

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

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

Acid Fast and Fluorescent Stains

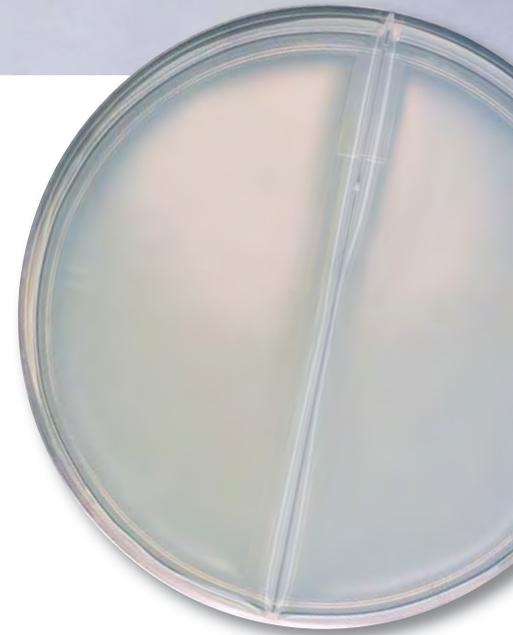
BD (Difco™ and BBL™) stains offer clear and distinct options for acid fast bacilli staining in the most advanced and complete methodologies. Each ready-to-use kit comes in a compact tray that doubles as a work station (stains are also available in 250 mL individual bottles). Bottles feature a hinged,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



CULTURE

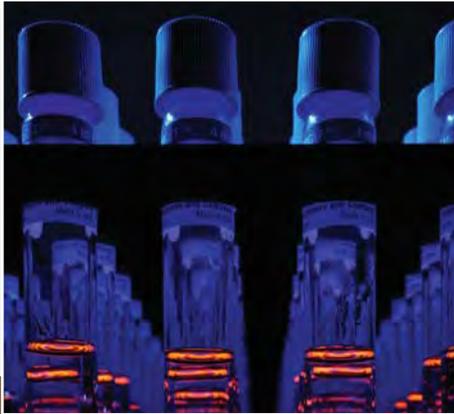
BD Solid Media Choices

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.



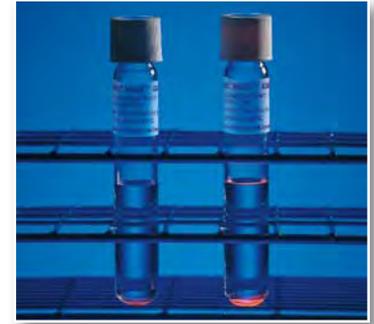
CULTURE: MANUAL MYCOBACTERIAL GROWTH SYSTEM

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

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



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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.