tuberculosis ATCC 27294	Positive	Susceptible	Susceptible	Susceptible

REPORTING OF RESULTS

The BD BACTEC MGIT instrument will monitor susceptibility test 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).

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 0.5 McFarland turbidity standard and the appropriate dilutions may give inaccurate results.

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

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

Failure to use a 1:100 dilution of the isolate for the inoculation of the Growth Control tube may give inaccurate 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 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 RESULTS

The average time-to-result for susceptibility testing, using the critical concentrations, is 8.0 days (range 4 to 13).

PERFORMANCE CHARACTERISTICS

The performance of the BACTEC MGIT 960 SIRE test was internally evaluated using a panel of challenge strains obtained from the Centers for Disease Control and Prevention (CDC), GA, USA. The panel consisted of thirty strains of *M. tuberculosis* with known susceptibility patterns (using agar proportion method). Table 1 shows the BACTEC MGIT 960 SIRE test results compared to the expected results.

Evaluation of the BACTEC MGIT 960 SIRE test is being performed at five geographically diverse clinical sites, to include regional reference centers, university hospital-based laboratories, and one internal site. The BACTEC MGIT 960 SIRE test is being compared to the modified Method of Proportion (MOP).[6] Table 2 shows the initial BACTEC MGIT 960 SIRE test results compared to the equivalent drug concentration in MOP. Table 3 shows the second tier BACTEC MGIT 960 SIRE test results compared to the equivalent drug concentration in MOP. This data includes testing of both fresh and/or reference clinical isolates.

Reproducibility of the BACTEC MGIT 960 SIRE test was evaluated at the clinical sites using a panel of ten qualified strains, including several strains resistant to each of the drugs, and comparing the BACTEC MGIT 960 SIRE test results to the expected result. The reproducibility results are: 99.6% for STR, 97.7% for INH, 99.4% for RIF and 94.0% for EMB. Individual site reproducibility results ranged from 94.5% to 99.5% for combined drug results.

Table 1

CDC Challenge Panel		No. Tested	Category Agreement	
Drug			No.	%
STR	All	29	26	90.0
	S	24	21	88.0
	R	5	5	100.0
INH	All	29	29	100.0
	S	8	8	100.0
	R	21	21	100.0
RIF	All	29	29	100.0
	S	19	19	100.0
	R	10	10	100.0
EMB	All	29	29	100.0
	S	25	25	100.0
	R	4	4	100.0
STR 4.0	All	8	8	100.0
	S	3	3	100.0
	R	5	5	100.0
INH 0.4	All	21	21	100.0
	S	8	8	100.0
	R	13	13	100.0

Note: Results of MOP test for EMB 7.5 not available for comparison.

Table 2

Clinical Strains		No. Tested	Category Agreement	
Drug			No.	%
STR	All	113	104	92.0
	S	80	72	90.0
	R	33	32	97.0
INH	All	117	114	97.4
	S	70	67	95.7
	R	47	47	100.0
RIF	All	116	115	99.1
	S	82	82	100.0
	R	34	33	97.1
EMB	All	75	73	97.0
	S	67	65	97.0
	R	8	8	100.0

Table 3

Clinical Strains		No. Tested	Category Agreement	
Drug			No.	%
STR 4.0	All	31	22	71.0
	S	16	10	62.5
	R	15	12	80.0
INH 0.4	All	39	36	92.3
	S	6	5	83.3
	R	33	31	93.9
EMB 7.5	All	74	71	96.0
	S	66	66	100.0
	R	8	5	63.0

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.
245126	BD BACTEC™ MGIT™ 960 INH 0.4 Kit, carton of 1 lyophilized drug vial and 2 SIRE Supplements.
245127	BD BACTEC™ MGIT™ 960 EMB 7.5 Kit, carton of 1 lyophilized drug vial and 2 SIRE Supplements.

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. 2003. Approved Standard: M24-A. Susceptibility testing of mycobacteria, nocardiae, and other aerobic actinomycetes. CLSI, Wayne, Pa.
3. BD Diagnostic Systems. BD BACTEC 460TB System Product and Procedure Manual.
4. Kent, P.T., and G.P. Kubica. 1985. Public health mycobacteriology: a guide for the level III laboratory. USDHHS. Centers for Disease Control, Atlanta.
5. Data on file at BD Diagnostic Systems.
6. Clinical and Laboratory Standards Institute. 1994. Tentative Standard: M24-T. Antimycobacterial Susceptibility Testing for *Mycobacterium tuberculosis*. CLSI, Wayne, PA.

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
(04)	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 245127 added health hazard pictogram, signal word “Danger”, all hazard & precautionary codes and statements for BD BACTEC MGIT 960 Ethambutol.

US Customers only: For symbol glossary, refer to 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)
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IVD 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

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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 / Неративтік 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 / 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 әдісі – 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 әдісі – 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

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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

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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

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

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µL/test / µL/тест / µL/Test / µL/εξέτασηη / µL/prueba / µL/teszt / µL/테스트 / мкл/тест / µL/tyrimas / µL/pārbaude / µL/teste / мкл/аналіз / µL/檢測

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 / Feriţi 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

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