

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Becton Dickinson Distribution
Center NV
Laagstraat 57
B-9140 Temse
Belgium

Holds Certificate Number:

MD 611845

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

Handling, Packaging, Storage, Distribution and Transportation of Medical Devices, In Vitro Diagnostic Devices, Reagents, Equipment and Accessories, manufactured by Becton Dickinson and Company World Wide Businesses.



For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2014-05-13

Latest Revision Date: 2020-04-15

Effective Date: 2020-05-13

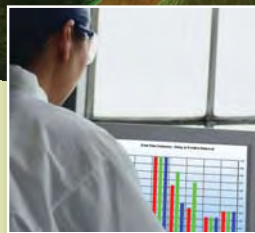
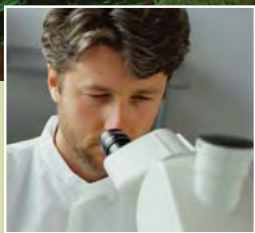
Expiry Date: 2023-05-12

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...making excellence a habit.™



Mycobacteria Diagnosis

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

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



Helping all people
live healthy lives

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-aminosalicylic 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 1998 2003 2004 2006 2007 2008

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

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.



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.

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.

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.

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.

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

Acid Fast and Fluorescent Stains

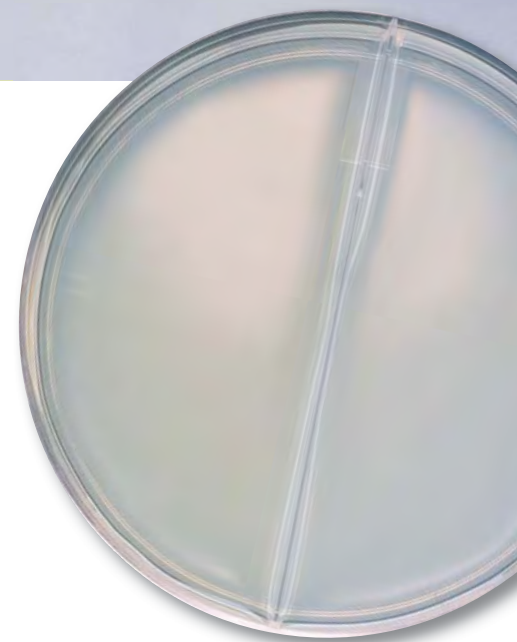
BD (Difco™ and BBL™) stains offer clear and distinct options for acid fast bacilli staining in the most advanced and complete methodologies. Each ready-to-use kit comes in a compact tray that doubles as a work station (stains are also available in 250 mL individual bottles). Bottles feature a hinged,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



CULTURE

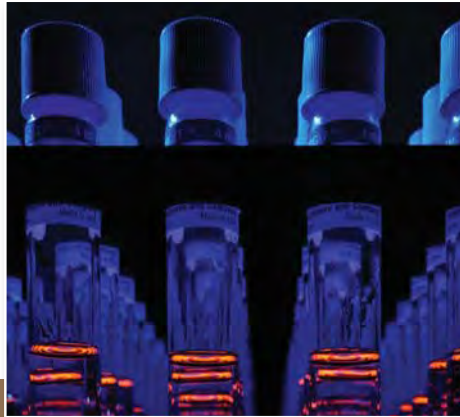
BD Solid Media Choices

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 mycobacteria, plus tight-fitting, rubber-lined screw tops prevent leakage and moisture loss.



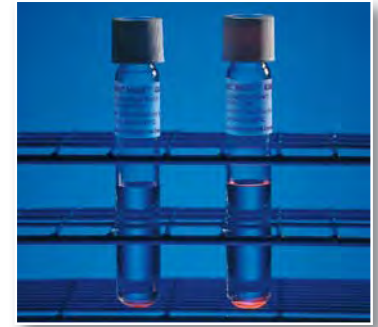
CULTURE: MANUAL MYCOBACTERIAL GROWTH SYSTEM

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 O₂ consumption without sharps.



SUSCEPTIBILITY

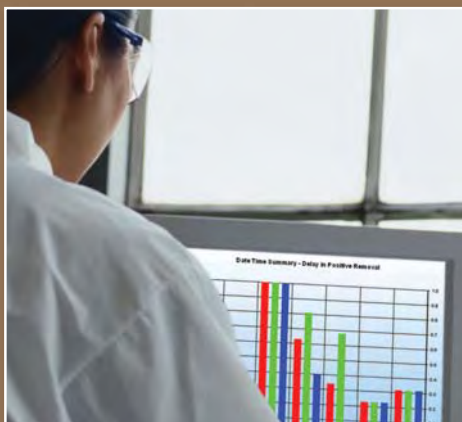
BD BACTEC™ MGIT™ 960 SIRE AND PZA Susceptibility Testing

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 Carbofuchsin and TB Quick Stain Methylene Blue.....	1 Each
212522	TB Stain Kit K 1 250 mL bottle each of TB Carbofuchsin 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 Carbofuchsin 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 Deepes (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
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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
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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



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www.bd.com/ds

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. USDHHS. 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.

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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.



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

Unloaded AST S	
Status	Drug Na
S	Strepto
R	Isoniaz
S	Rifampi
S	Ethambu
END OF AST SETS	

■ **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



Helping all people
live healthy lives

BD Diagnostics

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