By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Becton, Dickinson and Company (BD)
7 Loveton Circle
Sparks
Maryland
21152
USA

Holds Certificate Number: MD 595740

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design, development, manufacture, service and distribution of in-vitro diagnostic medical devices and microbiological products. These devices and products include equipment, in-vitro diagnostic test kits and reagents, prepared media products, dehydrated culture media, collection and transport, antimicrobial susceptibility tests, sample preparation, cytology devices, cytopathology auto-imaging devices with computerized microscopy, telepathology devices, lab automation, ancillary devices and instrument software for use in the screening and diagnosis of diseases, transmissible and sexually transmissible agents, and autoimmune status.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2013-03-14
Effective Date: 2024-10-11
Latest Revision Date: 2024-09-16
Expiry Date: 2027-10-10

...making excellence a habit.™

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Location	Registered Activities
Becton, Dickinson and Company (BD) 7 Loveton Circle Sparks Maryland 21152 USA	The design, development, manufacture, service and distribution of in-vitro diagnostic medical devices and microbiological products. These devices and products include equipment, in-vitro diagnostic test kits and reagents, collection and transport, antimicrobial susceptibility tests, sample preparation, devices with computerized microscopy, telepathology devices, ancillary devices and instrument software for use in the screening and diagnosis of diseases, transmissible and sexually transmissible agents, and autoimmune status.
Becton Dickinson and Company (BD) BD Diagnostic Systems 52/54 Loveton Circle Sparks Maryland 21152 USA	The design, development, manufacture, service and distribution of in-vitro diagnostic medical devices and microbiological products. These devices and products include in-vitro diagnostic test kits and reagents used in the diagnosis of diseases, transmissible and sexually transmissible agents, autoimmune status, sample preparation.
Becton Dickinson and Company (BD) BD Diagnostic Systems 39 Loveton Circle Sparks Maryland 21152 USA	The manufacture and distribution of in-vitro diagnostic medical devices and microbiological products. These devices and products include in-vitro diagnostic test kits and reagents used in the diagnosis of diseases, transmissible and sexually transmissible agents, autoimmune status, dehydrated culture media, sample preparation.
Becton Dickinson and Company (BD) BD Diagnostic Systems 250 Schilling Circle Cockeysville Maryland 21030 USA	The manufacture and distribution of in-vitro diagnostic medical devices and microbiological products. These devices and products include in-vitro diagnostic test kits and reagents used in the diagnosis of diseases, prepared media products.

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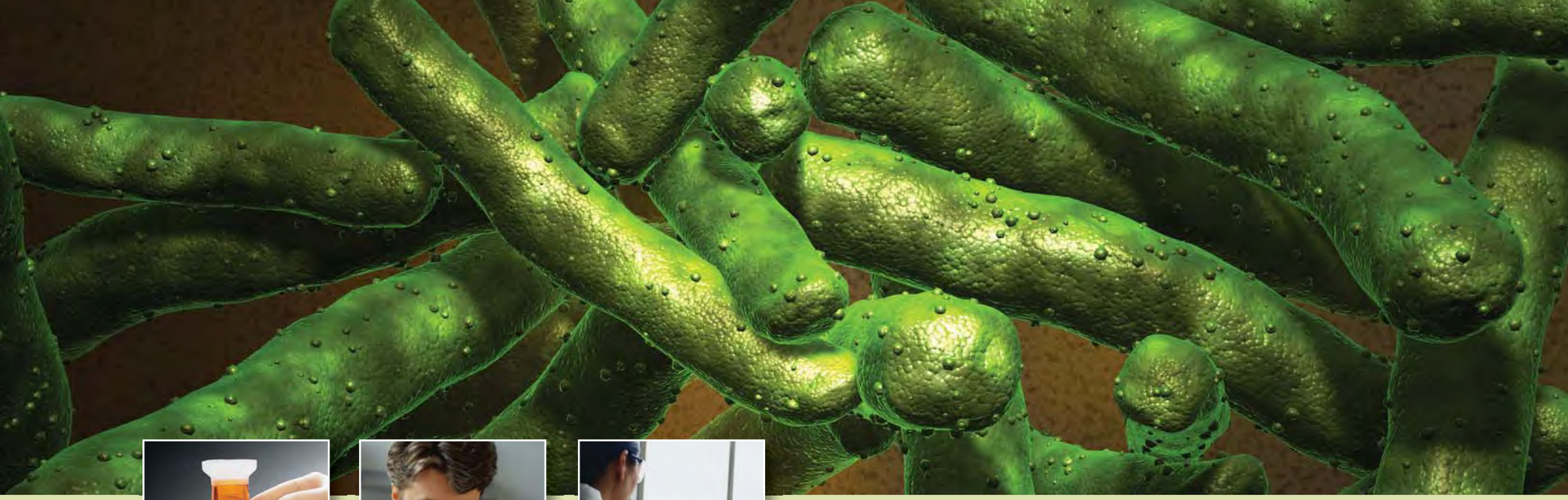
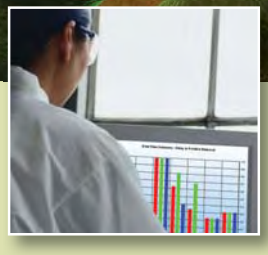




Mycobacteria Diagnosis

From specimen collection to final report, BD offers the right fit for your Mycobacteria testing needs.

BD

Helping all people live healthy lives

H.E.R.O.™ Solution for Mycobacterial Testing

History at a glance

The Diagnosis and Treatment of TB & the Role of BD in the Global Fight

1882

Dr. Robert Koch isolated *Mycobacterium tuberculosis, the microorganism* responsible for TB.[1]

1890

Carlo Forlanini, an Italian physician, created the first TB therapy by injecting air into the chest of a TB patient. He is given credit for the discovery of artificial pneumothorax as a practical procedure.[1]

1944

Shortly after Selman A. Waksman's development of Streptomycin, the antibiotic was administered to a live human being for the first time on November 20, 1944. The progression of the disease was halted, the bacteria were later absent from the sputum and the patient fully recovered.[1]

1946-1963

In the years following Waksman's development of Streptomycin, an antibiotic to treat TB, more therapies were discovered to treat TB: para-aminosalisylic acid (PAS), p-aminosalicylic acid, isoniazid (INH),pyrazinamide, cycloserine, ethambutol and rifampicin. With the onset of antibiotic resistance, multiple drug therapy has been used to treat TB.[1]

1955

BD entered the microbiology field. The acquisition of Baltimore Biological Laboratory provided a crucial impetus for BD to lead two fundamental changes in healthcare: the conversion to sterile disposables and the emergence of diagnostic medicine.[2]

1980

BD introduced the first automated system for mycobacteria testing, the BD BACTEC™ 460TB System.[3]

1982

A century after Dr. Koch announced the discovery of the TB bacillus, the World Health Organization (WHO) and the International Union Against Tuberculosis and Lung Disease (IUATLD) sponsored the first World TB Day to educate the public about TB and its global impact.[2]

1993

The WHO declared TB a global emergency, the first such declaration by the organization.[4]

1998

BD introduced the automated BD BACTEC™ MGIT™ 960 Mycobacteria Culture System, which features an unprecedented 960-tube capacity for processing up to 8000 specimens per year.

2003

BD launched its global "Trusted Partners" Communications Campaign to bring attention to urgent global healthcare needs as well as to the Company's commitment to *"Helping all people live healthy lives"* throughout the world through its partnerships with organizations such as the Foundation for Innovative New Diagnostics (FIND), March of Dimes, UNICEF and the American Red Cross.

2004

On December 15th, BD and FIND announced their international collaboration aimed at improving rapid diagnosis of pulmonary TB in HIV-infected patients in developing countries. This agreement provided a blueprint for modern TB technology, such as the BD MGIT (Mycobacteria Growth Indicator Tube) system, to be made more widely available globally in an effort to help reduce TB deaths and decrease transmission rates in high-risk areas.

2006

BD is named an Organizational Partner of the global Stop TB Partnership, the official sponsors of World TB Day.

www.stoptb.org

BD formed the "TB Core Team" focused on discovering new technologies to improve TB diagnostics.

In September 2006, the WHO issued an alert about the threat of XDR-TB and called for the strengthening of TB control worldwide as a strategic and necessary response.

2007

In response to WHO recommendations for the use of liquid culture systems for TB diagnosis, BD and FIND announced a pricing agreement to make BD MGIT liquid culture testing available to 39 high-burden, low-income countries.

BD responds to threat of XDR-TB with expanded support of FIND, including a grant toward strengthening laboratory capabilities worldwide.

2008

BD, in a public-private partnership with the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), continues working to improve overall laboratory systems and services in African countries severely affected by HIV/AIDS and tuberculosis.

BD offers the right fit for your Mycobacteria testing needs

In 1882, Dr. Robert Koch isolated *Mycobacterium tuberculosis*, the microorganism responsible for TB.[1] Today, we are working to diagnose and treat this deadly disease. BD, a leading global medical technology company that manufactures and sells medical devices, instrument systems and reagents, is dedicated to improving people's health throughout the world. BD provides a range of products, from collection devices to growth/detection methods to actionable reporting, to support the clinical lab in the diagnosis of Mycobacterium.

Mycobacteria Diagnosis

From Specimen Collection to Report

SPECIMEN COLLECTION	DECONTAMINATION/ DIGESTION	ACID FAST AND FLUORESCENT STAINS	CULTURE	IDENTIFICATION	SUSCEPTIBILITY TESTING	REPORTS AND STATISTICS
BD Falcon™ Sputum Collection System	BD BBL™ MycoPrep™	BD Stain Kits	Solid Media BD BBL™ MGIT™ Tubed Media BD BACTEC™ MGIT™ 960	BD BBL™ Taxo™ TB Niacin and Nitrate Test Strips	BD BACTEC™ MGIT™ 960 BD BBL™ MGIT™ SIRE/PZA BD BBL™ Sensi-Disc™	BD EpiCenter™ Data Management

SPECIMEN COLLECTION

BD Falcon™ Brand Sputum Collection System

The BD Sputum Collection System provides safe collection, transport and handling of potentially infected specimens. BD Sputum Collection System's unique, patented no-touch design eliminates the need to contact the cap or tube top. The system is especially suited for collection of specimens for TB culture. Samples arrive ready for digestion, decontamination and centrifugation without transfer to a special processing tube.

DECONTAMINATION / DIGESTION

BD BBL™ MycoPrep™ System

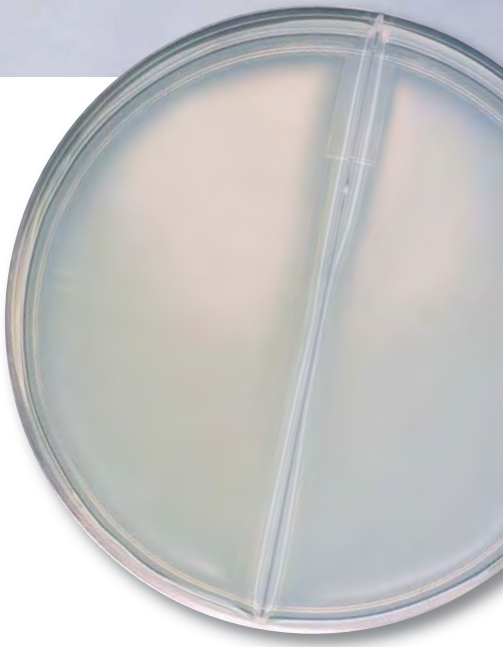
BD BBL MycoPrep System eliminates much of the time and labor traditionally associated with reagent preparation. A simple snap and a gentle shake give you a NALC-NaOH reagent that's stable for up to 24 hours. You save valuable technologist time while avoiding the difficulties associated with reconstituting, weighing and mixing materials and inventorying separate ingredients.

Pre-packaged BD BBL MycoPrep reagent utilizes the recommended formulation for mycobacterial specimen processing to give you gentle, effective digestion/decontamination.[5] And since the all-inclusive product stores at room temperature and includes powdered phosphate buffer in pre-measured packages, your lab saves materials, time and labor while decreasing safety hazards.

Acid Fast and Fluorescent Stains

BD (Difco™ and BBL™) stains offer clear and distinct options for acid fast bacilli staining in the most advanced and complete methodologies. Each ready-to-use kit comes in a compact tray that doubles as a work station (stains are also available in 250 mL individual bottles). Bottles feature a hinged, easy-open, "keep clean" spout and easy-to-read, color coded labels that wipe clean without staining.

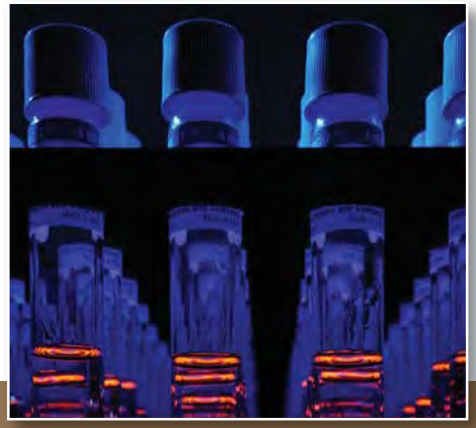
BD Solid Media Choices



Lowenstein-Jensen and Middlebrook provide the optimal media to meet the needs of today's busy laboratories. They are available in a variety of plate and tube configurations. 98The tubes feature a broad dimension agar slant to facilitate inoculation and recovery of myco-bacteria, plus tight-fitting, rubber-lined screw tops prevent leakage and moisture loss.

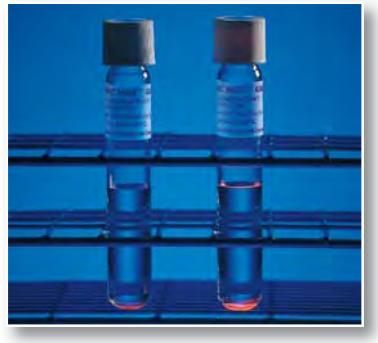
CULTURE: MANUAL MYCOBACTERIAL GROWTH SYSTEM

BD BBL™ MGIT™ (Mycobacteria Growth Indicator Tube)



Rapid, Dependable, Visually Distinct Mycobacteria Detection

The BD BBL MGIT System gives your lab a rapid, dependable, easy and safe method for growth and detection of mycobacteria from clinical specimens. MGIT conveniently creates an environment suitable for rapid mycobacterial growth. You inoculate the plastic tube with a pretreated specimen suspension and incubate. Under UV light, growth is indicated by an unmistakable orange fluorescent glow. Mycobacteria are then easily extracted for use with identification and susceptibility tests.



CULTURE: INSTRUMENTED MYCOBACTERIAL GROWTH SYSTEM

BD BACTEC™ MGIT™ 960 System

The BD BACTEC MGIT 960 System was designed with simplicity in mind, ensuring maximum productivity with minimal staffing and training. The fully automated testing system identifies positives as they occur—often at a faster rate than the other instrumented systems.[6, 7,8] Faster results may help improve patient care and lower health care costs by reducing hospital stays and optimizing equipment and staff utilization. The BACTEC MGIT 960 System uses MGIT media and patented sensors, making efficient use of advanced fluorometric technology, which permits highly accurate detection of O_2 consumption without sharps.

SUSCEPTIBILITY

BD BACTEC™ MGIT™ 960 SIRE AND PZA Susceptibility Testing

The fully automated AST reading and interpretation for consistent results is designed for an easy 4 step process (inoculate the SIRE/PZA set, scan the set into the instrument, remove the set once completed and print the S or R interpretation).

REPORT AND STATISTICS

BD EpiCenter™ Data Management System

Monitor, Analyze, and Communicate — the BD BACTEC™ MGIT™ 960 System with BD EpiCenter Data Management.

EpiCenter allows for monitoring drug resistance trending, tracking multi-drug resistance patterns, generation of public health reports, performing solid and liquid media time-to-detection studies, and the examination of method comparison studies.

Ordering Information

Cat. No.	Description	Quantity

SPECIMEN COLLECTION

290020	Falcon™ Sputum Collection System	Ctn. of 72
240862	MycoPrep™ Specimen Digestion/Decontamination Kit 10 75 mL bottles of NALC-NaOH Solution and 5 packages of Phosphate Buffer (pH 6.8)	Kit
240863	MycoPrep™ Specimen Digestion/Decontamination Kit 10 150 mL bottles of NALC-NaOH Solution and 10 packages of Phosphate Buffer (pH 6.8)	Kit

ACID FAST AND FLUORESCENT STAINS

212521	TB Fluorescent Stain Kit T 1 250 mL bottle each of TB Auramine-Rhodamine T, TB Decolorizer TM, TB Potassium Permanganate	1 Each
212315	TB Quick Stain Kit 1 250 mL bottle each of TB Quick Stain Carbolfuchsin and TB Quick Stain Methylene Blue	1 Each
212522	TB Stain Kit K 1 250 mL bottle each of TB Carbolfuchsin KF, TB Decolorizer, TB Brilliant Green K	1 Each
212515	TB Auramine-Rhodamine T, 250 mL	4 SP
212523	TB Brilliant Green K, 250 mL	4 SP
212518	TB Carbolfuchsin KF, 250 mL	4 SP
212517	TB Decolorizer, 250 mL	4 SP
212512	TB Decolorizer TM, 250 mL	4 SP
212513	TB Potassium Permanganate, 250 mL	4 SP
231391	BBL™ AFB QC Slides	50 SP

Cat. No.	Description	Quantity	Tube*

PREPARED TUBED MEDIA

221257	Lowenstein-Jensen Medium Deeps (for Semi-Qualitative Catalase Test)	Pkg. of 10	A
221115	Lowenstein-Jensen Medium Mycoflask	Pkg. of 10	M
221116	Lowenstein-Jensen Medium Mycoflask	Ctn. of 100	M
220908	Lowenstein-Jensen Medium Slants	Pkg. of 10	A
220909	Lowenstein-Jensen Medium Slants	Ctn. of 100	A
221387	Lowenstein-Jensen Medium Slants	Pkg. of 10	C
221388	Lowenstein-Jensen Medium Slants	Ctn. of 100	C
297211	Lowenstein-Jensen Medium Slants Gruft (with Penicillin and Nalidixic Acid)	Pkg. of 10	C
291896	Lowenstein-Jensen Medium Slants with 5% Sodium Chloride, 7 mL	Pkg. of 10	C
295939	Middlebrook 7H9 Broth, 8 mL	Pkg. of 10	K
220958	Middlebrook and Cohn 7H10 Agar Slants	Pkg. of 10	A
220959	Middlebrook and Cohn 7H10 Agar Slants	Ctn. of 100	A
221413	Mycobactosel™ L-J Medium Slants	Pkg. of 10	A
221414	Mycobactosel™ L-J Medium Slants	Ctn. of 100	A
297315	Selective Seven H11 (Mitchison) Agar Slants	Pkg. of 10	A
297639	Selective Seven H11 (Mitchison) Agar Slants	Ctn. of 100	A
221391	Seven H11 Agar Slants	Pkg. of 10	A
221392	Seven H11 Agar Slants	Ctn. of 100	A
296105	Seven H11 Agar Slants	Pkg. of 10	C
297704	Seven H11 Agar Slants	Ctn. of 100	C

PREPARED PLATED MEDIA

231174	Middlebrook and Cohn 7H10 Agar (Deep Fill)	Pkg. of 20
221868	Selective Seven H11 Agar (Deep Fill)	Pkg. of 10
221870	Seven H11 Agar (Deep Fill)	Pkg. of 10
297250	Middlebrook 7H11/ 7H11 Selective Agar (Bi-plate)	Pkg. of 20

***Tube Sizes**
A ..... 20 x 148 mm with cap
C ..... 20 x 116 mm with cap
K ..... 16.5 x 105 mm with cap
M ..... Mycoflask™ bottle

Cat. No.	Description	Quantity

BD BBL™ SEPTI-CHEK™ AFB MYCOBACTERIA CULTURE SYSTEM

243558	Septi-Chek™ AFB Culture Bottle	Pkg. of 10
211834	Septi-Chek™ AFB Slide	Pkg. of 10
243560	Septi-Chek™ AFB Supplement	Pkg. of 5

MANUAL MYCOBACTERIAL GROWTH SYSTEM

245111	BBL™ MGIT™ Mycobacterial Growth Indicator Tube (4 mL prefilled with indicator and broth)	Pkg. of 25
245113	BBL™ MGIT™ Mycobacterial Growth Indicator Tube (4 mL prefilled with indicator and broth)	Ctn. of 100
245116	BBL™ MGIT™ OADC Enrichment	Pkg. of 6
245114	BBL™ MGIT™ PANTA™ Antibiotic Mixture, Lyophilized	Pkg. of 6

INSTRUMENTED MYCOBACTERIAL GROWTH SYSTEMS — BD BACTEC™ MGIT™ 960

245122	BACTEC™ MGIT™ Barcoded 7 mL Tube	Ctn. of 100
245124	BACTEC™ MGIT™ 960 Supplement Kit (100 tests)	1 Kit
245123	BACTEC™ MGIT™ 960 SIRE Kit	1 Kit
245126	BACTEC™ MGIT™ 960 Isoniazid 0.4 Kit	1 Kit
245125	BACTEC™ MGIT™ 960 Streptomycin 4.0 Kit	1 Kit
245157	BACTEC™ MGIT™ 960 IR (Isoniazid and Rifampin) Kit	1 Kit
245128	BACTEC™ MGIT™ 960 PZA Drug Kit	1 Kit
245115	BACTEC™ MGIT™ 960 PZA Medium	Ctn. of 25

BD BACTEC™ 9000MB

442187	Myco/F – Sputa	Case of 50
442188	PANTA™/F (50 tests)	1 Kit
442189	Supplement/F (50 tests)	1 Kit

Cat. No.	Description	Quantity	Code

BD BACTEC™ 460TB

442004	12B: Mycobacterial Middlebrook 7H12 Medium	Case of 100
442102	BACTEC™ S.I.R.E. Drug Kit (Anti TB Drugs), 100 tests	1 Kit
442104	Diluting Fluid (10 tests)	1 Kit
442146	Isoniazid	1 Kit
444764	PANTA™ Plus (250 tests)	1 Kit
442139	PZA Test Medium (5 tests)	Pkg. of 10
442143	PZA Drug/Reconstituting Fluid (50 tests)	1 Kit

BD TAXO™ DIFFERENTIATION STRIPS

231741	Taxo™ TB Niacin	1 Cartridge
231742	Taxo™ Nitrate	1 Cartridge
231735	Taxo™ TB Niacin Test Control	1 Cartridge

BD BBL™ SENSI-DISC™ ANTIMYCOBACTERIAL DISCS FOR USE IN CULTURE MEDIA

231575	Ethambutol (Myambutol™), 25 µg	1 Cartridge	EM-25
231576	Ethambutol (Myambutol™), 50 µg	1 Cartridge	EM-50
231577	Ethionamide (Trecator™), 25 µg	1 Cartridge	EA-25
231571	Isoniazid, 1 µg	1 Cartridge	INH-1
231572	Isoniazid, 5 µg	1 Cartridge	INH-5
231573	P-Aminosalicylic Acid, 10 µg	1 Cartridge	PAS-10
231574	P-Aminosalicylic Acid, 50 µg	1 Cartridge	PAS-50
231578	Rifampin, 25 µg	1 Cartridge	RA-25
231570	Streptomycin, 50 µg	1 Cartridge	S-50

[1] The History of Tuberculosis. Available at: http://www.arches.uga.edu/~efletch/history.htm

[2] Stop TB Partnership. History of World TB Day. Available at: http://www.stoptb.org/events/world_tb_day/2002/PPT_Presentation/sld002.htm

[3] Becton, Dickinson and Company. BD History. Available at: http://www.bd.com/aboutbd

[4] World Health Organization. Tuberculosis. Available at: http://www.who.int/tdr/diseases/tb/files/tb-poster.pdf

[5] Kent and Kubica. 1985. Public health mycobacteriology: a guide for the level III laboratory. USDHHHS. Centers for Disease Control, Atlanta. Also, Roberts et al. 1991. Mycobacterium, p.304-339. In Balows et al. (ed.) Manual of clinical microbiology, 5th ed. Am. Soc. Microbiol., Wash., D.C. Also Isenberg, H.D. (ed.) 1992. Clinical microbiology procedures handbook, vol. 1. Am. Soc. Microbiol., Wash., D.C

[6] Tortoli et al. JCM, Vol. 37, No. 3, p. 3578-3582.

[7] Alcaide et al. JCM, Vol. 38, No. 1, p. 398-401.

[8] Hanna et al. JCM, Vol.37, No. 3, p. 748-752.

BD Diagnostics
7 Loveton Circle
Sparks, MD 21152-0999
800.638.8663
www.bd.com/ds

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BD BACTEC™ MGIT™ 960

Susceptibility Testing for *Mycobacterium tuberculosis*

Now with SIRE, PZA and separate IR kit!
NEW capabilities from the automated system that provides the fastest mycobacteria growth and detection.

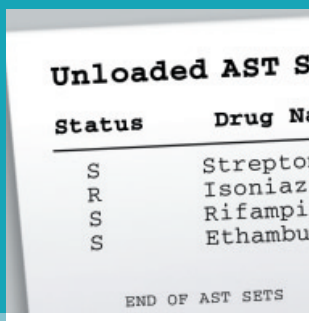
BD
Helping all people live healthy lives

BACTEC™ MGIT™ 960 Susceptibility Testing (AST) features

- **Fully automated** AST reading and **interpretation** of results for consistency and ease of use
- Comparable **performance** to BACTEC™ 460TB system
- **Enhanced safety**:
  - plastic tubes with screw cap
  - no sharps needed for inoculation or further work-up of positive tubes
- **Flexible offering**:
  - full SIRE kit with critical concentrations
  - IR kit for first line testing
  - high concentrations for STR, INH and EMB for profiling in case of resistance to critical concentrations
  - special low pH PZA medium and susceptibility testing kit

Step 1. Inoculate the SIRE set

Step 2. Scan the set into the instrument



Step 3. Remove the set once completed

Step 4. Print the interpretation (S or R) report

BACTEC™ MGIT™ 960 AST Products

To test the critical concentrations :

BACTEC™ MGIT™ 960 SIRE KIT	40 tests	245123
SIRE=streptomycin (1,0 µg/ml), isoniazid (0,1 µg/ml), rifampin (1,0 µg/ml), ethambutol (5,0 µg/ml)		
BACTEC™ MGIT™ 960 IR KIT	40 tests	245157
IR=isoniazid (0,1µg/ml), rifampin (1,0 µg/ml)		

To test the high level concentrations :

BACTEC™ MGIT™ 960 STR 4,0 KIT	20 tests	245125
BACTEC™ MGIT™ 960 INH 0,4 KIT	20 tests	245126
BACTEC™ MGIT™ 960 EMB 7,5 KIT	20 tests	245127

PZA (pyrazinamide Testing) :

BACTEC™ MGIT™ 960 PZA Medium	25 tubes	245115
BACTEC™ MGIT™ 960 PZA Kit	50 tests	245128

BD

Helping all people live healthy lives

BD Diagnostics

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Tel.: (33).4.76.68.36.36
www.bd.com/diagnostics

BD BBL™ MGIT™

Mycobacteria Growth Indicator Tube 7 mL With BD BACTEC™ MGIT™ 960 Supplement Kit

R_x Only CE IVD

L000180JAA(05)
2019-09

INTENDED USE

The BD BBL™ MGIT™ Mycobacteria Growth Indicator Tube supplemented with BD BACTEC™ MGIT™ Growth Supplement and BD BBL™ MGIT™ PANTA™ antibiotic mixture is intended for the detection and recovery of mycobacteria using the BD BACTEC™ MGIT™ 960 and BD BACTEC MGIT 320 Systems. Acceptable specimen types are digested and decontaminated clinical specimens (except urine), and sterile body fluids (except blood).

SUMMARY AND EXPLANATION

From 1985 to 1992, the number of reported cases of infection with *Mycobacterium tuberculosis* (MTB) increased 18%. Tuberculosis still kills an estimated 3 million persons a year worldwide, making it the leading infectious disease cause of death.[1] Between 1981 and 1987, AIDS case surveillances indicated that 5.5% of the patients with AIDS had disseminated nontuberculous mycobacterial infections; e.g., MAC. By 1990, the increased cases of disseminated nontuberculous mycobacterial infections had resulted in a cumulative incidence of 7.6%.[2] In addition to the resurgence of MTB, multidrug-resistant MTB (MDR-TB) has become an increasing concern. Laboratory delays in the growth, identification and reporting of these MDR-TB cases contributed at least in part to the spread of the disease.[3]

The U.S. Centers for Disease Control and Prevention (CDC) have recommended that every effort must be made for laboratories to use the most rapid methods available for diagnostic mycobacteria testing. These recommendations include the use of both a liquid and a solid medium for mycobacterial culture.[3,4]

The MGIT Mycobacteria Growth Indicator Tube contains 7 mL of modified Middlebrook 7H9 Broth base.[5,6] The complete medium, with OADC enrichment and PANTA antibiotic mixture, is one of the most commonly used liquid media for the cultivation of mycobacteria.

All types of clinical specimens, pulmonary as well as extrapulmonary (except blood and urine) can be processed for primary isolation in the MGIT tube using conventional methods.[4] The processed specimen is inoculated into a MGIT tube, placed into the BD BACTEC MGIT instrument for continuous monitoring until positive or the end of the testing protocol.

PRINCIPLES OF THE PROCEDURE

A fluorescent compound is embedded in silicone on the bottom of 16 x 100 mm round bottom tubes. The fluorescent compound is sensitive to the presence of oxygen dissolved in the broth. Initially, the large amount of dissolved oxygen quenches emissions from the compound and little fluorescence can be detected. Later, actively respiring microorganisms consume the oxygen and allow the fluorescence to be detected.

Tubes entered into the BD BACTEC MGIT instrument are continuously incubated at 37 °C and monitored every 60 min for increasing fluorescence. Analysis of the fluorescence is used to determine if the tube is instrument positive; i.e., the test sample contains viable organisms. An instrument positive tube contains approximately 10^5 to 10^6 colony forming units per milliliter (CFU/mL). Culture vials which remain negative for a minimum of 42 days (up to 56 days) and which show no visible signs of positivity are removed from the instrument as negatives and sterilized prior to discarding.

The BD BACTEC MGIT Growth Supplement is added to each MGIT tube to provide substances essential for the rapid growth of mycobacteria. Oleic acid is utilized by tubercle bacteria and plays an important role in the metabolism of mycobacteria. Albumin acts as a protective agent by binding free fatty acids which may be toxic to *Mycobacterium* species, thereby enhancing their recovery. Dextrose is an energy source. Catalase destroys toxic peroxides that may be present in the medium.

Contamination is reduced when supplementing the BD BBL MGIT broth base with BD BACTEC MGIT Growth Supplement/ BD BBL MGIT PANTA antibiotic mixture prior to inoculation with a clinical specimen.

REAGENTS

The BD BBL MGIT Mycobacteria Growth Indicator Tube contains: 110 µL of fluorescent indicator and 7 mL of broth. The indicator contains Tris 4,7-diphenyl-1, 10-phenanthroline ruthenium chloride pentahydrate in a silicone rubber base. The tubes are flushed with 10% CO_2 and capped with polypropylene caps.

Approximate Formula* Per L of Purified Water:

Modified Middlebrook 7H9 Broth base	5.9 g
Casein peptone	1.25 g

BACTEC MGIT Growth Supplement contains 15 mL Middlebrook OADC enrichment.

Approximate Formula* Per L of Purified Water:

Bovine albumin	50.0 g	Catalase	0.03 g
Dextrose	20.0 g	Oleic acid	0.1 g
Polyoxyethylene stearate (POES)	1.1 g		

The BBL MGIT PANTA vial contains a lyophilized mixture of antimicrobial agents.

Approximate Formula* Per Vial Lyophilized PANTA:

Polymyxin B	6,000 units		Trimethoprim	600	µg
Amphotericin B	600 µg		Azlocillin	600	µg
Nalidixic acid	2,400 µg				

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

Storage of Reagents: BD BBL MGIT Mycobacteria Growth Indicator Tubes – On receipt, store at 2–25 °C. DO NOT FREEZE. Minimize exposure to light. Broth should appear clear and colorless. Do not use if turbid. MGIT tubes stored as labeled prior to use may be inoculated up to the expiration date and incubated for up to eight weeks.

BD BACTEC MGIT Growth Supplement – On receipt, store in the dark at 2–8 °C. Avoid freezing or overheating. Do not open until ready to use. Minimize exposure to light.

BD BBL MGIT PANTA Antibiotic Mixture – On receipt, store lyophilized vials at 2–8 °C. Once reconstituted, the PANTA mixture must be stored at 2–8 °C and used within 5 days.

WARNINGS AND PRECAUTIONS:

For *in vitro* Diagnostic Use.

This Product Contains Dry Natural Rubber.

Pathogenic microorganisms, including hepatitis viruses and Human Immunodeficiency Virus, may be present in clinical specimens. "Standard Precautions"[7-10] and institutional guidelines should be followed in handling all items contaminated with blood and other body fluids.

Working with *Mycobacterium tuberculosis* grown in culture requires Biosafety Level 3 practices, containment equipment and facilities.[4]

Prior to use, each MGIT tube should be examined for evidence of contamination or damage. Discard any tubes 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 vial may produce an aerosol of mycobacteria; appropriate handling should be observed.

Autoclave all inoculated MGIT tubes prior to disposal.

SPECIMEN COLLECTION AND HANDLING

All specimens should be collected and transported as recommended by the CDC, the *Clinical Microbiology Procedures Handbook* or your laboratory procedure manual.[11]

DIGESTION, DECONTAMINATION AND CONCENTRATION

Specimens from different body sites should be processed for inoculation of MGIT tubes as follows:

SPUTUM: Specimens should be processed using the NALC-NaOH method as recommended by the CDC's *Public Health Mycobacteriology: A Guide for the Level III Laboratory*.[4] Alternatively, use the BD BBL™ MycoPrep™ kit for processing mycobacterial specimens (see "Availability").

GASTRIC ASPIRATES: Specimens should be decontaminated as for sputum. If the volume of the specimen is more than 10 mL, concentrate by centrifugation. Resuspend the sediment in about 5 mL of sterile water and then decontaminate. Add a small amount of NALC powder (50 to 100 mg) if the specimen is thick or mucoid. After decontamination, concentrate again prior to inoculation into MGIT tube.

BODY FLUIDS: (CSF, synovial fluid, pleural fluid, etc.): Specimens which are collected aseptically and are expected to contain no other bacteria can be inoculated without decontamination. If the specimen volume is more than 10 mL, concentrate by centrifugation at 3,000 x *g* for 15 min. Pour off supernatant fluid. Inoculate MGIT tube with sediment. Specimens that are expected to contain other bacteria must be decontaminated.

TISSUE: Tissue specimens should be processed as recommended by the CDC's *Public Health Mycobacteriology: A Guide for the Level III Laboratory*.[4]

The routine inoculation of solid media is especially important for optimal recovery of mycobacteria from tissue specimens as these specimen types are particularly susceptible to sporadic organism recovery.

STOOL: Suspend 1 g of feces in 5 mL of Middlebrook Broth. Agitate the suspension on a vortex mixer for 5 s. Proceed to the NALC-NaOH procedure as recommended by the CDC's *Public Health Mycobacteriology: A Guide for the Level III Laboratory*.[4]

NOTE: For all specimen processing methods, a phosphate buffer solution (pH 6.8) should be used to QS the sample decontaminant mixture to 50 mL prior to centrifugation. Resuspension of pellet must also be done using a fresh preparation of phosphate buffer solution (pH 6.8).

PROCEDURE

Materials Provided: BD BBL MGIT Mycobacteria Growth Indicator Tubes and BD BACTEC MGIT 960 Supplement Kit, containing BD BACTEC MGIT Growth Supplement and BBL MGIT PANTA Antibiotic Mixture (see "Availability").

Materials Required But Not Provided: Falcon™ brand 50 mL centrifuge tubes, 4% sodium hydroxide, 2.9% sodium citrate solution, N-acetyl-L-cysteine powder, phosphate buffer pH 6.8, vortex mixer, 37 °C incubator, 1 mL sterile pipettes, sterile transfer pipettes, BD BBL Middlebrook and Cohn 7H10 Agar, BD BBL MycoPrep Specimen Digestion / Decontamination Kit, BD BBL Middlebrook 7H9 Broth (see "Availability") or other mycobacterial agars or egg-based media. Tissue homogenizer or sterile swab, BD BBL Normal Saline (see "Availability"), microscope and materials for staining slides, adjustable 1,000 µL pipetter, corresponding sterile pipette tips, 5% sheep blood agar plates and tuberculocidal disinfectant.

INOCULATION OF MGIT TUBES:

BD BBL MGIT 7 mL Tubes must be used with a BD BACTEC MGIT instrument.

1. Reconstitute a lyophilized vial of BD BBL MGIT PANTA Antibiotic Mixture with 15 mL of BD BACTEC MGIT Growth Supplement.
2. Label the MGIT tube with the specimen number.
3. Unscrew the cap and aseptically add 0.8 mL of Growth Supplement/ BD BBL MGIT PANTA Antibiotic Mixture. For best results, the addition of Growth Supplement/ BD BBL MGIT PANTA Antibiotic Mixture should be made just prior to specimen inoculation.
4. Add 0.5 mL of the concentrated specimen suspension prepared above. Also add a drop (0.1 mL) of specimen to a 7H10 agar plate or other mycobacterial solid agar or egg-based medium.
5. Tightly recap the tube and mix well.
6. Tubes entered into the instrument will be automatically tested for the duration of the recommended 42 day testing protocol.

   For specimens in which mycobacteria with different incubation requirements are suspected, a duplicate MGIT tube can be set up and incubated at the appropriate temperature; e.g., 30 or 42 °C.[13] Inoculate and incubate at the required temperature. These tubes must be manually read (refer to the BD BACTEC MGIT Instrument *User's Manual*).

   For specimens suspected of containing *Mycobacterium haemophilum*, a source of hemin must be introduced into the tube at the time of inoculation and the tube incubated at 30 °C. These tubes must be manually read (refer to the BD BACTEC MGIT Instrument *User's Manual*).
7. Positive tubes, identified by the BD BACTEC MGIT instrument should be subcultured and an acid-fast smear prepared (see "Results").

All quality control testing, reprocessing, smear preparations, sub-culturing, etc., of presumptive positive tubes must be performed using bio-safety level (BSL) III practices and containment facilities.

Processing a Positive MGIT Tube: NOTE – All steps should be performed in a biological safety cabinet.

1. Remove the MGIT tube from the instrument and transport to an area using BSL III practices and containment facilities.
2. Using a sterile transfer pipet, remove an aliquot from the bottom of the tube (approx. 0.1 mL) for stain preparations (AFB and Gram stains).
3. Inspect smear and preparations. Report preliminary results only after acid-fast smear evaluation.

At the end of six weeks incubation, perform a visual check of all instrument negative tubes. If the tube appears visually positive (i.e., non-homogenous turbidity, small grains or clumps) it should be subcultured, acid-fast stained and treated as a presumptive positive, provided the acid-fast smear result is positive. If the tube shows no signs of positivity, it should be sterilized prior to discarding.

Reprocessing Contaminated MGIT tubes: Contaminated MGIT tubes may be re-decontaminated and re-concentrated using the procedure in Appendix E - Supplemental Procedures of the BD BACTEC MGIT Instrument *User's Manual*.

User Quality Control: Quality control requirements must be performed in accordance with applicable local, state and/or federal regulations or accreditation requirements and your laboratory's standard Quality Control procedures. It is recommended that the user refer to pertinent CLSI guidance and CLIA regulations for appropriate Quality Control practices.

Quality Control Certificates are provided on the BD website. Quality Control Certificates list test organisms, including ATCC® cultures specified in the CLSI Approved Standard M22-A3, *Quality Control for Commercially Prepared Microbiological Culture Media*.[12]

NOTE: Middlebrook 7H9 Broth (supplemented) is exempt from User QC testing according to CLSI M22-A3.[12]

RESULTS

An instrument-positive sample is determined by the BD BACTEC MGIT instrument and confirmed by an acid-fast smear.

REPORTING OF RESULTS

An instrument positive tube must be confirmed by acid-fast smear. A positive AFB smear result indicates the presence of mycobacteria.

If AFB smear positive, subculture to solid media and report as: Instrument positive, AFB smear positive, ID pending.

If microorganisms other than AFB are present report as: Instrument positive, AFB smear negative. Contaminated.

If no microorganisms are present: Reenter the tube into the instrument as an ongoing negative tube within 5 h of removal. Allow tube to complete test protocol. No reportable result.

Perform subculture from the BD BBL MGIT tube for identification and drug susceptibility testing.

LIMITATIONS OF THE PROCEDURE

Recovery of mycobacteria in the MGIT tube is dependent on the number of organisms present in the specimen, specimen collection methods, patient factors such as presence of symptoms, prior treatment and the methods of processing.

Decontamination with the N-acetyl-L-cysteine Sodium hydroxide (NALC-NaOH) method is recommended. Other decontamination methods have not been tested in conjunction with the BD BBL MGIT medium. Digestant/decontaminant solutions may have harmful effects on mycobacteria.

Colony morphology and pigmentation can only be determined on solid media. Mycobacteria may vary in acid-fastness depending on strain, age of culture and other variables. The consistency of microscopic morphology in BD BBL MGIT medium has not been established.

An AFB smear-positive MGIT tube can be subcultured, to both selective and nonselective mycobacterial media, for isolation to perform identification and susceptibility testing.

MGIT tubes which are instrument-positive may contain other non-mycobacterial species. Non-mycobacterial species may overgrow mycobacteria present. Such MGIT tubes should be re-decontaminated and re-cultured (refer to the BD BACTEC MGIT Instrument *User's Manual*). Reprocessing is strongly recommended if the original specimen source cannot be easily recollected; e.g. tissue specimen.

MGIT tubes which are instrument-positive may contain one or more species of mycobacteria. Faster growing mycobacteria may be detected prior to slower growing mycobacteria; therefore, it is important to subculture positive MGIT tubes to ensure proper identification of all mycobacteria present in the sample.

Due to the richness of the MGIT broth and to the non-selective nature of the MGIT indicator, it is important to follow the stated digestion/decontamination procedure to reduce the possibility of contamination. Adherence to procedural instructions, which includes use of recommended inoculum volume (0.5 mL), is critical for optimum recovery of mycobacteria.

The use of PANTA antibiotic mixture, although necessary for all non-sterile specimens, may have inhibitory effects on some mycobacteria.

Seeded culture studies were performed with twenty-four species (ATCC and wild strains) of mycobacteria using inoculum levels ranging from 10^1 to 10^2 CFU/mL. The following species were detected as positive in the BD BACTEC MGIT 960 System:

*M. avium**	*M. gordonae**	*M. nonchromogenicum*	*M. terrae*
M. abscessus	*M. haemophilum*†	*M. phlei*	*M. trivale*
M. bovis	*M. intracellulare*	*M. simiae**	*M. tuberculosis**
M. celatum	*M. kansasii**	*M. scrofulaceum*	*M. xenopi**
*M. fortuitum**	*M. malmoense*	*M. smegmatis*	
M. gastri	*M. marinum*	*M. szulgai**	

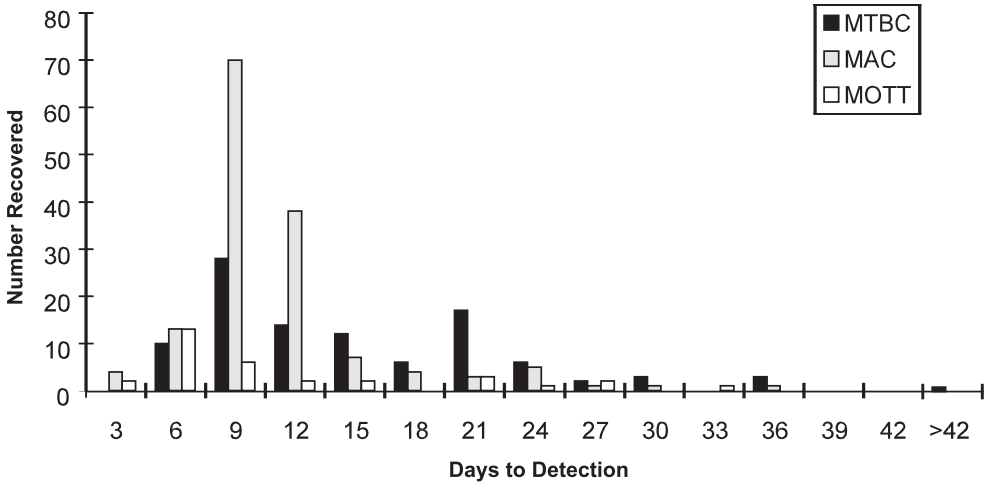
*Species recovered during clinical evaluation of the BACTEC MGIT 960 System. In addition, *M. mucogenicum* was recovered at one of the clinical sites.

†The *M. haemophilum* was recovered using the addition of a source of hemin to the MGIT tube prior to inoculation.

Clinical studies have demonstrated recovery of mycobacteria from respiratory specimens, gastric aspirates, tissue, stool and sterile body fluids except blood; recovery of mycobacteria from other body fluids has not been established for this product.

EXPECTED VALUES

Figure 1 – Frequency distribution of recovery times for clinical trial specimens positive in the BD BACTEC MGIT 960 System



PERFORMANCE CHARACTERISTICS

The BD BACTEC MGIT 960 System was evaluated at six clinical sites including one non-US site, which represented public health laboratories as well as large acute care hospitals in geographically diverse areas. The site population included patients infected with HIV, immunocompromised patients and transplant patients. The BD BACTEC MGIT 960 System was compared to the BD BACTEC 460TB radiometric system and conventional solid growth media for the detection and recovery of mycobacteria from clinical specimens, except blood. A total of 3,330 specimens were tested during the study. A total of 353 specimens were positive which represented 362 isolates recovered during the study. The distribution of positives by specimen type is: respiratory (90%), tissue (7%), body fluids (1%), stool (0.85%) and bone marrow (0.65%). Of the 362 isolates, 289 (80%) were recovered by the BD BACTEC MGIT 960 System, 271 (75%) were recovered by the BD BACTEC 460TB System and 250 (69%) were recovered by conventional solid media. Of the 3,330 specimens tested in the clinical study, 27 (0.8%) MGIT 960 tubes were determined to be false positive (instrument-positive, smear and/or subculture-negative). Of the 313 MGIT 960 instrument positive tubes, 27 (8.6%) were determined to be false positive. The false negative rate (instrument-negative, smear and/or subculture-positive) was determined to be 0.5% based on terminal subcultures of 15% of instrument negative vials. The average breakthrough contamination rate for the BD BACTEC MGIT 960 System was 8.1% with a range of 1.8–14.6%.

Table 1: Detection of Mycobacteria Positive Isolates in Clinical Evaluations

Isolates	Total isolates	Total MGIT 960	MGIT Only	Total BD BACTEC 460TB	BD BACTEC 460TB Only	Total CONV	CONV Only
MTB	132	102	4	119	11	105	3
MAC	172	147	36	123	12	106	3
M. asiaticum	1	0	0	0	0	1	1
M. fortuitum/chelonae	22	18	6	13	1	15	1
M. genavense	1	0	0	1	0	1	0
M. kansasii	5	5	1	4	0	4	0
M. malmoense	1	0	0	1	0	1	0
M. marinum	1	0	0	0	0	1	1
M. mucogenicum	1	1	1	0	0	0	0
M. simiae	1	1	0	1	0	1	0
M. szulgai	2	2	0	2	0	2	0
M. xenopi	2	2	1	1	0	0	0
MOTT	2	1	1	1	1	0	0
Mycobacteria spp.	2	2	1	1	0	1	0
M. gordonae	11	6	3	3	2	6	3
M. nonchromogenicum	6	2	0	1	0	6	4
All MYCO	362	289	54	271	27	250	16

AVAILABILITY

Cat. No.	Description
245122	BD BBL™ MGIT™ Mycobacteria Growth Indicator Tubes, 7 mL, carton of 100 tubes.
245124	BD BACTEC™ MGIT™ 960 Supplement Kit, 6 vials, 15 mL, BD BACTEC™ MGIT™ Growth Supplement and 6 vials, lyophilized, BD BBL™ MGIT™ PANTA™ Antibiotic Mixture. Each Growth Supplement/BD PANTA™ vial sufficient for 15–18 BD MGIT™ tubes.
220908	BD BBL™ Lowenstein-Jensen Medium Slants, package of 10 (20 x 148 mm tubes with cap).
220909	BD BBL™ Lowenstein-Jensen Medium Slants, carton of 100 (20 x 148 mm tubes with cap).
240862	BD BBL™ MycoPrep™ Specimen Digestion/Decontamination Kit, ten 75 mL bottles of NALC-NaOH solution and 5 packages of phosphate buffer.
240863	BD BBL™ MycoPrep™ Specimen Digestion/Decontamination Kit, ten 150 mL bottles of NALC-NaOH solution and 10 packages of phosphate buffer.
221174	BD BBL™ Middlebrook and Cohn 7H10 Agar, package of 20.
221819	BD BBL™ Normal Saline, 5 mL, carton of 100.

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

Change History

Revision	Date	Change Summary
(05)	2019-09	Converted printed instructions for use to electronic format and added access information to obtain the document from BD.com/e-labeling.

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

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AAAA-KK-PP / AAAA-KK (KK = kuu lõpp)
AAAA-MM-JJ / AAAA-MM (MM = fin du mois)
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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)
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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）

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Lower limit of temperature / Долен лимит на температурата / Dolní hranice teploty / Nedre temperaturgrænse / Temperaturuntergrenze / Κατώτερο όριο θερμοκρασίας / Límite inferior de temperatura / Alumine temperatuuripiir / Limite inférieure de température / Najniža dozvoljena temperatura / Alsó hőmérsékleti határ / Limite inferiore di temperatura / Температураның төменгі руқсат шеri / 하한 온도 / Žemiausia laikymo temperatūra / Temperatūras zemākā robeža / Laagste temperatuurlimiet / Nedre temperaturgrense / Dolna granica temperatury / Limite mínimo de temperatura / Limită minimă de temperatură / Нижний предел температуры / Spodná hranica teploty / Donja granica temperature / Nedre temperaturgräns / Sıcaklık alt sınırı / Мінімальна температура / 温度下限

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

CONTROL + Positive control / Положителен контрол / Pozitivní kontrola / Positiv kontrol / Positive Kontrolle / Θετικός μάρτυρας / Control positivo / Positiivne kontroll / Contrôle positif / Pozitivna kontrola / Pozitív kontroll / Controllo positivo / Оң бақылау / 양성 컨트롤 / Teigiama kontrolė / Pozitīvā kontrole / Positieve controle / Kontrola dodatnia / Controlo positivo / Control pozitiv / Положительный контроль / Pozitif kontrol / Позитивний контроль / 阳性对照试剂

CONTROL – Negative control / Отрицателен контрол / Negativní kontrola / Negativ kontrol / Negative Kontrolle / Αρνητικός μάρτυρας / Control negativo / Negatiivne kontroll / Contrôle négatif / Negativna kontrola / Negatív kontroll / Controllo negativo / Негативтік бақылау / 음성 컨트롤 / Neigiama kontrolė / Negatīvā kontrole / Negatieve controle / Kontrola ujemna / Controlo negativo / Control negativ / Отрицательный контроль / Negatif kontrol / Негативний контроль / 阴性对照试剂

STERILE EO Method of sterilization: ethylene oxide / Метод на стерилизация: етиленов оксид / Způsob sterilizace: etylenoxid / Steriliseringsmetode: ethylenoxid / Sterilisationsmethode: Ethylenoxid / Μέθοδος αποστείρωσης: αιθυλενοξείδιο / Método de esterilización: óxido de etileno / Steriliseerimismeetod: etüleenoksiid / Méthode de stérilisation : oxyde d'éthylène / Metoda sterilizacije: etilen oksid / Sterilizálás módszere: etilén-oxid / Metodo di sterilizzazione: ossido di etilene / Стерилизация әдici – этилен тотығы / 소독 방법: 에틸렌옥사이드 / Sterilizavimo būdas: etileno oksidas / Sterilizēšanas metode: etilēnoksīds / Gesteriliseerd met behulp van ethyleenoxide / Steriliseringsmetode: etylenoksid / Metoda sterylizacji: tlenek etylu / Método de esterilização: óxido de etileno / Metodă de sterilizare: oxid de etilenă / Метод стерилизации: этиленоксид / Metóda sterilizácie: etylénoxid / Metoda sterilizacije: etilen oksid / Steriliseringsmetod: etenoxid / Sterilizasyon yöntemi: etilen oksit / Метод стерилізації: етиленоксидом / 灭菌方法：环氧乙烷

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

Biological Risks / Биологични рискове / Biologická rizika / Biologisk fare / Biogefährdung / Βιολογικοί κίνδυνοι / Riesgos biológicos / Bioloogilised riskid / Risques biologiques / Biološki rizik / Biológiailag veszélyes / Rischio biologico / Биологиялық тәуекелдер / 생물학적 위험 / Biologinis pavojus / Bioloģiskie riski / Biologisch risico / Biologisk risiko / Zagrożenia biologiczne / Perigo biológico / Riscuri biologice / Биологическая опасность / Biologické riziko / Biološki rizici / Biologisk risk / Biyolojik Riskler / Біологічна небезпека / 生物学风险

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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

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

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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 / Кесіңіз / 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/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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