BD BBL MGIT

Mycobacteria Growth Indicator Tube 7 mL

Cu BACTEC MGIT 960 Supplement Kit

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UTILIZARE SPECIFICĂ

Flaconul **BBL MGIT** Mycobacteria Growth Indicator Tube suplimentat cu **BACTEC MGIT** Growth Supplement şi **BBL MGIT PANTA** antibiotic mixture este destinat detectării şi recuperării micobacteriilor cu ajutorul sistemelor **BACTEC MGIT** 960 şi **BACTEC MGIT** 320. Tipurile de probe acceptate sunt probe clinice extrase şi decontaminate (cu excepţia urinei) şi lichide biologice sterile (cu excepţia sângelui).

REZUMAT ŞI EXPLICAŢII

În perioada 1985-1992, numărul de cazuri de infecţie cu *Mycobacterium tuberculosis* (MTB) raportate au crescut cu 18%. Tuberculoza încă ucide aproximativ 3 milioane de oameni pe an în întreaga lume, fiind boala infecţioasă care determină cele mai multe decese.[1] Între 1981 şi 1987, studiile făcute pe pacienţi cu SIDA au arătat că 5,5% dintre aceştia au infecţii micobacteriene netuberculoase; adică, MAC. Până în 1990, creşterea numărului de cazuri de infecţie micobacteriană netuberculoasă diseminată a rezultat într-o incidenţă cumulată de 7,6%.[2] Pe lângă recrudescenţa MTB, MTB multirezistentă la medicamente (MDR-TB) a devenit un motiv serios de îngrijorare. Întârzierile laboratoarelor în creşterea culturilor, identificarea şi raportarea cazurilor de MDR-TB au contribuit, cel puţin în parte, la răspândirea bolii.[3]

Centrele de control şi prevenire a bolilor (CDC), din S.U.A., au recomandat depunerea oricărui efort din partea laboratoarelor pentru a utiliza cele mai rapide metode disponibile pentru diagnosticarea micobacteriilor. Aceste recomandări includ folosirea atât a mediilor lichide cât şi a celor solide pentru cultura micobacteriilor.[3,4]

Flaconul **MGIT** Mycobacteria Growth Indicator Tube conţine 7 mL de bază de bulion modificat Middlebrook 7H9.[5,6] Mediul complet, îmbogaţit cu OADC, şi amestecul antibiotic **PANTA**, este unul dintre cele mai folosite medii lichide de cultură pentru micobacterii.

Toate tipurile de specimene clinice, pulmonare şi extrapulmonare, (cu excepţia sângelui şi a urinei) pot fi procesate pentru izolare primară în flaconul **MGIT** folosind metode convenţionale.[4] Proba procesată este inoculată într-un flacon **MGIT**, plasat în instrumentul **BACTEC MGIT** pentru monitorizare continuă până la pozitivare sau până la încheierea protocolului de testare.

PRINCIPIILE PROCEDURII

Un compus fluorescent este înglobat în silicon pe fundul flacoanelor cu fund rotund de 16 x 100 mm. Compusul fluorescent este sensibil la prezenţa oxigenului dizolvat în bulion. Concentraţia iniţială a oxigenului dizolvat reprimă degajarea din compus, putând fi astfel observată o mică fluorescenţă. Mai târziu, microorganismele care respiră activ consumă oxigenul şi permit detectarea fluorescenţei.

Flacoanele introduse în instrumentul **BACTEC MGIT** sunt incubate continuu la 37 °C şi monitorizate pentru creşterea fluorescenţei la fiecare 60 de minute. Analizarea fluorescenţei este folosită pentru a determina dacă flaconul este pozitiv conform criteriilor dispozitivului, adică dacă mostrele testate conţin organisme viabile. Un flacon pozitiv în dispozitiv conţine aproximativ 10^5 până la 10^6 unităţi formatoare de colonii pe mililitru (UFC/mL). Fiolele de cultură care rămân negative minim 42 de zile (până la 56 de zile) şi care nu prezintă nici un semn vizibil de pozitivare sunt scoase din dispozitiv fiind considerate negative şi se sterilizează înainte de a fi aruncate.

BACTEC MGIT Growth Supplement este adăugat în fiecare flacon **MGIT** pentru a asigura substanţe esenţiale pentru creşterea rapidă a micobacteriilor. Acidul oleic este utilizat de bacteriile tuberculoase şi joacă un rol important în metabolismul micobacteriilor. Albumina acţionează ca un agent protector prin legarea acizilor graşi liberi ce ar putea fi toxici pentru speciile de *Mycobacterium*, potenţând astfel recuperarea lor. Dextroza este o sursă de energie. Catalaza distruge peroxizii toxici ce ar putea fi prezenţi în mediu.

Contaminarea se reduce prin suplimentarea bazei de bulion **BBL MGIT** cu **BACTEC MGIT** Growth Supplement/**BBL MGIT PANTA** antibiotic mixture înainte de inocularea cu o probă clinică.

REACTIVI

BBL MGIT Mycobacteria Growth Indicator Tube conţine: 110 µL de indicator fluorescent şi 7 mL de bulion. Indicatorul conţine pentahidrat clorură de ruteniu tri 4, 7-difenil-1, 10-fenantrolină într-o bază de latex siliconat. Flacoanele sunt curaţate cu $CO_2$10% şi acoperite cu capace de polipropilenă.

Formula* aproximativă pentru un L de apă purificată:

Bază de bulion Middlebrook 7H9 modificat	5,9 g
Peptonă de cazeină	1,25 g

BACTEC MGIT Growth Supplement conţine 15 mL de agent de îmbogăţire Middlebrook OADC

Formula* aproximativă pentru un L de apă purificată:

Albumină bovină	50,0 g	Catalază	0,03 g
Dextroză	20,0 g	Acid oleic	0,1 g
Stearat de polioxietilenă (POES)	1,1 g		

Fiola de **BBL MGIT PANTA** conţine un amestec liofilizat de agenţi antimicrobieni.

Formula* aproximativă pentru o fiolă liofilizată **PANTA**:

Polimixină B	6,000 unităţ	Trimetoprim	600 µg
Amfotericină B	600 µg	Azlocilină	600 µg
Acid nalidixic	2,400 µg		

**Ajustată şi/sau suplimentată după cum este necesar pentru a îndeplini criteriile de performanţă.*

Depozitarea reactivilor: BBL MGIT Mycobacteria Growth Indicator Tubes – La recepţie, depozitaţi-le la 2 – 25 °C. NU

CONGELAȚI. Reduceți la minim expunerea la lumină. Bulionul trebuie să fie clar și incolor. Nu îl utilizați dacă este tulbure. Flacoanele **MGIT** păstrate conform etichetei înainte de a fi folosite, pot fi inoculate până la termenul de expirare și incubate până la opt săptămâni.

BACTEC MGIT Growth Supplement – La recepție, trebuie depozitat la întuneric la 2 – 8 °C. Evitați congelarea sau supraîncălzirea. Deschideți numai înainte de utilizare. Reduceți la minim expunerea la lumină.

BBL MGIT PANTA Antibiotic Mixture – La recepție, depozitați fiolele liofilizate la 2 – 8 °C. După reconstituirea amestecului **PANTA**, acesta trebuie depozitat la 2 – 8 °C și utilizat în maxim 5 zile.

AVERTISMENTE ȘI PRECAUȚII

În scopul diagnosticului *in vitro*.

Acest produs conține cauciuc natural uscat.

În probele clinice pot fi prezente microorganisme patogene, inclusiv virusurile hepatitice și virusul imunodeficienței umane. La manevrarea tuturor elementelor contaminate cu sânge și alte lichide biologice trebuie respectate „Precauțiile standard”[7-10] și regulamentul instituției.

Lucrul cu *Mycobacterium tuberculosis* crescut în cultură necesită practici conforme cu nivelul de securitate biologică 3, echipament de izolare și facilități.[4]

Înainte de utilizare, fiecare flacon **MGIT** trebuie verificat pentru a descoperi eventualele semne de contaminare sau deteriorare. Înlăturați toate flacoanele sau fiolele care par necorespunzătoare.

Flacoanele scăpate trebuie examinate cu atenție. Dacă se observă deteriorări, flaconul trebuie înlăturat.

În eventualitatea spargerii unui flacon: 1) Închideți sertarele instrumentului; 2) Opriți instrumentul; 3) Părăsiți imediat zona; 4) Consultați regulamentul CDC sau al unității dumneavoastră. Scurgerea unui inocul sau spargerea unei fiole poate produce aerosoli cu micobacterii; trebuie adoptate măsuri corespunzătoare.

Înainte de a fi înlăturate, autoclavați toate flacoanele **MGIT** inoculate.

COLECTAREA ȘI MANIPULAREA PROBELOR

Toate probele trebuie colectate și transportate conform recomandărilor CDC, *Clinical Microbiology Procedures Handbook* sau manualului de proceduri al laboratorului dumneavoastră.[11]

EXTRACȚIA, DECONTAMINAREA ȘI CONCENTRAREA

Probe din diferite părți ale corpului trebuie pregătite pentru inocularea flacoanelor **MGIT** după cum urmează:

SPUTA: Probele trebuie pregătite folosind metoda NALC-NaOH după recomandărilor CDC din *Public Health Mycobacteriology: A Guide for the Level III Laboratory*.[4] Ca alternativă folosiți kitul **BBL MycoPrep** pentru procesarea probelor micobacteriene (consultați „Disponibilitate”).

ASPIRATUL GASTRIC: Probele trebuie decontaminate la fel ca sputa. Dacă volumul probei este mai mare de 10 mL, se va concentra prin centrifugare. Treceți din nou sedimentul în aproximativ 5 mL de apă sterilă și apoi decontaminați. Adăugați o cantitate mică de pudră NALC (50 până la 100 mg) dacă proba este densă sau mucoidă. După decontaminare, concentrați din nou înaintea inoculării în flaconul **MGIT**.

LICHIDE BIOLOGICE: (LCR, lichid sinovial, lichid pleural etc.): Probele colectate aseptic și despre care se presupune că nu conțin alte bacterii pot fi inoculate fără decontaminare. Dacă volumul probelor este mai mare de 10 mL, concentrați prin centrifugare la 3.000 x *g* timp de 15 min. Vărsați supernatantul. Inoculați flaconul **MGIT** cu sediment. Probele care pot conține alte bacterii trebuie decontaminate.

ȚESUT: Probele de țesut trebuie pregătite după recomandărilor CDC din *Public Health Mycobacteriology: A Guide for the Level III Laboratory*.[4]

Inocularea de rutină pe medii solide este în mod special importantă pentru recuperarea optimă a micobacteriilor din probele de țesut, deoarece aceste tipuri de probe sunt sensibile în mod deosebit la o recuperare sporadică a organismelor.

MATERII FECALE: Suspendați 1 g de fecale în 5 mL de bulion Middlebrook. Agitați suspensia timp de 5 s cu ajutorul unui mixer prin rotație. Continuați cu procedura NALC-NaOH conform recomandărilor CDC din *Public Health Mycobacteriology: A Guide for the Level III Laboratory*.[4]

NOTĂ: Pentru toate metodele de pregătire a probelor, trebuie utilizată o soluție fosfat tampon (pH 6,8) pentru a completa amestecul decontaminant până la 50 mL înaintea centrifugării. Refacerea suspensiei de granule trebuie de asemenea făcută folosind o soluție fosfat tampon proaspătă (pH 6,8).

PROCEDURĂ

Materiale furnizate: BBL MGIT Mycobacteria Growth Indicator Tubes și **BACTEC MGIT** 960 Supplement Kit, conținând **BACTEC MGIT** Growth Supplement și **BBL MGIT PANTA** Antibiotic Mixture (consultați „Disponibilitate”).

Materiale necesare dar nefurnizate: Flacoane pentru centrifugă marca **Falcon** de 50 mL, soluție 4% hidroxid de sodiu, soluție 2,9% citrat de sodiu, pudră N-acetil-L-cisteină, fosfat tampon pH 6,8, mixer cu mișcare rotațională, incubator pentru 37 °C, pipete sterile de 1 mL, pipete de transfer sterile, agar **BBL** Middlebrook și Cohn 7H10, kit pentru extragerea / decontaminarea probelor **BBL MycoPrep** , bulion **BBL** Middlebrook 7H9 (consultați „Disponibilitate”) sau alte medii pentru micobacterii pe bază de agar sau ou. Omogenizator de țesut sau tampon steril, **BBL** Normal Saline (consultați „Disponibilitate”), microscop și materiale pentru colorarea lamelor, pipetă ajustabilă de 1000 µL, vârfuri sterile de pipetă corespunzătoare, plăci cu agar cu 5% sânge de oaie și dezinfectant tuberculocid.

INOCULAREA FLACOANELOR MGIT:

Flacoanele **BBL MGIT** de 7 mL trebuie utilizate cu un instrument **BACTEC MGIT**.

1. Reconstituiți o fiolă liofilizată de **BBL MGIT PANTA** Antibiotic Mixture cu 15 mL de **BACTEC MGIT** Growth Supplement.
2. Etichetați flaconul **MGIT** cu numărul probei.
3. Deșurubați capacul și adăugați, în condiții de asepsie, 0,8 mL de supliment de creștere/**MGIT PANTA** Antibiotic Mixture. Pentru a obține cele mai bune rezultate, adăugarea suplimentului de creștere/**MGIT PANTA** Antibiotic Mixture trebuie făcută chiar înaintea inoculării probei.

4. Adăugaţi 0,5 mL din suspensia concentrată a probei pregătită anterior. De asemenea adăugaţi o picătură (0,1 mL) din probă pe o placă de agar 7H10 sau pe orice alt mediu solid pe bază de agar sau ou.
5. Închideţi bine flaconul şi amestecaţi bine.
6. Flacoanele introduse în instrument vor fi testate automat pe toată durata desfăşurării protocolului de testare recomandat de 42 de zile.

   Pentru probele în care sunt suspectate micobacterii cu cerinţe de incubare diferite, un flacon duplicat **MGIT** poate fi pregătit şi incubat la temperatura corespunzătoare; de exemplu: 30 sau 42 °C. Inoculaţi şi incubaţi la temperatura corespunzătoare. Aceste flacoane trebuie interpretate manual (consultaţi *Manualul utilizatorului* pentru instrumentul **BACTEC MGIT**).

   Pentru probele suspectate a conţine *Mycobacterium haemophilum*, o sursă de hemoglobină trebuie introdusă în flacon în momentul inoculării, iar incubarea trebuie făcută la 30 °C. Plasaţi în condiţii aseptice o bandă cu factor X **BBL Taxo** în fiecare flacon **MGIT** ce are nevoie de adăugarea de hemoglobină înaintea inoculării probei (consultaţi „Disponibilitate”). Aceste flacoane trebuie interpretate manual (consultaţi *Manualul utilizatorului* pentru instrumentul **BACTEC MGIT**).
7. Flacoanele pozitive, identificate de instrumentul **BACTEC MGIT** trebuie recultivate şi trebuie pregătit un frotiu acido-rezistent (consultaţi „Rezultate”).

Toate testele de control de calitate, reprocesările, pregătirile frotiurilor, recultivarea, etc., flacoanelor probabil pozitive trebuie realizate folosind tehnici conforme nivelului de bio–securitate (BSL) III şi facilităţi de carantină.

Prelucrarea unui flacon MGIT pozitiv: NOTĂ - Toate etapele trebuie realizate într-o boxă sigură din punct de vedere biologic.

1. Scoateţi flaconul **MGIT**din instrument şi transportaţi-l într-o arie ce respectă standardele BSL III în ceea ce priveşte modul de lucru şi facilităţile de carantină.
2. Utilizând o pipetă de transfer sterilă, scoateţi o alicotă de pe fundul flaconului (aprox. 0,1 mL) pentru pregătirea coloraţiilor (AFB şi Gram).
3. Examinaţi frotiul şi pregătirile. Raportaţi rezultatele preliminare numai după evaluarea frotiului acido-rezistent.

La sfârşitul a şase săptămâni de incubaţie inspectaţi vizual toate flacoanele negative în instrument. Dacă tuburile par vizual pozitive (adică turbiditate neomogenă, mici granule sau aglomerări) ar trebui recultivate, colorate acido-rezistent şi tratate ca presupuse pozitive, doar dacă rezultatul frotiului acido-rezistent este pozitiv. Dacă flacoanele nu prezintă nici un semn pozitiv, ele trebuie sterilizate înainte de a fi aruncate.

Reprelucrarea flacoanelor MGIT contaminate: Flacoanele **MGIT** contaminate pot fi re-decontaminate şi reconcentrate folosind procedura din Anexa E - proceduri suplimentare din *Manualul utilizatorului* pentru instrumentul **BACTEC MGIT**.

Controlul calităţii efectuat de utilizator: Cerinţele controlului de calitate trebuie realizate conform reglementărilor aplicate local, naţional şi/sau federal sau cerinţelor de acreditare şi procedurilor de laborator standard pentru controlul calităţii. Se recomandă ca utilizatorul să apeleze la ghidurile adecvate CLSI şi reglementările CLIA pentru tehnici adecvate ale controlului calităţii.

Certificate de control al calităţii sunt furnizate pe site-ul Web BD. Certificatele de control al calităţii enumeră organismele pentru testare, inclusiv culturile ATCC specificate în Standardul aprobat de CLSI M22-A3, *Quality Control for Commercially Prepared Microbiological Culture Media* (Controlul calităţii pentru mediile de cultură microbiologică preparate comercial).[12]

NOTĂ: Bulionul Middlebrook 7H9 (suplimentat) este scutit de la testarea controlului calităţii de către utilizator conform CLSI M22-A3.[12]

REZULTATE

O mostră pozitivă în instrument este determinată de instrumentul **BACTEC MGIT** şi confirmată de un frotiu acido-rezistent.

RAPORTAREA REZULTATELOR

Un flacon pozitiv în instrument trebuie confirmat prin frotiu acido-rezistent. Un rezultat la frotiul AFB pozitiv indică prezenţa micobacteriilor.

Dacă frotiul AFB este pozitiv, recultivaţi pe medii solide şi raportaţi ca: Pozitiv în instrument, frotiu AFB pozitiv, ID în aşteptare.

Dacă alte microorganisme în afară de AFB sunt prezente raportaţi ca: Pozitiv în instrument, frotiu AFB negativ. Contaminat.

Dacă nu sunt prezente microorganisme: Reintroduceţi flaconul în instrument ca un flacon continuu negativ în cel mult 5 h de la scoaterea lui. Permiteţi flaconului să efectueze protocolul de testare. Niciun rezultat raportabil.

Realizaţi subcultivarea din flaconul **BBL MGIT** pentru identificarea şi testarea sensibilităţii la medicamente.

LIMITĂRILE PROCEDURII

Recuperarea micobacteriilor din flaconul **MGIT** este dependentă de numărul de organisme prezente în probă, metodele de recoltare a probei, factori ce ţin de pacient cum ar fi simptomatologia, tratamentul anterior şi metodele de pregătire.

Este recomandă decontaminarea prin metoda cu N-acetil-L-cisteină hidroxid de sodiu (NALC-NaOH). Alte metode de decontaminare nu au fost testate împreună cu mediul **BBL MGIT**. Soluţiile enzimatice/decontaminante pot avea efecte negative pe micobacterii.

Morfologia şi pigmentaţia coloniilor pot fi determinate numai pe medii solide. Micobacteriile pot varia în responsivitatea la soluţiile acide în funcţie de tulpină, vârsta culturii şi alte variabile. Acurateţea morfologiei microscopice în mediul **BBL MGIT** nu a fost stabilită.

Un flacon **MGIT** pozitiv la frotiu AFB poate fi recultivat, atât în medii selective cât şi neselective pentru micobacterii, pentru a izola cu scopul efectuării testelor de identificare şi sensibilitate.

Flacoanele **MGIT** care sunt pozitive în instrument pot conţine alte specii non-micobacteriene. Speciile non-micobacteriene pot depăşi în creştere micobacteriile prezente. Asemenea flacoane **MGIT** trebuie re-decontaminate şi recultivate (consultaţi *Manualul utilizatorului* pentru instrumentul **BACTEC MGIT**). Reprelucrarea este recomandată în cazurile în care nu poate fi recoltată din nou o probă din sursa originală; de exemplu probele de ţesut.

Flacoanele **MGIT** care sunt pozitive în instrument pot conţine una sau mai multe specii de micobacterii. Micobacteriile cu o rată de creştere mai rapidă pot fi identificate înaintea celor cu rată de creştere mai lentă; de aceea este importantă recultivarea din flacoanele **MGIT** pozitive pentru a asigura identificarea exactă a tuturor micobacteriilor prezente în mostră.

Datorită bogăţiei în nutrienţi a bulionului **MGIT** şi a naturii neselective a indicatorului **MGIT**, este important de urmat procedura enzimatică/decontaminantă enunţată pentru a reduce posibilitatea contaminării. Respectarea instrucţiunilor procedurale, care include folosirea volumului de inoculare recomandat (0,5 mL), este importantă pentru recuperarea optimă a micobacteriilor.

Utilizarea amestecului antibiotic **PANTA**, deşi necesară pentru probele nesterile, poate avea efecte inhibitorii pe anumite micobacterii.

Au fost efectuate studii pe culturi însămânţate cu douăzeci şi patru de tulpini de micobacterii (ATCC şi sălbatice) folosind nivele ale inoculării variind între 10^1 şi până la 10^2 UFC/mL. Următoarele specii au fost identificate ca fiind pozitive cu sistemul **BACTEC MGIT** 960:

*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**	

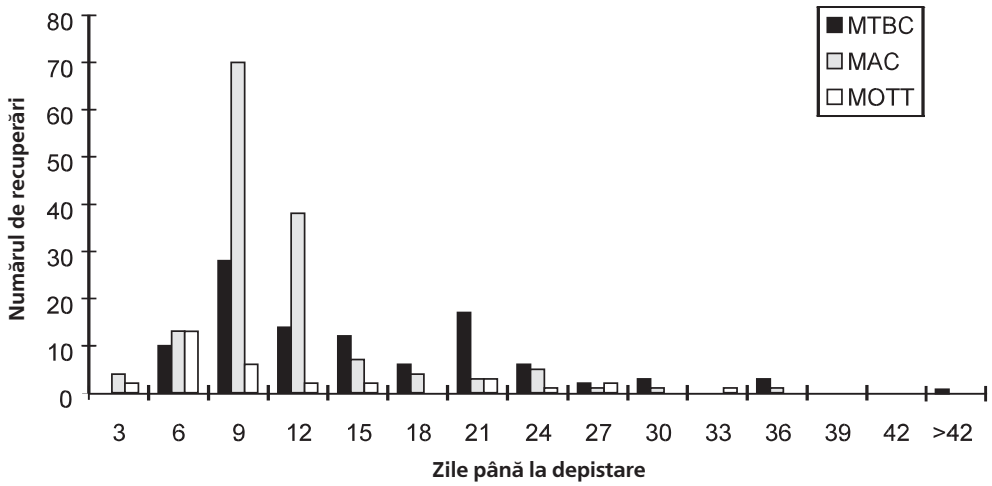
*Specii recuperate în timpul evaluării clinice a sistemului **BACTEC MGIT** 960. În plus, *M. mucogenicum* a fost recuperat la una din clinici.

†*M. haemophilum* a fost recuperat adăugând o sursă de hemin în flaconul **MGIT** înainte de inoculare.

Studiile clinice au demonstrat recuperarea micobacteriilor din probe respiratorii, aspirate gastrice, ţesut, materii fecale şi lichide biologice sterile cu excepţia sângelui; recuperarea micobacteriilor din alte lichide biologice nu a fost stabilită pentru acest produs.

VALORI ESTIMATE

Figura 1 ––Distribuţia frecvenţei timpilor de recuperare pentru probele din studiul clinic, pozitive în sistemul BACTEC MGIT 960



CARACTERISTICI DE PERFORMANŢĂ

Sistemul **BACTEC MGIT** 960 a fost evaluat în şase clinici incluzând una din afara S.U.A., reprezentate de laboratoare de sănătate publică dar şi mari spitale pentru tratamentul afecţiunilor acute, din diverse arii geografice. Populaţia cuprinsă în studiu a inclus pacienţi infectaţi cu HIV, pacienţi imunodeprimaţi şi pacienţi cu transplant. Sistemul **BACTEC MGIT** 960 a fost comparat cu sistemul radiometric **BACTEC** 460TB şi cu mediile de creştere solide convenţionale pentru detectarea şi recuperarea micobacteriilor din probe clinice cu excepţia sângelui. În total au fost testate 3330 de probe în timpul studiului. Un total de 353 de probe au fost pozitive, reprezentând 362 de izolate recuperate în timpul studiului. Distribuţia pozitivităţii pe tipuri de probe este: respirator (90%), ţesut (7%), lichide biologice (1%), materii fecale (0,85%) şi măduvă osoasă (0,65%). Din cele 362 de izolate, 289 (80%) au fost recuperate de sistemul **BACTEC MGIT** 960, 271 (75%) au fost recuperate de sistemul **BACTEC** 460TB şi 250 (69%) au fost recuperate de medii solide convenţionale. Din cele 3330 de probe testate în studiul clinic, 27 (0,8%) de flacoane **MGIT** 960 au fost considerate fals pozitive (pozitive în instrument, frotiu şi/sau subculturi negative). Dintre cele 313 flacoane **MGIT** 960 pozitive în instrument, 27 (8,6%) au fost considerate fals pozitive. Rata fals negativă (negativă în instrument, frotiu şi/sau subculturi-pozitive) a fost de 0,5%, bazată pe subcultivările terminale a 15% din fiolele negative în instrument. Rata medie de contaminare pentru sistemul **BACTEC MGIT** 960 a fost de 8,1%, variind între 1,8 – 14,6%.

Tabelul 2: Detectarea izolatelor pozitive de micobacterii în evaluările clinice

Izolate	Total Izolate	Total **MGIT** 960	**MGIT** Only	Total **BACTEC** 460TB	**BACTEC** 460TB numai	Total CONV	CONV numai
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
Toate MICO	362	289	54	271	27	250	16

DISPONIBILITATE

Nr. cat.	**Descriere**
245122	**BBL MGIT** Mycobacteria Growth Indicator Tubes, 7 mL, cutie cu 100 de flacoane.
245124	**BACTEC MGIT** 960 Supplement Kit, 6 fiole, 15 mL, **BACTEC MGIT** Growth Supplement şi 6 fiole lifilizate de **BBL MGIT PANTA** Antibiotic Mixture. Fiecare fiolă cu supliment de creştere/**PANTA** este suficientă pentru 15 – 18 flacoane **MGIT**.
220908	**BBL** Lowenstein-Jensen Medium Slants, pachet de 10 (flacoane cu capac de 20 x 148 mm).
220909	**BBL** Lowenstein-Jensen Medium Slants, cutie de 100 (flacoane cu capac de 20 x 148 mm).
240862	**BBL MycoPrep** Specimen Digestion/Decontamination Kit, zece sticle de 75 mL de soluţie NALC-NaOH şi 5 pachete de tampon fosfat.
240863	**BBL MycoPrep** Specimen Digestion/Decontamination Kit, zece sticle de 150 mL de soluţie de NALC-NaOH şi 10 pachete de tampon fosfat.
221174	Agar **BBL** Middlebrook şi Cohn 7H10, pachet de 20.
295939	**BBL** Middlebrook 7H9 Broth, 8 mL, pachet cu 10 flacoane.
221818	**BBL** Normal Saline, 5 mL, pachet cu 10.
221819	**BBL** Normal Saline, 5 mL, cutie de 100.
231106	**BBL** Taxo X Factor Strips, 1 fiolă, 50 benzi.

REFERINŢE

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Manufacturer / Výrobce / Producent / Fabrikant / Tootja / Valmistaja / Fabricant / Hersteller / Κατασκευαστής / Gyártó / Ditta produttrice / Gamintojas / Producent / Fabricante / Výrobca / Tillverkare / Производител / Producător / Üretici / Proizvođač / Производитель / Атқарушы

Use by / Spotřebujte do / Anvendes før / Houdbaar tot / Kasutada enne / Viimeinkäyttöpäivä / A utiliser avant / Verwendbar bis / Ημερομηία λήξης / Felhasználhatóság dátuma / Usare entro / Naudokite iki / Brukes før / Stosować do / Utilizar em / Použite do / Usar antes de / Använd före / Използвайте до / A se utiliza până la / Son kullanma tarihi / Upotrebiti do / Использовать до / дейін пайдалануға / Upotrijebiti do /
YYYY-MM-DD / YYYY-MM (MM = end of month) /
RRRR-MM-DD / RRRR-MM (MM = konec měsíce)
ÅÅÅÅ-MM-DD / ÅÅÅÅ-MM (MM = slutning af måned) /
JJJJ-MM-DD / JJJJ-MM (MM = einde maand)
AAAA-KK-PP / AAAA-KK (KK = kuu lõpp)
VVVV-KK-PP / VVVV-KK (kuukauden loppuun mennessä)
AAAA-MM-JJ / AAAA-MM (MM = fin du mois) /
JJJJ-MM-TT / JJJJ-MM (MM = Monatsende) /
EEEE-MM-HH / EEEE-MM (MM = τέλος του μήνα) /
ÉÉÉÉ-HH-NN / ÉÉÉÉ-HH (HH = hónap utolsó napja)
AAAA-MM-GG / AAAA-MM (MM = fine mese) /
MMMM-MM-DD / MMMM-MM (MM = mėnesio pabaiga)
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) /
RRRR-MM-DD / RRRR-MM (MM = koniec mesiaca)
aaaa-mm-dd / aaaa-mm (mm = fin del mes) /
ÅÅÅÅ-MM-DD / ÅÅÅÅ-MM (MM = slutet på månaden) /
ГГГГ-ММ-ДД / ГГГГ-ММ (ММ = края на месеца) /
AAAA-LL-ZZ / AAAA-LL (LL = sfârşitul lunii) /
YYYY-AA-GG / YYYY-AA (AA = ayın sonu) /
GGGG-MM-DD / GGGG-MM (MM = kraj meseca) /
ГГГГ-ММ-ДД / ГГГГ-ММ (ММ = конец месяца) /
ЖЖЖЖ-АА-КК / ЖЖЖЖ-АА (АА = айдың соңы) /
GGGG-MM-DD / GGGG-MM (MM = kraj mjeseca)

REF Catalog number / Katalogové číslo / Katalognummer / Catalogusnummer / Kataloogi number / Tuotenumero / Numéro catalogue / Bestellnummer / Αριθμός καταλόγου / Katalógusszám / Numero di catalogo / Katalogo numeris / Numer katalogowy / Número do catálogo / Katalógové číslo / Número de catálogo / Каталожен номер / Număr de catalog / Katalog numarası / Kataloški broj / Номер по каталогу / Каталог нөмірі

EC REP Authorized Representative in the European Community / Autorizovaný zástupce pro Evropskou unii / Autoriseret repræsentant i EU / Erkend vertegenwoordiger in de Europese Unie / Volitatud esindaja Euroopa Nõukogus / Valtuutettu edustaja Euroopan yhteisössä / Représentant agréé pour la C.E.E. / Autorisierte EG-Vertretung / Εξουσιοδοτημένος αντιπρόσωπος στην Ευρωπαϊκή Κοινότητα / Hivatalos képviselet az Európai Unióban / Rappresentante autorizzato nella Comunità europea / Įgaliotasis atstovas Europos Bendrijoje / Autorisert representant i EU / Autoryzowane przedstawicielstwo w Unii Europejskiej / Representante autorizado na União Europeia / Autorizovaný zástupca v Európskom spoločenstve / Representante autorizado en la Comunidad Europea / Auktoriserad representant i EU / Оторизиран представител в ЕU / Reprezentant autorizat în Uniunea Europeană / Avrupa Topluluğu Yetkili Temsilcisi / Ovlašćeni predstavnik u Evropskoj zajednici / Уполномоченный представитель в Европейском сообществе / Европа қауымдастығындағы уәкілетті өкіл / Autorizuirani predstavnik u EU

IVD In Vitro Diagnostic Medical Device / Lékařské zařízení určené pro diagnostiku in vitro / In vitro diagnostisk medicinsk anordning / Medisch hulpmiddel voor in vitro diagnose / In vitro diagnostika meditsiiniaparatuur / Lääkinnällinen in vitro -diagnostiikkalaite / Dispositif médical de diagnostic in vitro / Medizinisches In-vitro-Diagnostikum / In vitro διαγνωστική ιατρική συσκευή / In vitro diagnosztikai orvosi eszköz / Dispositivo medico diagnostico in vitro. / In vitro diagnostikos prietaisas / In vitro diagnostisk medisinsk utstyr / Urządzenie medyczne do diagnostyki in vitro / Dispositivo médico para diagnóstico in vitro / Medicínska pomôcka na diagnostiku in vitro / Dispositivo médico de diagnóstico in vitro / Medicinsk anordning för in vitro-diagnostik / Медицински уред за диагностика ин витро / Aparatură medicală de diagnosticare in vitro / In Vitro Diyagnostik Tıbbi Cihaz / Medicinski uređaj za in vitro dijagnostiku / Медицинский прибор для диагностики in vitro / Жасанды жағдайда жүргізетін медициналық диагностика аспабы / Medicinska pomagala za In Vitro Dijagnostiku

Temperature limitation / Teplotní omezení / Temperaturbegrænsning / Temperatuurlimiet / Temperatuuri piirang / Lämpötilarajoitus / Température limite / Zulässiger Temperaturenbereich / Όριο θερμοκρασίας / Hőmérsékleti határ / Temperatura limite / Laikymo temperatūra / Temperaturbegrensning / Ograniczenie temperatury / Limitação da temperatura / Ohraničenie teploty / Limitación de temperatura / Temperaturbegränsning / Температурни ограничения / Limitare de temperatură / Sıcaklık sınırlaması / Ograničenje temperature / Ограничение температуры / Температураны шектеу / Dozvoljena temperatura

LOT Batch Code (Lot) / Kód (číslo) šarže / Batch kode (Lot) / Chargenummer (lot) / Partii kood / Eräkoodi (LOT) / Code de lot (Lot) / Chargencode (Chargenbezeichnung) / Κωδικός παρτίδας (Παρτίδα) / Tétel száma (Lot) / Codice del lotto (partita) / Partijos numeris (Lot) / Batch-kode (Serie) / Kod partii (seria) / Código do lote (Lote) / Kód série (šarža) / Código de lote (Lote) / Satskod (parti) / Код (Партида) / Număr lot (Lotul) / Parti Kodu (Lot) / Kod serije / Код партии (лот) / Топтама коды / Lot (kod)

Consult Instructions for Use / Prostudujte pokyny k použití / Læs brugsanvisningen / Raadpleeg gebruiksaanwijzing / Lugeda kasutusjuhendit / Tarkista käyttöohjeista / Consulter la notice d'emploi / Gebrauchsanweisung beachten / Συμβουλευτείτε τις οσηγίες χρήσης / Olvassa el a használati utasítást / Consultare le istruzioni per l'uso / Skaitykite naudojimo instrukcijas / Se i bruksanvisningen / Zobacz instrukcja użytkowania / Consulte as instruções de utilização / Pozri Pokyny na používanie / Consultar las instrucciones de uso / Se bruksanvisningen / Направете справка в инструкциите за употреба / Consultaţi instrucţiunile de utilizare / Kullanım Talimatları'na başvurun / Pogledajte uputstvo za upotrebu / См. руководство по эксплуатации / Пайдалану нұсқаулығымен танысып алыңыз / Koristi upute za upotrebu

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EC REP Benex Limited
Pottery Road, Dun Laoghaire
Co. Dublin, Ireland

Date: 21.09.2018

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Kit Components

Kit Product No.	Kit Product Description
245124	BACTEC MGIT 960 Growth Supplement Kit

Kit Component(s)	Kit Component(s) Description
800632JAA	MGIT PANTA, Lyophilized
WP245124JAA	BACTEC MGIT 960 Growth Supplement

IMDG

Special precautions for user: Not regulated.

IATA

Special precautions for user: Not regulated.

Please note: If a listed component does not have a corresponding document included, this means that the product is not hazardous and does not require a Safety Data Sheet.

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SAFETY DATA SHEET

1. Identification

Product identifier

Product No.:	Product name:	Common name(s), synonym(s)
800632JAA	MGIT PANTA, Lyophilized	

Other means of identification
SDS number: 088100165422

Recommended use and restriction on use
Recommended use: Laboratory Chemicals
Restrictions on use: None known.

Manufacturer/Importer/Supplier/Distributor Information

Manufacturer

Company Name: BD Diagnostic Systems
Address: 7 Loveton Circle
21152 Sparks, MD USA
Telephone: 1 410 771 0100 or 1 800 638 8663
Fax:
Contact Person: Tech Services

Emergency telephone number: ChemTrec 1 800 424 9300

2. Hazard(s) identification

Hazard Classification

Not classified

Label Elements

Hazard Symbol: No symbol

Signal Word: No signal word.

Hazard Statement: Not applicable
Precautionary Statements Not applicable

Other hazards which do not result in GHS classification: None.

3. Composition/information on ingredients

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Mixtures

Composition Comments: The components are not hazardous or are below required disclosure limits.

4. First-aid measures

General information: Get medical attention if symptoms occur.

Ingestion: Get medical attention if symptoms occur.

Inhalation: Provide fresh air, warmth and rest, preferably in comfortable upright sitting position.

Skin Contact: Wash contact areas with soap and water. Remove contaminated clothing. Launder contaminated clothing before reuse.

Eye contact: Flush thoroughly with water. If irritation occurs, get medical assistance.

Most important symptoms/effects, acute and delayed

Symptoms: No data available.

Indication of immediate medical attention and special treatment needed

Treatment: No data available.

5. Fire-fighting measures

General Fire Hazards: Extinguish all ignition sources. Avoid sparks, flames, heat and smoking. Ventilate. Use water spray to keep fire-exposed containers cool.

Suitable (and unsuitable) extinguishing media

Suitable extinguishing media: Water spray, fog, CO2, dry chemical, or alcohol resistant foam.

Unsuitable extinguishing media: None known.

Specific hazards arising from the chemical: None known.

Special protective equipment and precautions for firefighters

Special fire fighting procedures: No unusual fire or explosion hazards noted.

Special protective equipment for fire-fighters: Firefighters must use standard protective equipment including flame retardant coat, helmet with face shield, gloves, rubber boots, and in enclosed spaces, SCBA.

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6. Accidental release measures

Personal precautions, protective equipment and emergency procedures: No special precautionary health measures should be needed under anticipated conditions of use.

Methods and material for containment and cleaning up: No specific clean-up procedure noted.

Environmental Precautions: Avoid release to the environment.

7. Handling and storage

Precautions for safe handling: When using do not eat, drink or smoke. Read and follow manufacturer's recommendations. Use personal protective equipment as required.

Conditions for safe storage, including any incompatibilities: Store in a cool, dry place. Keep container tightly closed.

8. Exposure controls/personal protection

Control Parameters

Occupational Exposure Limits

None of the components have assigned exposure limits.

Appropriate Engineering Controls No special requirements under ordinary conditions of use and with adequate ventilation.

Individual protection measures, such as personal protective equipment

General information: Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing to remove contaminants. Discard contaminated footwear that cannot be cleaned.

Eye/face protection: Wear safety glasses with side shields (or goggles).

Skin Protection

Hand Protection: Chemical resistant gloves Suitable gloves can be recommended by the glove supplier. Wash hands after contact.

Other: Wear a lab coat or similar protective clothing.

Respiratory Protection: Respiratory protection not required.

Hygiene measures: Observe good industrial hygiene practices.

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9. Physical and chemical properties

Appearance	
Physical state:	No data available.
Form:	No data available.
Color:	No data available.
Odor:	No data available.
Odor threshold:	No data available.
pH:	No data available.
Melting point/freezing point:	No data available.
Initial boiling point and boiling range:	No data available.
Flash Point:	No data available.
Evaporation rate:	No data available.
Flammability (solid, gas):	No data available.
Upper/lower limit on flammability or explosive limits	
Flammability limit - upper (%):	No data available.
Flammability limit - lower (%):	No data available.
Explosive limit - upper (%):	No data available.
Explosive limit - lower (%):	No data available.
Vapor pressure:	No data available.
Vapor density:	No data available.
Relative density:	No data available.
Solubility(ies)	
Solubility in water:	No data available.
Solubility (other):	No data available.
Partition coefficient (n-octanol/water):	No data available.
Auto-ignition temperature:	No data available.
Decomposition temperature:	No data available.
Viscosity:	No data available.

10. Stability and reactivity

Reactivity:	Stable under normal temperature conditions and recommended use.
Chemical Stability:	Material is stable under normal conditions.
Possibility of hazardous reactions:	Not known.
Conditions to avoid:	Avoid exposure to high temperatures or direct sunlight.
Incompatible Materials:	Strong oxidizers.

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Hazardous Decomposition Products: Not known.

11. Toxicological information

General information: No data on possible toxicity effects have been found.

Information on likely routes of exposure

Ingestion: No harmful effects expected in amounts likely to be ingested by accident.

Inhalation: Limited inhalation hazard at normal work temperatures.

Skin Contact: Negligible irritation to skin at ambient temperatures.

Eye contact: Do not get in eyes.

Symptoms related to the physical, chemical and toxicological characteristics

Ingestion: No data available.

Inhalation: No data available.

Skin Contact: No data available.

Eye contact: No data available.

Information on toxicological effects

Acute toxicity (list all possible routes of exposure)

Oral
Product: No data available.

Dermal
Product: No data available.

Inhalation
Product: No data available.

Repeated dose toxicity
Product: No data available.

Skin Corrosion/Irritation
Product: No data available.

Serious Eye Damage/Eye Irritation
Product: No data available.

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Respiratory or Skin Sensitization
Product: No data available.

Carcinogenicity
Product: No data available.

IARC Monographs on the Evaluation of Carcinogenic Risks to Humans:
No carcinogenic components identified

US. National Toxicology Program (NTP) Report on Carcinogens:
No carcinogenic components identified

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050):
No carcinogenic components identified

Germ Cell Mutagenicity

In vitro
Product: No data available.

In vivo
Product: No data available.

Reproductive toxicity
Product: No data available.

Specific Target Organ Toxicity - Single Exposure
Product: No data available.

Specific Target Organ Toxicity - Repeated Exposure
Product: No data available.

Aspiration Hazard
Product: No data available.

Other effects: None known.

12. Ecological information

Ecotoxicity:

Acute hazards to the aquatic environment:

Fish
Product: No negative effects on the aquatic environment are known.

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Aquatic Invertebrates
Product: No negative effects on the aquatic environment are known.

Chronic hazards to the aquatic environment:

Fish
Product: No negative effects on the aquatic environment are known.

Aquatic Invertebrates
Product: No negative effects on the aquatic environment are known.

Toxicity to Aquatic Plants
Product: No negative effects on the aquatic environment are known.

Persistence and Degradability

Biodegradation
Product: Expected to be readily biodegradable.

BOD/COD Ratio
Product: No data available.

Bioaccumulative potential
Bioconcentration Factor (BCF)
Product: No data available.

Partition Coefficient n-octanol / water (log Kow)
Product: No data available.

Mobility in soil: No data available.

Known or predicted distribution to environmental compartments

Other adverse effects: The product is not expected to be hazardous to the environment.

13. Disposal considerations

General information: Dispose of waste and residues in accordance with local authority requirements.

Disposal instructions: No specific disposal method required.

Contaminated Packaging: No data available.

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14. Transport information

DOTUN Number:	Not regulated.
UN Proper Shipping Name:	Not regulated.
Transport Hazard Class(es)	
Class:	Not regulated.
Label(s):	Not regulated.
Packing Group:	Not regulated.
Marine Pollutant:	Not regulated.
Limited quantity	Not regulated.
Excepted quantity	Not regulated.
Special precautions for user:	Not regulated.

IMDG

UN Number:	Not regulated.
UN Proper Shipping Name:	Not regulated.
Transport Hazard Class(es)	
Class:	Not regulated.
Subsidiary risk:	Not regulated.
EmS No.:	Not regulated.
Packing Group:	Not regulated.
Environmental Hazards	
Marine Pollutant:	Not regulated.
Special precautions for user:	Not regulated.

IATA

UN Number:	Not regulated.
Proper Shipping Name:	Not regulated.
Transport Hazard Class(es):	
Class:	Not regulated.
Subsidiary risk:	Not regulated.
Packing Group:	Not regulated.
Environmental Hazards	
Marine pollutant:	Not regulated.
Special precautions for user:	Not regulated.

15. Regulatory information

US Federal Regulations

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)
None present or none present in regulated quantities.

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)
None present or none present in regulated quantities.

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CERCLA Hazardous Substance List (40 CFR 302.4):

Chemical Identity	Reportable quantity
Phosphoric acid, sodium salt (1:2)	5000 lbs.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories
Not classified
Not classified

SARA 302 Extremely Hazardous Substance
None present or none present in regulated quantities.

SARA 304 Emergency Release Notification

Chemical Identity	Reportable quantity
Phosphoric acid, sodium salt (1:2)	5000 lbs.

SARA 311/312 Hazardous Chemical

None present or none present in regulated quantities.

SARA 313 (TRI Reporting)
None present or none present in regulated quantities.

Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3)

Chemical Identity	Reportable quantity
Phosphoric acid, sodium salt (1:2)	Reportable quantity: 5000 lbs.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130):
None present or none present in regulated quantities.

US State Regulations

US. California Proposition 65
No ingredient regulated by CA Prop 65 present.

US. New Jersey Worker and Community Right-to-Know Act

Chemical Identity
Phosphoric acid, sodium salt (1:2)

US. Massachusetts RTK - Substance List

Chemical Identity
Phosphoric acid, sodium salt (1:2)

US. Pennsylvania RTK - Hazardous Substances

Chemical Identity
Phosphoric acid, sodium salt (1:2)

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US. Rhode Island RTK

No ingredient regulated by RI Right-to-Know Law present.

16.Other information, including date of preparation or last revision

Issue Date:	08/28/2018
Version #:	1.0
Revision Information:	No data available.
Further Information:	No data available.
Disclaimer:	Disclaimer: The information contained herein has been obtained from various sources and is believed to be correct as of the date issued. However, neither BD nor any of its subsidiaries assumes any liabilities whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability for a particular use of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist. BD provides SDS in electronic form so the information may be more easily accessed. Due to the possibility of errors during transmission, BD makes no representations as to the completeness or accuracy of the information.

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SAFETY DATA SHEET

1. Identification

Product identifier

Product No.:	Product name:	Common name(s), synonym(s)
WP245124JAA	BACTEC MGIT 960 Growth Supplement	

Other means of identification
SDS number: 088100177572

Recommended use and restriction on use
Recommended use: Laboratory Chemicals
Restrictions on use: None known.

Manufacturer/Importer/Supplier/Distributor Information

Manufacturer

Company Name: BD Diagnostic Systems
Address: 7 Loveton Circle
21152 Sparks, MD USA
Telephone: 1 410 771 0100 or 1 800 638 8663
Fax:
Contact Person: Tech Services

Emergency telephone number: ChemTrec 1 800 424 9300

2. Hazard(s) identification

Hazard Classification

Not classified

Label Elements

Hazard Symbol: No symbol

Signal Word: No signal word.

Hazard Statement: Not applicable
Precautionary Statements Not applicable

Other hazards which do not result in GHS classification: None.

3. Composition/information on ingredients

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Mixtures

Chemical Identity	Common name and synonyms	CAS number	Content in percent (%)*
Ethanol		64-17-5	28.158%
9-Octadecenoic acid (9Z)-		112-80-1	1.224%

* All concentrations are percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

4. First-aid measures

General information: Get medical attention if symptoms occur.

Ingestion: Get medical attention if symptoms occur.

Inhalation: Provide fresh air, warmth and rest, preferably in comfortable upright sitting position.

Skin Contact: Wash contact areas with soap and water. Remove contaminated clothing. Launder contaminated clothing before reuse.

Eye contact: Flush thoroughly with water. If irritation occurs, get medical assistance.

Most important symptoms/effects, acute and delayed

Symptoms: No data available.

Indication of immediate medical attention and special treatment needed

Treatment: No data available.

5. Fire-fighting measures

General Fire Hazards: Extinguish all ignition sources. Avoid sparks, flames, heat and smoking. Ventilate. Use water spray to keep fire-exposed containers cool.

Suitable (and unsuitable) extinguishing media

Suitable extinguishing media: Water spray, fog, CO2, dry chemical, or alcohol resistant foam.

Unsuitable extinguishing media: None known.

Specific hazards arising from the chemical: None known.

Special protective equipment and precautions for firefighters

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Special fire fighting procedures:	No unusual fire or explosion hazards noted.
Special protective equipment for fire-fighters:	Firefighters must use standard protective equipment including flame retardant coat, helmet with face shield, gloves, rubber boots, and in enclosed spaces, SCBA.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures:	No special precautionary health measures should be needed under anticipated conditions of use.
Methods and material for containment and cleaning up:	No specific clean-up procedure noted.
Environmental Precautions:	Avoid release to the environment.

7. Handling and storage

Precautions for safe handling:	When using do not eat, drink or smoke. Read and follow manufacturer's recommendations. Use personal protective equipment as required.
Conditions for safe storage, including any incompatibilities:	Store in a cool, dry place. Keep container tightly closed.

8. Exposure controls/personal protection

Control Parameters

Occupational Exposure Limits

Chemical Identity	Type	Exposure Limit Values	Source
Ethanol	TWA	1,000 ppm 1,900 mg/m3	US. OSHA Table Z-1-A (29 CFR 1910.1000) (1989)
	TWA	1,000 ppm 1,900 mg/m3	US. Tennessee. OELs. Occupational Exposure Limits, Table Z1A (06 2008)
	AN ESL	1,000 ppb	US. Texas. Effects Screening Levels (Texas Commission on Environmental Quality) (12 2010)
	ST ESL	10,000 ppb	US. Texas. Effects Screening Levels (Texas Commission on Environmental Quality) (12 2010)
	AN ESL	1,880 µg/m3	US. Texas. Effects Screening Levels (Texas Commission on Environmental Quality) (12 2010)
	ST ESL	18,800 µg/m3	US. Texas. Effects Screening Levels (Texas Commission on Environmental Quality) (12 2010)
	TWA PEL	1,000 ppm 1,900 mg/m3	US. California Code of Regulations, Title 8, Section 5155. Airborne Contaminants (08 2010)
	STEL	1,000 ppm	US. ACGIH Threshold Limit Values (12 2010)

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	REL	1,000 ppm 1,900 mg/m3	US. NIOSH: Pocket Guide to Chemical Hazards (2005)
	PEL	1,000 ppm 1,900 mg/m3	US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000) (02 2006)

Appropriate Engineering Controls No special requirements under ordinary conditions of use and with adequate ventilation.

Individual protection measures, such as personal protective equipment

General information: Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing to remove contaminants. Discard contaminated footwear that cannot be cleaned.

Eye/face protection: Wear safety glasses with side shields (or goggles).

Skin Protection
Hand Protection: Chemical resistant gloves Suitable gloves can be recommended by the glove supplier. Wash hands after contact.

Other: Wear a lab coat or similar protective clothing.

Respiratory Protection: Respiratory protection not required.

Hygiene measures: Observe good industrial hygiene practices.

9. Physical and chemical properties

Appearance

Physical state: solid
Form: Solid or Flake
Color: No data available.
Odor: No data available.
Odor threshold: No data available.
pH: No data available.
Melting point/freezing point: No data available.
Initial boiling point and boiling range: No data available.
Flash Point: Not applicable
Evaporation rate: No data available.
Flammability (solid, gas): No data available.
Upper/lower limit on flammability or explosive limits
Flammability limit - upper (%): No data available.
Flammability limit - lower (%): No data available.
Explosive limit - upper (%): No data available.
Explosive limit - lower (%): No data available.
Vapor pressure: No data available.
Vapor density: No data available.

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Relative density:	No data available.
Solubility(ies)	
Solubility in water:	Completely Soluble
Solubility (other):	Water.: No data available.
Partition coefficient (n-octanol/water):	No data available.
Auto-ignition temperature:	No data available.
Decomposition temperature:	No data available.
Viscosity:	Not determined.

10. Stability and reactivity

Reactivity:	Stable under normal temperature conditions and recommended use.
Chemical Stability:	Material is stable under normal conditions.
Possibility of hazardous reactions:	Not known.
Conditions to avoid:	Avoid exposure to high temperatures or direct sunlight.
Incompatible Materials:	Strong oxidizers.
Hazardous Decomposition Products:	Not known.

11. Toxicological information

General information: No data on possible toxicity effects have been found.

Information on likely routes of exposure

Ingestion:	No harmful effects expected in amounts likely to be ingested by accident.
Inhalation:	Limited inhalation hazard at normal work temperatures.
Skin Contact:	Negligible irritation to skin at ambient temperatures.
Eye contact:	Do not get in eyes.

Symptoms related to the physical, chemical and toxicological characteristics

Ingestion:	No data available.
Inhalation:	No data available.
Skin Contact:	No data available.
Eye contact:	No data available.

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Information on toxicological effects

Acute toxicity (list all possible routes of exposure)

Oral
Product: No data available.

Dermal
Product: No data available.

Inhalation
Product: No data available.

Repeated dose toxicity
Product: No data available.

Specified substance(s):

Ethanol	Based on available data, the classification criteria are not met. LOAEL (Rat(Female, Male), Inhalation, 7,318 - 7,496 h): 1.3 mg/l Inhalation Read-across from supporting substance (structural analogue or surrogate), Weight of Evidence study NOAEL (Guinea pig, Inhalation, 10.5 Weeks): 3,000 ppm(m) Inhalation Experimental result, Supporting study LOAEL (Rat(Male), Inhalation, 1 - 6 Weeks): 13.3 mg/l Inhalation Read-across from supporting substance (structural analogue or surrogate), Supporting study LOAEL (Monkey, Inhalation, 5 - 20 d): 3.99 mg/l Inhalation Read-across from supporting substance (structural analogue or surrogate), Supporting study

Skin Corrosion/Irritation
Product: No data available.

Specified substance(s):

Ethanol	in vivo (Rabbit): Not irritant Experimental result, Key study

Serious Eye Damage/Eye Irritation
Product: No data available.

Specified substance(s):

Ethanol	in vivo (Rabbit, 24 - 72 hrs): Not irritating EU

Respiratory or Skin Sensitization
Product: No data available.

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Specified substance(s):

Ethanol	Based on available data, the classification criteria are not met. Skin sensitization:, in vivo (Guinea pig): Non sensitising

Carcinogenicity

Product:	No data available.
Specified substance(s):	
Ethanol	Based on available data, the classification criteria are not met.

IARC Monographs on the Evaluation of Carcinogenic Risks to Humans:
No carcinogenic components identified

US. National Toxicology Program (NTP) Report on Carcinogens:
No carcinogenic components identified

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050):
No carcinogenic components identified

Germ Cell Mutagenicity

In vitro

Product:	No data available.
Specified substance(s):	
Ethanol	Based on available data, the classification criteria are not met.

In vivo

Product:	No data available.
Specified substance(s):	
Ethanol	Based on available data, the classification criteria are not met.

Reproductive toxicity

Product:	No data available.
Specified substance(s):	
Ethanol	Based on available data, the classification criteria are not met.

Specific Target Organ Toxicity - Single Exposure

Product:	No data available.
Specified substance(s):	
Ethanol	Based on available data, the classification criteria are not met.

Specific Target Organ Toxicity - Repeated Exposure

Product:	No data available.
Specified substance(s):	
Ethanol	Based on available data, the classification criteria are not met.

Aspiration Hazard

Product:	No data available.

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Other effects: None known.

12. Ecological information

Ecotoxicity:

Acute hazards to the aquatic environment:

Fish
Product: No negative effects on the aquatic environment are known.

Aquatic Invertebrates
Product: No negative effects on the aquatic environment are known.

Chronic hazards to the aquatic environment:

Fish
Product: No negative effects on the aquatic environment are known.

Aquatic Invertebrates
Product: No negative effects on the aquatic environment are known.

Toxicity to Aquatic Plants
Product: No negative effects on the aquatic environment are known.

Persistence and Degradability

Biodegradation
Product: Expected to be readily biodegradable.

BOD/COD Ratio
Product: No data available.

Bioaccumulative potential
Bioconcentration Factor (BCF)
Product: No data available.

Specified substance(s):

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Ethanol	Potential to bioaccumulate is low. Cyprinus carpio, Bioconcentration Factor (BCF): 4.5 Aquatic sediment Read-across from supporting substance (structural analogue or surrogate), Supporting study Cyprinus carpio, Bioconcentration Factor (BCF): 3 Aquatic sediment Read-across from supporting substance (structural analogue or surrogate), Supporting study Leuciscus idus, Bioconcentration Factor (BCF): 0.2 Aquatic sediment Read-across from supporting substance (structural analogue or surrogate), Not specified Cyprinus carpio, Bioconcentration Factor (BCF): 1 Aquatic sediment Read-across from supporting substance (structural analogue or surrogate), Supporting study

Partition Coefficient n-octanol / water (log Kow)

Product:	Log Kow: No data available.

Mobility in soil: No data available.

Known or predicted distribution to environmental compartments

Ethanol	soil - Very mobile liquid
9-Octadecenoic acid (9Z)-	No data available.

Other adverse effects: The product is not expected to be hazardous to the environment.

13. Disposal considerations

General information: Dispose of waste and residues in accordance with local authority requirements.

Disposal instructions: No specific disposal method required.

Contaminated Packaging: No data available.

14. Transport information

DOTUN Number:	Not regulated.
UN Proper Shipping Name:	Not regulated.
Transport Hazard Class(es)	
Class:	Not regulated.
Label(s):	Not regulated.
Packing Group:	Not regulated.
Marine Pollutant:	Not regulated.
Limited quantity	Not regulated.
Excepted quantity	Not regulated.
Special precautions for user:	Not regulated.

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IMDG

UN Number:	Not regulated.
UN Proper Shipping Name:	Not regulated.
Transport Hazard Class(es)	
Class:	Not regulated.
Subsidiary risk:	Not regulated.
EmS No.:	Not regulated.
Packing Group:	Not regulated.
Environmental Hazards	
Marine Pollutant:	Not regulated.
Special precautions for user:	Not regulated.

IATA

UN Number:	Not regulated.
Proper Shipping Name:	Not regulated.
Transport Hazard Class(es):	
Class:	Not regulated.
Subsidiary risk:	Not regulated.
Packing Group:	Not regulated.
Environmental Hazards	
Marine pollutant:	Not regulated.
Special precautions for user:	Not regulated.

15. Regulatory information

US Federal Regulations

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)
None present or none present in regulated quantities.

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)
None present or none present in regulated quantities.

CERCLA Hazardous Substance List (40 CFR 302.4):

Chemical Identity	Reportable quantity
Ethanol	100 lbs.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories
Not classified
Not classified

SARA 302 Extremely Hazardous Substance
None present or none present in regulated quantities.

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SARA 304 Emergency Release Notification

Chemical Identity	Reportable quantity
Ethanol	100 lbs.

SARA 311/312 Hazardous Chemical

Chemical Identity	Threshold Planning Quantity
Ethanol	10000 lbs
9-Octadecenoic acid (9Z)-	10000 lbs

SARA 313 (TRI Reporting)

None present or none present in regulated quantities.

Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3)

None present or none present in regulated quantities.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130):

None present or none present in regulated quantities.

US State Regulations

US. California Proposition 65

US. New Jersey Worker and Community Right-to-Know Act

Chemical Identity
Ethanol

US. Massachusetts RTK - Substance List

Chemical Identity
Ethanol

US. Pennsylvania RTK - Hazardous Substances

Chemical Identity
Ethanol
9-Octadecenoic acid (9Z)-

US. Rhode Island RTK

Chemical Identity
Ethanol
9-Octadecenoic acid (9Z)-

16.Other information, including date of preparation or last revision

Issue Date: 08/28/2018

Version #: 3.1

Revision Information: No data available.

Further Information: No data available.

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BD BBL MGIT

Mycobacteria Growth Indicator Tube, OADC Enrichment, PANTA Antibiotic Mixture

См. глоссарий символов в конце вкладыша.

CE 8809501JAA (2005/11)

Русский

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Европейский патент EP 0 509 791 B1

НАЗНАЧЕНИЕ

BBL MGIT Mycobacteria Growth Indicator Tube (Пробирка с индикатором роста микобактерий), поставляемая с обогащающей добавкой **BBL MGIT** OADC Enrichment и **BBL MGIT PANTA** antibiotic mixture (Смесь антибиотиков), используемой при необходимости, предназначена для обнаружения и выделения микобактерий. К допустимым типам образцов относятся ферментированные и деконтаминированные клинические образцы (за исключением мочи) и стерильные биологические жидкости (за исключением крови).

КРАТКИЙ ОБЗОР И ОПИСАНИЕ

В период с 1985 до 1992 гг. число зарегистрированных клинических случаев туберкулеза возросло на 18 %. От туберкулеза в мире ежегодно умирает около 3 млн. человек, что ставит его на первое место среди всех инфекционных заболеваний, являющихся причиной смерти.[1] Наблюдение за больными ВИЧ в период с 1981 по 1987 гг. показало, что 5,5 % пациентов с ВИЧ страдают диссеминированными формами нетуберкулезной микобактериальной инфекции (например, вызванной комплексом *Mycobacterium avium*). К 1990 г. возросшая заболеваемость диссеминированной нетуберкулезной микобактериальной инфекцией достигла суммарного показателя 7,6 %.[2] Помимо возобновления активности туберкулеза, серьезной проблемой стал туберкулез со множественной лекарственной устойчивостью (ТБ МЛУ). Задержки, вызванные необходимостью лабораторного выращивания, идентификации и составления отчетов о случаях ТБ МЛУ, способствовали, по крайней мере отчасти, распространению заболевания.[3]

Центры по контролю и профилактике заболеваний США (CDC) рекомендовали приложить все усилия для перевода лабораторий на самые быстрые и доступные методики диагностических тестов на микобактериальную инфекцию. В число этих рекомендаций входило использование как жидких, так и твердых питательных сред для культивирования микобактерий.[3]

Пробирка **MGIT** Mycobacteria Growth Indicator Tube содержит 4 мл модифицированной бульонной среды Миддлбрука Middlebrook 7H9 Broth.[4,5] Полный комплекс среды вместе с 0,5 мл питательной добавки OADC и 0,1 мл смеси антибиотиков **PANTA** antibiotic mixture является одной из наиболее часто используемых жидких сред для культивирования микобактерий.

Клинические образцы всех типов – как легочные, так и внелегочные (за исключением крови и мочи) – могут быть обработаны для первичного выделения в пробирке **MGIT** с использованием традиционных методов.[6] Обработанный образец засеивают в пробирку **MGIT**, инкубируют и, начиная со второго дня, ежедневно считывают показания с помощью длинноволнового УФ-излучения. К моменту обнаружения положительного результата в пробирке будут присутствовать около 10^4 – 10^7 КОЕ/мл микобактерий.

ПРИНЦИПЫ МЕТОДИКИ

В силикон на дне пробирок 16 x 100 мм с закругленным дном введен флуоресцентный компонент. Флуоресцентный компонент чувствителен к присутствию кислорода, растворенного в бульоне. Первоначально большое количество растворенного кислорода гасит выделения этого вещества, и обнаруживается лишь небольшая флуоресценция. В дальнейшем активно дышащие микроорганизмы потребляют кислород, и флуоресценция становится заметной и может быть обнаружена с помощью УФ-трансиллюминатора с длиной волны излучения 365 нм или с помощью длинноволнового УФ-излучения (лампа Вуда). Рост может быть также обнаружен по присутствию негомогенной мутности, мелких частиц или хлопьев в среде культуры.

Компоненты среды – это вещества, необходимые для быстрого роста микобактерий. Олеиновая кислота потребляется туберкулезными бациллами и играет важную роль в метаболизме микобактерий. Альбумин служит защитным компонентом, связывающим свободные жирные кислоты, которые могут быть токсичными для организмов *Mycobacterium*, и таким образом способствует их выделению. Декстроза является источником энергии. Каталаза разрушает токсичные пероксиды, которые могут присутствовать в среде.

Уровень загрязнения может быть снижен путем введения в смесь основы **BBL MGIT** и питательной добавки **BBL MGIT** OADC смеси антибиотиков **BBL MGIT PANTA** antibiotic mixture перед засеиванием бульона клиническим образцом.

РЕАГЕНТЫ

Пробирка **BBL MGIT** Mycobacteria Growth Indicator Tube содержит: 110 мкл флуоресцентного индикатора и 4 мл бульона. Индикатор содержит пентагидрат трис (4,7-дифенил-1,10-фенантролин) рутения хлорида в силиконовой основе. Пробирки заполнены 10 % CO_2 и закрыты полипропиленовыми крышками.

Приблизительная рецептура* на литр очищенной воды

Модифицированная основа бульонной среды Миддлбрука 7H9	5,9 г
Казеинпептон	1,25 г

BBL MGIT OADC содержит 15 мл обогащающей добавки Middlebrook OADC.

Приблизительная рецептура* на литр очищенной воды

Альбумин бычьей сыворотки	50,0 г	Каталаза	0,03 г
Декстроза	20,0 г	Олеиновая кислота	0,6 г

Флакон **BBL MGIT PANTA** содержит лиофилизированную смесь противомикробных препаратов.

Приблизительная рецептура* на флакон лиофилизированного реагента **PANTA**

Полимиксин B	6 000 единиц	Триметоприм	600 мкг
Амфотерицин B	600 мкг	Азлоциллин	600 мкг
Налидиксовая кислота	2 400 мкг		

**При необходимости изменяется и/или дополняется для соответствия критериям эффективности.*

Инструкции по применению. Восстанавливают лиофилизированный флакон смеси антибиотиков **BBL MGIT PANTA** antibiotic mixture 3 мл стерильной дистиллированной или деионизированной воды.

Меры предосторожности. Для диагностического использования в условиях *in vitro*.

В образцах могут присутствовать патогенные микроорганизмы, в том числе вирус гепатита B и вирус иммунодефицита человека (ВИЧ). При работе с любыми предметами, загрязненными кровью и другими биологическими жидкостями, следует соблюдать универсальные меры предосторожности[1,2].

При работе с *Mycobacterium tuberculosis*, выращенными в культуре, рекомендуется использовать оборудование и инструменты для биологической защиты, а также применять меры биологической безопасности 3 уровня.[6]

Перед использованием необходимо осмотреть все пробирки **MGIT** на предмет признаков загрязнения или повреждения. Все пробирки с подозрительными внешними признаками, в том числе с заметной флуоресценцией до использования, необходимо утилизировать.

Пробирки, подвергавшиеся падению, необходимо тщательно осмотреть. При обнаружении повреждений пробирку следует утилизировать.

Наблюдая за флуоресценцией, надевайте очки, защищающие от УФ-излучения, и используйте только длинноволновое излучение (365 нм). НЕ ИСПОЛЬЗУЙТЕ КОРОТКОВОЛНОВОЕ УФ-ИЗЛУЧЕНИЕ ДЛЯ СЧИТЫВАНИЯ ПОКАЗАНИЙ ПРОБИРОК.

Перед утилизацией выполняйте автоклавирование всех засеянных пробирок **MGIT**.

Хранение реагентов. Пробирки **BBL MGIT** Mycobacteria Growth Indicator Tube: после получения храните при температуре 2 – 25 °C. НЕ ЗАМОРАЖИВАЙТЕ. Сведите к минимуму воздействие света. Бульон должен быть прозрачным и бесцветным. Не используйте его, если он мутный. Пробирки **MGIT**, хранящиеся в указанных условиях, могут быть засеяны в любое время до даты завершения срока годности и инкубированы на срок до восьми недель.

BBL MGIT OADC: после получения храните в темноте при температуре 2 – 8 °C. Избегайте замораживания или перегревания. Открывайте непосредственно перед использованием. Сведите к минимуму воздействие света.

Смесь антибиотиков **BBL MGIT PANTA** antibiotic mixture: после получения храните лиофилизированные флаконы при температуре 2 – 8° C. После восстановления смесь **PANTA** пригодна к использованию в течение 72 ч в условиях хранения при температуре 2 – 8 °C или до 6 месяцев при температуре -20 °C или ниже. После размораживания смесь **PANTA** необходимо использовать немедленно. Утилизируйте неиспользованную часть.

ВЗSSТИЕ ОБРАЗЦОВ

Все образцы следует собирать и транспортировать в соответствии с рекомендациями CDC, *Clinical Microbiology Procedures Handbook* (Руководство по клиническим микробиологическим процедурам) или руководством по процедурам лаборатории.[6,8]

ФЕРМЕНТАЦИSS, ДЕКОНТАМИНАЦИSS И КОНЦЕНТРАЦИSS

Образцы из различных участков тела необходимо подготовить к посеву в пробирки **MGIT** следующим образом.

МОКРОТА. Образцы необходимо обработать с помощью метода NALC-NaOH по рекомендациям CDC *Public Health Mycobacteriology: A Guide for the Level III Laboratory* (Микобактериология в здравоохранении: руководство для лабораторий уровня III).[6] В качестве альтернативы для обработки микобактериологических образцов используйте комплект **BBL MycoPrep** (см. раздел «Наличие»).

ЖЕЛУДОЧНЫЕ АСПИРАТЫ. Образцы следует деконтаминировать аналогично мокроте. Если объем образца превышает 10 мл, его концентрируют центрифугированием. Растворяют осадок в стерильной воде объемом около 5 мл, а затем выполняют деконтаминацию. Добавляют немного порошка NALC (50 – 100 мг), если образец слишком густой или слизеподобный. После деконтаминации снова концентрируют перед посевом в пробирку **MGIT**.

БИОЛОГИЧЕСКИЕ ЖИДКОСТИ (цереброспинальная жидкость, синовиальная жидкость, плевральный выпот и т. п.). Образцы, полученные с соблюдением правил асептики и не вызывающие подозрений о присутствии других бактерий, можно засеивать без деконтаминации. Если объем образца больше 10 мл, его концентрируют центрифугированием при 3000 x *g* в течение 15 мин. Сливают надосадочную жидкость. Засевают пробирку **MGIT** осадком. Образцы, для которых имеются подозрения о наличии других бактерий, необходимо деконтаминировать.

ТКАНИ. Образцы тканей необходимо обработать в соответствии с рекомендациями CDC *Public Health Mycobacteriology: A Guide for the Level III Laboratory* (Микобактериология в здравоохранении: руководство для лабораторий уровня III).[6]

СТУЛ. Растворяют 1 г кала в 5 мл бульона Миддлбрука. Встряхивают суспензию на вихревой мешалке в течение 5 с. После этого выполняют процедуру NALC-NaOH в соответствии с рекомендациями CDC *Public Health Mycobacteriology: A Guide for the Level III Laboratory* (Микобактериология в здравоохранении: руководство для лабораторий уровня III).[6]

МЕТОДИКА

Предоставленные материалы. Пробирки **BBL MGIT** Mycobacteria Growth Indicator Tube, 4 мл, в упаковках по 25 и 100 пробирок или **BBL MGIT** OADC, 6 флаконов, 15 мл или смесь антибиотиков **BBL MGIT PANTA** antibiotic mixture, 6 лиофилизированных флаконов (см. раздел «Наличие»).

Непредоставленные материалы. Пробирки для центрифугирования **Falcon** 50 мл, 4 % раствор гидроксида натрия, 2,9 % раствор цитрата натрия, порошок N-ацетил-L-цистеина, фосфатный буфер с pH 6,8, вихревая мешалка, инкубатор с температурой 37 °C, стерильные пипетки 1 мл, стерильные пипетки без градуировки, УФ-трансиллюминатор (365 нм) или лампа Вуда с источником длинноволнового или ультрафиолетового излучения, 0,4 % раствор сульфита натрия (методика описана далее), агар Миддлбрука и Кона **BBL** Middlebrook and Cohn 7H10 Agar, **BBL MycoPrep**, бульон Миддлбрука **BBL** Middlebrook 7H9 Broth (см. раздел «Наличие») или другой микобактериальный агар или среда на яичной основе, гомогенизатор тканей или стерильный тампон, физиологический раствор **BBL** Normal Saline (см. раздел «Наличие»), штаммы ATCC № 27294, 12478, 6841, микроскоп и материалы для окрашивания на предметном стекле, пипетки 100 мкл и 500 мкл, соответствующие наконечники для пипеток, пластинка агара с 5 % овечьей крови, защитные очки (UVP № UVC-303, San Gabriel, CA) и дезинфицирующее средство, уничтожающее микобактерии туберкулеза.

Посев в пробирки MGIT.

1. Помечают пробирку **MGIT** номером образца.
2. Отвинчивают крышку и добавляют в пробирку 0,5 мл добавки **MGIT** OADC, соблюдая правила асептики.
3. Добавляют 0,1 мл восстановленной смеси антибиотиков **MGIT PANTA** antibiotic mixture, соблюдая правила асептики. Для достижения наилучших результатов добавление обогащающей добавки OADC и смеси антибиотиков **PANTA** antibiotic mixture необходимо выполнять непосредственно перед посевом образцов.
4. Добавляют 0,5 мл концентрированной суспензии образца, подготовленной, как описано выше. Добавляют также каплю (0,1 мл) образца на пластинку агара 7H10 или другого микобактериологического агара или среды на яичной основе. *ПРИМЕЧАНИЕ. Объемы образцов более 0,5 мл могут увеличить загрязнение или другим способом отрицательно повлиять на эффективность пробирок.*
5. Плотно завинчивают крышку пробирки и тщательно перемешивают смесь.
6. Помещают пробирки в инкубатор, поддерживающий температуру 37 °C.

   Для образцов с подозрениями на наличие микобактерий, требующих различных условий инкубации, можно подготовить вторую пробирку **MGIT** и инкубировать ее при соответствующей температуре, например 30 °C или 42 °C. Засеивают и инкубируют пробирку при требуемой температуре.

   Для образцов с подозрением на содержание *Mycobacterium haemophilum* в пробирку во время посева необходимо ввести источник гемина, а инкубацию осуществлять при температуре 30 °C. Соблюдая правила асептики, помещают одну полоску **BBL Taxo** X Factor Strip в каждую пробирку **MGIT**, требующую добавления гемина, перед посевом образцов (см. раздел «Наличие»).
7. Начиная со второго дня, ежедневно считывают показания пробирок, следуя инструкциям раздела «Считывание показаний пробирок» далее.

Подготовка интерпретативных контрольных пробирок с отрицательным и положительным результатами. Контрольные пробирки с положительным и отрицательным результатами используются только для интерпретации флуоресценции и не предназначены для контроля производительности среды.

Контрольная пробирка с положительным результатом.

1. Удаляют бульон из незасеянной пробирки **MGIT**.
2. Помечают пробирку как «положительный контроль» с указанием даты.
3. Готовят 0,4 % раствор сульфита натрия (0,4 г на 100 мл стерильной дистиллированной или деионизированной воды). Утилизируют неиспользованную часть.
4. Добавляют 5 мл раствора сульфита натрия в пробирку, плотно закрывают ее крышкой и оставляют как минимум на час при комнатной температуре перед использованием.
5. Контрольные пробирки с положительным результатом можно использовать несколько раз. Каждую контрольную пробирку с положительным результатом можно использовать до четырех недель в условиях хранения при комнатной температуре.

Контрольная пробирка с отрицательным результатом. В качестве контрольной пробирки используют неоткрытую и незасеянную пробирку **MGIT**.

Считывание показаний пробирок.

1. Контрольные пробирки с положительным и отрицательным результатами важны для правильной интерпретации результатов.
2. Извлекают пробирки из инкубатора. Помещают пробирки под УФ-излучение рядом с контрольной пробиркой с положительным результатом и незасеянной пробиркой (контрольной пробиркой с отрицательным результатом). Рекомендуется помещать под УФ-излучение по одному штативу пробирок (4 x 10 пробирок) за раз. *ПРИМЕЧАНИЕ. Наблюдая за флуоресценцией, надевайте очки, защищающие от УФ-излучения. В помещении следует использовать обычное комнатное освещение. Не считывайте показания пробирок при солнечном свете или в темноте*.
3. Визуально определяют пробирки **MGIT** с яркой флуоресценцией. Флуоресценция определяется как ярко-оранжевое свечение на дне пробирки, а также оранжевое отражение на мениске. Затем пробирку **MGIT** необходимо извлечь из штатива и сравнить с контрольными пробирками с положительным и отрицательным результатами. Контрольная пробирка с положительным результатом должна обнаруживать более яркую флуоресценцию (очень яркий оранжевый цвет). Контрольная пробирка с отрицательным результатом не проявляет флуоресценции, или эта флуоресценция очень слаба. Если флуоресценция в пробирке **MGIT** больше похожа на флуоресценцию в «положительной» контрольной пробирке, результат считается положительным. Если она больше похожа на флуоресценцию в «отрицательной» пробирке – результат отрицательный. Рост может быть также обнаружен по присутствию негомогенной мутности, мелких частиц или хлопьев в среде культуры.
4. Для пробирок с положительными результатами следует выполнить окрашивание на предмет кислотоустойчивых бацилл. Пробирки с мазками, показавшие отрицательные результаты, должны быть проверены на бактериальное загрязнение. Пересев для идентификации и проверки чувствительности к лекарствам можно выполнить, используя жидкость из пробирки **BBL MGIT**.
5. Ежедневное считывание показаний пробирок с отрицательными результатами необходимо продолжать в течение восьми недель или дольше в зависимости от типа образца и последующей работы лаборатории. Можно установить другой график считывания показаний. Пропуск чтения показаний пробирок в течение нескольких дней, например в выходные или праздники, может задержать определение пробирок с положительными результатами, однако других отрицательных воздействий на эффективность среды оказано не будет. Перед утилизацией пробирки необходимо осмотреть на наличие мутности, мелких частиц или гранул. Пробирки **MGIT** с отрицательными результатами нельзя использовать повторно. При подозрении на рост микобактерий выполняют процедуру обработки пробирки **MGIT** с положительным результатом, как описано далее.

Повторная обработка загрязненных пробирок MGIT. Загрязненные пробирки **MGIT** можно повторно деконтаминировать и восстановить их концентрацию, используя ту же процедуру, как и при первоначальной обработке образца.

1. Помещают содержимое загрязненной пробирки **MGIT** в пластиковую пробирку для центрифугирования объемом 50 мл.
2. Добавляют 5 мл раствора NALC-NaOH в пробирку для центрифугирования. Закрыв крышку, встряхивают пробирку в течение 5 – 20 с.
3. Оставляют пробирку стоять в течение 15 – 20 мин. Не оставляют ее дольше, чем на 20 мин.
4. Добавляют 35 мл стерильного фосфатного буферного раствора с pH 6,8. Закрывают крышкой и перемешивают содержимое.
5. Концентрируют образец в центрифуге при скорости 3000 x *g* в течение 15 мин.
6. Осторожно сливают всю надосадочную жидкость. Повторно суспендируют осадок, используя стерильную стеклянную пипетку с фосфатным буферным раствором с pH 6,8.
7. Засеивают 0,5 мл суспензии в новую пробирку **MGIT**.

Контроль качества. После получения новой поставки или партии пробирок **MGIT** рекомендуется подготовить суспензии контрольных микроорганизмов ATCC в бульоне Миддлбрука 7H9.

1. Для культур твердых сред возрастом менее 15 дней готовят суспензию в бульоне Миддлбрука 7H9.
2. Оставляют суспензию отстояться в течение 20 мин.
3. Сливают надосадочную жидкость в пустую стерильную пробирку и дают ей отстояться еще 15 мин.
4. Сливают надосадочную жидкость в другую пустую стерильную пробирку.
5. С помощью нефелометра добиваются мутности суспензии 0,5 по стандарту Макфарланда.
6. Разбавляют контрольные суспензии микроорганизмов в соответствии со схемой разбавления, приведенной в табл. 1.
7. Засеивают пробирки **MGIT**, следуя инструкциям раздела «Посев в пробирки **MGIT**».

В пробирках **MGIT** должна быть обнаружена флуоресценция в течение времени, указанного в табл. 1.

Таблица 1

Культура	Номер ATCC	Разбавление суспензии с мутностью 0,5 по стандарту Макфарланда в физиологическом растворе	Дней до проявления положительного результата
M. tuberculosis	**27294**	**1:50**	**6 – 10**
M. kansasii	12478	1:5000	7 – 11
M. fortuitum	6841	1:5000	2 – 3

К моменту обнаружения положительного результата в пробирке будет присутствовать около 10^4 – 10^7 КОЕ/мл микобактерий. Если хотя бы одна из пробирок **MGIT** для контроля качества не показала ожидаемого результата, не используйте оставшиеся пробирки, пока не свяжетесь с местным представителем компании BD.

РЕЗУЛЬТАТЫ

Образец с положительным результатом на культуру характеризуется наличием флуоресценции или негомогенной мутности, мелких частиц или хлопьев в засеянной пробирке **MGIT**. Следует пересеять содержимое «положительных» пробирок и подготовить мазки кислотоустойчивых штаммов. Положительный результат теста мазков кислотоустойчивых штаммов указывает на предположительное присутствие в пробирке жизнеспособных микроорганизмов.

Обработка «положительной» пробирки MGIT.

ПРИМЕЧАНИЕ. Все действия должны выполняться в биологическом защитном шкафу.

а) Извлекают пробирку **MGIT** из тестового штатива.

б) С помощью стерильной пипетки отбирают аликвоту со дна пробирки (около 0,1 мл) для окрашивания микропрепаратов (окрашивание кислотоустойчивых штаммов и окрашивание по Граму).

в) Исследуют мазок и препараты. Составляют отчет о предварительных результатах только после оценки окрашивания кислотоустойчивых штаммов.

Если окрашивание кислотоустойчивых штаммов дает положительный результат, выполняют пересев культуры на плотную среду и составляют отчет по следующей схеме: рост – положительно, окрашивание кислотоустойчивых штаммов – положительно, требуется идентификация.

При присутствии микроорганизмов, отличных от кислотоустойчивых штаммов, составляют отчет следующим образом: рост – положительно, окрашивание кислотоустойчивых штаммов – отрицательно, загрязнено.

В случае отсутствия микроорганизмов результат заносить в отчет не нужно. Пересевают бульон на пластинку агара с кровью и среду для микобактериальной культуры, повторяют мазок с добавлением белка, чтобы обеспечить необходимую фиксацию посевного материала на предметном стекле.

ОГРАНИЧЕНISS МЕТОДИКИ

Извлечение микобактерий в пробирке **MGIT** зависит от количества микроорганизмов, присутствующих в образце, от методов сбора образцов, от состояния пациента, например наличия симптомов заболевания, предыдущего лечения и способа обработки.

Рекомендуется выполнить деконтаминацию с помощью N-ацетил-L-цистеина и гидроксида натрия (NALC-NaOH) или методов с использованием щавелевой кислоты. Другие методы деконтаминации не тестировались со средой **BBL MGIT**. Растворы для ферментации и деконтаминации могут оказать отрицательное влияние на микобактерии.

Морфологию и пигментацию колонии можно определить только в плотной среде. Микобактерии могут различаться по кислотоустойчивости в зависимости от штамма, возраста культуры и других факторов. Четкая морфология микропрепаратов в среде **BBL MGIT** не установлена.

Содержимое пробирки **MGIT** с положительным результатом окрашивания кислотоустойчивых штаммов можно пересеять как в селективную, так и в неселективную микобактериальную среду для выделения в целях идентификации и проверки чувствительности.

Пробирки **MGIT** с положительными результатами могут содержать и другие (не микобактериальные) культуры. Культуры, отличные от микобактериальных, могут развиваться лучше присутствующих микобактерий. Пробирки **MGIT** с таким содержимым необходимо подвергнуть деконтаминации и пересеву.

Пробирки **MGIT** с положительными результатами могут содержать один или несколько видов микобактерий. Микобактерии с более высокой скоростью роста могут вызывать положительную флуоресценцию до ее вызова более медленно растущими микобактериями, поэтому важно выполнить пересев содержимого «положительных» пробирок **MGIT** для обеспечения надлежащей идентификации всех микобактерий, присутствующих в образце.

Объемы образцов более 0,5 мл могут увеличить загрязнение или другим способом отрицательно повлиять на эффективность пробирок **MGIT**.

Из-за насыщенности бульона **MGIT** и неселективной природы индикатора **MGIT** важно выполнять указанную процедуру ферментации и деконтаминации во избежание загрязнения. Для оптимального выделения микобактерий необходимо строго соблюдать инструкции методики.

Использование смеси антибиотиков **PANTA** antibiotic mixture является обязательным для всех нестерильных образцов, однако она может оказать ингибирующее действие на некоторые микобактерии.

Во время клинических исследований заключительные пересевы не выполнялись регулярно. Таким образом, действительный уровень ложных отрицательных результатов (определяемых как пробирки **MGIT**, оставшиеся «отрицательными» в течение всего восьминедельного периода инкубации, подвергшиеся пересеву и обнаружившие рост микобактерий) в это время определить невозможно.

Исследования засеянных культур были проведены для двадцати трех видов (ATCC и диких штаммов) микобактерий с уровнями посева от 10^3 до 10^5 КОЕ/мл. В пробирке **MGIT** обнаружены положительные результаты для следующих видов:

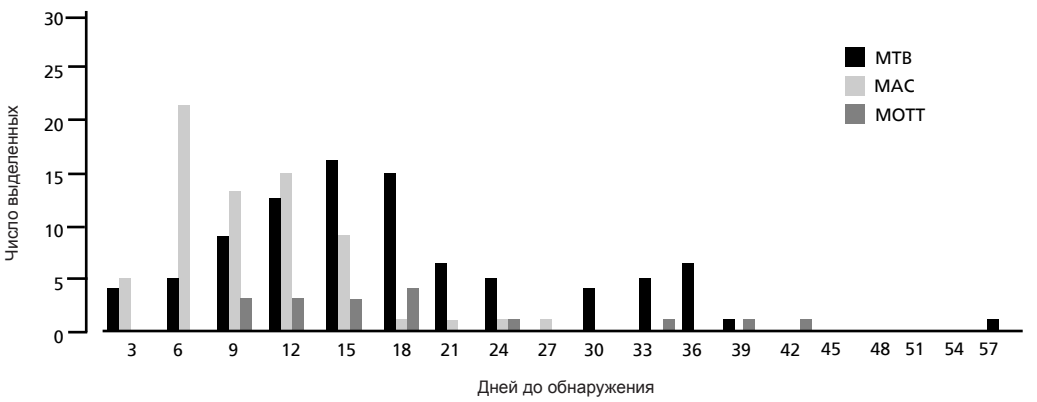
M. africanum	*M. gordonae**	*M. nonchromogenicum*	*M. terrae*
M. avium комплекс*	*M. haemophilum*	*M. phlei*	*M. triviale*
*M. chelonae**	*M. intracellulare*	*M. scrofulaceum*	*M. tuberculosis**
*M. flavescens**	*M. kansasii**	*M. simiae**	*M. vaccae*
*M. fortuitum**	*M. malmoense*	*M. smegmatis*	*M. xenopi**
M. gastri	*M. marinum*	*M. szulgai*	

*Бактерии, выделенные во время клинической оценки пробирки **MGIT**.

Клинические исследования подтвердили выделение микобактерий в образцах из дыхательных путей, желудочных аспиратов, тканей, стула и стерильных биологических жидкостей за исключением крови. Выделения микобактерий из других биологических жидкостей для данного продукта не было обнаружено.

ОЖИДАЕМЫЕ РЕЗУЛЬТАТЫ

1. Частотное распределение времени выделения «положительных» образцов в ходе клинического испытания системы BBL MGIT показано на следующем рисунке.



КОНКРЕТНЫЕ РАБОЧИЕ ХАРАКТЕРИСТИКИ

Пробирки **BBL MGIT** Mycobacteria Growth Indicator Tube испытаны в шести клинических учреждениях, в число которых входили как медицинские лаборатории, так и крупные медицинские учреждения интенсивной терапии в различных географических регионах. Популяционная выборка учреждения включала пациентов, зараженных ВИЧ, пациентов с ослабленным иммунитетом и пациентов, перенесших пересадку органов. Пробирки **BBL MGIT** подвергались сравнению с радиометрической системой **BACTEC** 460TB, системой **BBL SEPTI-CHEK** для исследования микобактериальных кислотоустойчивых культур и с традиционными плотными средами для выращивания культур с целью определения и выделения микобактерий из клинических образцов (за исключением крови и мочи). В ходе исследования был протестирован 2801 образец. По источникам взятые образцы распределяются следующим образом: дыхательные пути (78 %), желудок (0,4 %), биологические жидкости (9,8 %), ткани (7,0 %), стул (2,5 %) и другие источники (2,4 %). 318 образцов, представленных 330 выделенными изолятами, в ходе исследования дали положительные результаты. Из этих 330 изолятов 253 (77 %) были выделены в пробирках **BBL MGIT**, 260 (79 %) – в системах **BACTEC** 460TB и **BBL SEPTI-CHEK** AFB и 219 (66 %) – в традиционных плотных средах. В пробирках **BBL MGIT** обнаружено 0,5 % ложных положительных результатов (флуоресценция **MGIT** при отсутствии кислотоустойчивых бацилл). В пробирках **BBL MGIT** не удалось выделить 3,7 % изолятов, которые были выделены в одной или нескольких эталонных системах (**BACTEC** 460TB, **BBL SEPTI-CHEK** AFB или традиционных плотных средах). Несмотря на то, что это значение представляет потенциальную потерю выделения, оно не является показателем действительного ложного отрицательного определения (см. раздел «Ограничения методики»). Использование второй среды в соответствии с рекомендациями повышает вероятность выделения микобактерий. Средняя частота проникновения загрязнения для пробирок **BBL MGIT** составила 9,7 %.

УЧРЕЖДЕНИЯ BACTEC

Таблица 2. Обнаружение «положительных» изолятов микобактерий в клинических исследованиях

Изолят	Всего изолятов	Всего MGIT	Только MGIT	Всего BACTEC	Только BACTEC	Всего традиционных	Только традиционные
MTB	113	91	2	98	7	92	6
MAC	99	76	9	86	13	57	3
M. kansasii	5	2	0	5	1	4	0
M. fortuitum	9	5	3	3	1	5	3
M. chelonae	2	0	0	2	1	1	0
M. xenopi	2	0	0	2	2	0	0
M. simiae	1	1	0	1	0	0	0
M. gordonae	11	4	1	4	1	9	5
M. flavescens	2	1	0	2	1	0	0
Все микобактерии	244*	180*	15*	203	27	168	17

ПРИМЕЧАНИЕ. В эти данные не включены 14 изолятов, исследованных ТОЛЬКО в пробирках **MGIT**. Предположительная идентификация была выполнена без окончательного подтверждения идентификации.

УЧРЕЖДЕНИЯ SEPTI-CHEK

Таблица 3. Обнаружение «положительных» изолятов микобактерий в клинических исследованиях

Изолят	Всего изолятов	Всего MGIT	Только MGIT	Всего SEPTI-CHEK	Только SEPTI-CHEK	Всего традиционных	Только традиционные
MTB	30	25	1	29	2	26	0
MAC	34	26	5	28	2	25	0
M. kansasii	1	1	1	0	0	0	0
M. gordonae	2	2	2	0	0	0	0
Все микобактерии	67*	54*	9*	57	4	51	0

ПРИМЕЧАНИЕ. В эти данные не включены 5 изолятов, исследованных ТОЛЬКО в пробирках **MGIT**. Предположительная идентификация была выполнена без окончательного подтверждения идентификации.

НАЛИЧИЕ

№ по кат.	Описание
245111	**BBL MGIT** Mycobacteria Growth Indicator Tubes, 4 мл, 25 пробирок в картонной упаковке.
245113	**BBL MGIT** Mycobacteria Growth Indicator Tubes, 4 мл, 100 пробирок в картонной упаковке.
245116	**BBL MGIT** OADC, 15 мл, 6 флаконов в картонной упаковке. Содержимого каждого флакона достаточно для 25 пробирок **MGIT**.
220908	**BBL** Lowenstein-Jensen Medium Slants, 10 шт. в упаковке (пробирки 20 x 148 мм с крышками).
220909	**BBL** Lowenstein-Jensen Medium Slants, 100 шт. в картонной упаковке (пробирки 20 x 148 мм с крышками).
240862	**BBL MycoPrep** Specimen Digestion/Decontamination Kit, 10 флаконов по 75 мл с раствором NALC-NaOH и 5 упаковок фосфатного буфера.
240863	**BBL MycoPrep** Specimen Digestion/Decontamination Kit, 10 флаконов по 150 мл с раствором NALC-NaOH и 10 упаковок фосфатного буфера.
245114	**BBL MGIT PANTA** antibiotic mixture, лиофилизированная, 6 флаконов в картонной упаковке. Содержимого каждого флакона достаточно для 25 пробирок **MGIT**.
220959	**BBL** Middlebrook and Cohn 7H10 Agar Slants, 100 шт. в упаковке.
295939	**BBL** Middlebrook 7H9 Broth, 8 мл, 10 пробирок в упаковке.
221818	**BBL** Normal Saline, 5 мл, 10 шт. в упаковке.
221819	**BBL** Normal Saline, 5 мл, 100 шт. в картонной упаковке.
231106	**BBL Taxo** X Factor Strips, 1 флакон, 50 полосок.

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Use by / Spotřebujte do / Anvendes før / Houdbaar tot / Kasutada enne / Viimeinkäyttöpäivä / A utiliser avant / Verwendbar bis / Ημερομηία λήξης / Felhasználhatóság dátuma / Usare entro / Naudokite iki / Brukes før / Stosować do / Utilizar em / Použite do / Usar antes de / Använd före / Използвайте до / A se utiliza până la / Son kullanma tarihi / Upotrebiti do / Использовать до
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RRRR-MM-DD / RRRR-MM (MM = konec měsíce)
ÅÅÅÅ-MM-DD / ÅÅÅÅ-MM (MM = slutning af måned) /
JJJJ-MM-DD / JJJJ-MM (MM = einde maand)
AAAA-KK-PP / AAAA-KK (KK = kuu lõpp)
VVVV-KK-PP / VVVV-KK (kuukauden loppuun mennessä)
AAAA-MM-JJ / AAAA-MM (MM = fin du mois) /
JJJJ-MM-TT / JJJJ-MM (MM = Monatsende) /
EEEE-MM-HH / EEEE-MM (MM = τέλος του μήνα) /
ÉÉÉÉ-HH-NN / ÉÉÉÉ-HH (HH = hónap utolsó napja)
AAAA-MM-GG / AAAA-MM (MM = fine mese) /
MMMM-MM-DD / MMMM-MM (MM = ménesio pabaiga)
ÅÅÅÅ-MM-DD / ÅÅÅÅ-MM (MM = slutten av måneden)
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AAAA-MM-DD / AAAA-MM (MM = fim do mês) /
RRRR-MM-DD / RRRR-MM (MM = koniec mesiaca)
aaaa-mm-dd / aaaa-mm (mm = fin del mes) /
ÅÅÅÅ-MM-DD / ÅÅÅÅ-MM (MM = slutet på månaden) /
ГГГГ-ММ-ДД / ГГГГ-ММ (ММ = края на месеца) /
AAAA-LL-ZZ / AAAA-LL (LL = sfârşitul lunii) /
YYYY-AA-GG / YYYY-AA (AA = ayın sonu) /
GGGG-MM-DD / GGGG-MM (MM = kraj meseca) /
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IVD

In Vitro Diagnostic Medical Device / Lékařské zařízení určené pro diagnostiku in vitro / In vitro diagnostisk medicinsk anordning / Medisch hulpmiddel voor in vitro diagnose / In vitro diagnostika meditsiiniaparatuur / Lääkinnällinen in vitro -diagnostiikkalaite / Dispositif médical de diagnostic in vitro / Medizinisches In-vitro-Diagnostikum / In vitro διαγνωστική ιατρική συσκευή / In vitro diagnosztikai orvosi eszköz / Dispositivo medico diagnostico in vitro. / In vitro diagnostikos prietaisas / In vitro diagnostisk medisinsk utstyr / Urządzenie medyczne do diagnostyki in vitro / Dispositivo médico para diagnóstico in vitro / Medicínska pomôcka na diagnostiku in vitro / Dispositivo médico de diagnóstico in vitro / Medicinsk anordning för in vitro-diagnostik / Медицински уред за диагностика ин витро / Aparatură medicală de diagnosticare in vitro / In Vitro Diyagnostik Tıbbi Cihaz / Medicinski uređaj za in vitro dijagnostiku / Медицинский прибор для диагностики in vitro

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BACTEC™ MGIT™ 960 PZA Kit
For the Antimycobacterial Susceptibility Testing of *Mycobacterium tuberculosis*

I. INTENDED USE

The **BACTEC™ MGIT™** 960 PZA Kit is used as a rapid qualitative procedure for susceptibility testing of *Mycobacterium tuberculosis*, from culture, to pyrazinamide (PZA).The **BACTEC MGIT** 960 PZA Kit is used with the **BACTEC MGIT** 960 System.

II. SUMMARY AND EXPLANATION

Antimycobacterial susceptibility testing is necessary for the proper treatment of patients with tuberculosis. The treatment of tuberculosis is commonly through a multiple drug regimen that includes the antimycobacterial drug pyrazinamide. It is important that the antimycobacterial drug prescribed shows appropriate activity against *Mycobacterium tuberculosis*, i.e., susceptibility of the isolate to the drug.

Multidrug resistant *Mycobacterium tuberculosis* (MDR-TB) has recently become a serious public health problem.[1] Resistance to any of the primary drugs, including pyrazinamide, makes the disease more difficult and expensive to treat. The rapid detection of these resistant isolates is critical to the effective patient management.

Two methods have been widely used for antimycobacterial susceptibility testing. The first method, known as the Method of Proportion,[2] uses Middlebrook and Cohn 7H10 Agar. It compares colony counts on drug-containing and drug-free media. The testing for pyrazinamide requires some modification from the general methods because the drug is active *in vitro* only at lower pH values.[3] A modification to the method of proportion method was developed using a 7H10 agar medium at pH 5.5, with a drug concentration of 25-50 µg/mL.[4] A limitation of the method is that at a pH of 5.5, many isolates of *M. tuberculosis* either fail to grow or grow poorly. Agar-based methods such as the agar proportion method have not proven to be satisfactory for PZA susceptibility testing because of failure of many isolates to grow when the agar has been acidified for the PZA test.

The second method, known as the **BACTEC** 460TB radiometric susceptibility method,[5] is based on the production of radioactive ^{14}C-labeled carbon dioxide by the growing mycobacteria, manifested by a Growth Index increase in the system. A modification to the **BACTEC** 460TB susceptibility method was developed using a modified 7H12 radiometric medium, **BACTEC** PZA Test Medium, with a reduced pH of 6.0.[6] At this pH, PZA activity against mycobacteria can be determined without inhibiting the growth of most *M. tuberculosis* isolates. The **BACTEC** 460TB PZA susceptibility test uses a pyrazinamide drug concentraton of 100 µg/mL. Susceptibility testing in the **BACTEC** 460TB System has proven to be satisfactory and is presently considered the reference method for PZA susceptibility testing. The National Committee for Clinical Laboratory Standards (NCCLS) recommends the **BACTEC** 460TB method for PZA susceptibility testing.[2]

Use of the **BACTEC MGIT** 960 System in combination with the **BACTEC MGIT** 960 PZA kit is a non-radiometric method of determining antimycobacterial susceptibility to PZA. The **BACTEC MGIT** 960 PZA Kit has been developed to allow susceptibility testing at a PZA concentration of 100 µg/mL. This concentration correlates with the concentration used in the **BACTEC** 460TB System.

III. PRINCIPLES OF THE PROCEDURE

BACTEC MGIT 960 PZA Medium is a tube containing a modified Middlebrook 7H9 Broth, which supports the growth and detection of mycobacteria at a reduced pH of 5.9. The **MGIT** 960 PZA Medium tube contains a fluorescent compound embedded in silicone on the bottom of a 16 x 100 mm round-bottom tube. The fluorescent compound is sensitive to the presence of oxygen dissolved in the broth. The initial concentration of dissolved oxygen quenches the emission from the compound, and little fluorescence can be detected. Later, actively growing and respiring microorganisms consume the oxygen, which allows the compound to fluoresce.

The **BACTEC MGIT** 960 PZA Kit is a 4 – 21 day qualitative test. The test is based on growth of the *M. tuberculosis* isolate in a drug-containing tube compared to a drug-free tube (Growth Control). The **BACTEC MGIT** 960 instrument continually monitors tubes for increased fluorescence. Analysis of fluorescence in the drug-containing tube compared to the fluorescence of the Growth Control tube is used by the instrument to determine susceptibility results.

The **BACTEC MGIT** 960 instrument automatically interprets these results and reports a susceptible or resistant result.

IV. REAGENTS

The **BACTEC MGIT** PZA Medium contains 110 µL of fluorescent indicator and 7 mL of PZA broth. The indicator contains Tris 4, 7-diphenyl-1, 10 phenanthroline ruthenium chloride pentahydrate in a silicone rubber base. The tubes are capped with a polypropylene cap. The pH is adjusted to 5.9.

Approximate Formula* Per L of Purified Water:

Modified Middlebrook 7H9 broth	5.9 g
Casein peptone	1.25 g

BACTEC MGIT 960 PZA Kit contains two lyophilized vials of pyrazinamide and six vials of PZA Supplement.

Approximate Formula* Per Vial Lyophilized drug:

Pyrazinamide	20,000 µg

BACTEC MGIT 960 PZA Supplement contains 15 mL of enrichment

Approximate Formula* Per L 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

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

Storage and reconstitution of reagents:

BACTEC MGIT 960 PZA Medium - On receipt, store at 2 – 25ºC. DO NOT FREEZE. Broth should appear clear and colorless. Do not use if turbid. Minimize exposure to light. Tubes stored as labeled prior to use, may be inoculated up to the expiration date.

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

BACTEC MGIT 960 PZA Supplement – On receipt, store in dark at 2 – 8°C. Avoid freezing or overheating. Open and use prior to the expiration date. Minimize exposure to light.

Directions For Use:

Reconstitute each **BACTEC MGIT** 960 PZA lyophilized drug vial with **2.5 mL** of sterile distilled/deionized water to make a stock solution of 8000 µg/mL.

Warnings and Precautions: For *in vitro* Diagnostic Use.

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

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

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

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

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

Autoclave all inoculated **MGIT** tubes prior to disposal.

V. SPECIMEN PREPARATION

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

Preparation of the Isolate from Solid Media:

1. Add 4 mL of **BBL** Middlebrook 7H9 Broth (or **BBL MGIT** broth) to a 16.5 x 128 mm sterile tube with cap containing 8–10 glass beads.
2. Scrape with a sterile loop as many colonies as possible from growth no more than fourteen days old, trying not to remove any solid medium. Suspend the colonies in the Middlebrook 7H9 Broth.
3. Vortex the suspension for 2–3 minutes to break up the larger clumps. The suspension should exceed a 1.0 McFarland standard in turbidity.
4. Let the suspension sit for 20 min without disturbing.
5. Transfer the supernatant fluid to another 16.5 x 128 mm sterile tube with cap (avoid transferring any of the sediment) and let sit for another 15 min.
6. Transfer the supernatant fluid (it should be smooth, free of any clumps) to a third 16.5 x 128 mm sterile tube. NOTE: The organism suspension should be greater than a 0.5 McFarland standard at this step.
7. Adjust the suspension to a 0.5 McFarland standard by visual comparison to a 0.5 McFarland turbidity standard. Do not adjust below a 0.5 McFarland standard.
8. Dilute 1 mL of the adjusted suspension in 4 mL of sterile saline (1:5 dilution). Use this as the AST inoculum and proceed to "Inoculation Procedure for **BACTEC MGIT** 960 PZA Susceptibility Test."

Preparation from a Positive BACTEC MGlT Tube:

1. The first day of an instrument positive **BACTEC MGIT** tube is considered Day 0.
2. For the preparation of the test inoculum, a positive 7 mL **MGIT** tube should be used the day **after** it first becomes positive on the **BACTEC MGIT** 960 instrument (Day 1), up to and including the fifth day (Day 5) after instrument positivity. A tube which has been positive longer than five days should be subcultured to a fresh 7 mL **MGIT** tube containing **BACTEC MGIT** 960 Growth Supplement and tested on the **BACTEC MGIT** 960 instrument until positive, and used from one to five days following positivity.
3. If the tube is a Day 1 or Day 2 positive, no dilution is required. Use this as the AST inoculum and proceed to "Inoculation Procedure for **BACTEC MGIT** 960 PZA Susceptibility Test."
4. If the tube is a Day 3, Day 4, or Day 5 positive, then dilute 1 mL of the positive broth in 4 mL of sterile saline (1:5 dilution). Use this as the AST inoculum and proceed to "Inoculation Procedure for **BACTEC MGIT** 960 PZA Susceptibility Test."

VI. PROCEDURE

Materials Provided: **BACTEC MGIT** 960 PZA Kit containing two vials each lyophilized drug and six vials of PZA Supplement (approximately 50 tests per kit).

Materials Required But Not Provided: **BACTEC MGIT** 960 PZA Medium (25 tubes per carton), ancillary culture media, reagents, quality control organisms and laboratory equipment as required for this procedure.

Inoculation Procedure for BACTEC MGIT 960 PZA Susceptibility Test:

Important considerations when preparing the PZA AST Set are the proper reconstitution of the lyophilized drug, use of pure culture and the proper dilution of the organism for the Growth Control and PZA tube. It is important to add drug only to the corresponding **MGIT** tube labeled "PZA". Use only the **MGIT** 960 PZA supplement supplied with the kit and **MGIT** 960 PZA Medium tubes when performing the PZA AST set.

1. Label two 7 mL **MGIT** 960 PZA Medium tubes for each test isolate. Label one as GC (Growth Control), one as PZA. Place the tubes in the correct sequence in the two tube AST set carrier (see **BACTEC MGIT** 960 User's Manual, AST Instructions).
2. Aseptically add 0.8 mL of **BACTEC MGIT** 960 PZA Supplement to each tube.
3. Using a micropipet, aseptically pipet 100 µL of 8000 µg/mL **BACTEC MGIT** 960 PZA drug solution to the appropriately labeled **MGIT** PZA tube. No PZA drug solution should be added to the **MGIT** GC tube.

Drug	Concentration of Drug after Reconstitution*	Volume Added to MGIT Tubes for Test	Final Concentration in MGIT Tubes
MGIT PZA	8000 µg/mL	100 µL	100 µg/mL*

*PZA must be reconstituted using **2.5 mL** sterile/deionized water to achieve the concentration indicated.

4. **Growth Control tube preparation and inoculation**: Aseptically pipet 0.5 mL of the AST inoculum (see "SPECIMEN PREPARATION") into 4.5 mL of sterile saline to prepare the **1:10** Growth Control suspension. Mix the Growth Control suspension thoroughly. Inoculate 0.5 mL of the **1:10** Growth Control suspension into the **MGIT** tube labeled "GC."

   NOTE: It is important to use an appropriately prepared **1:10** dilution for the "GC" tube to ensure accurate AST results and avoid PZA AST set errors.
5. **Drug-containing tube inoculation**: Aseptically pipet 0.5 mL of the AST inoculum (see "SPECIMEN PREPARATION") into the **MGIT** tube labeled "PZA".
6. Tightly recap the tubes. Mix tubes thoroughly by gentle inversion three to four times.
7. Enter the PZA set into the **BACTEC MGIT** 960 instrument using the AST set entry feature (refer to the **BACTEC MGIT** 960 User's Manual, AST Instructions). Ensure that the Growth Control tube is in the first left tube position. Select PZA as the drug in the 2 tube AST set carrier definition when performing the AST set entry.
8. Streak 0.1 mL of the organism suspension to a **Trypticase**™ Soy Agar with 5% Sheep Blood (TSA II) plate. Enclose in a plastic bag. Incubate at 35 – 37°C.
9. Check the blood agar plate at 48 h for bacterial contamination. If the blood agar plate shows no growth, then allow PZA testing to proceed. If the blood agar plate shows growth, discard the PZA set (refer to the **BACTEC MGIT** 960 User's Manual, AST Instructions) and repeat testing with a pure culture of *Mycobacterium tuberculosis*.

VII USER QUALITY CONTROL

Upon receipt of a new shipment or lot number of **BACTEC MGIT** 960 PZA Kit vials or **BACTEC MGIT** PZA Medium, it is recommended that the control organism shown below be tested. The control organism should be a pure culture and the culture should be prepared according to "SPECIMEN PREPARATION" instructions.

The quality control (QC) AST Set should be prepared according to the "Inoculation Procedure for **BACTEC MGIT** 960 PZA Susceptiblity Test" instructions. Important considerations when preparing the QC AST Set are the proper reconstitution of the lyophilized drug, use of pure culture and the proper dilution of the QC organism for the Growth Control and PZA tubes. It is important to add drug only to the corresponding **MGIT** tube labeled "PZA".

The same control organism should be run as batch QC once each week when susceptibility testing is performed. Observation of the proper results, as shown below, within 4 - 20 days indicates that the **BACTEC MGIT** 960 PZA reagents are ready for use in testing patient isolates.

If the proper results are not observed, do not report patient results. Repeat QC and any patient isolates affected by the initial QC failure. If the repeat QC does not perform as expected, do not report patient results. Do not use the product until you have contacted Technical Services at (800) 638-8663 (United States Only).

Strain	GC	MGIT PZA
M. tuberculosis ATCC™ 27294	Positive	Susceptible

During the external evaluation of the **BACTEC MGIT** 960 PZA Kit the average time to result for the control organism was seven days with a range of four to eleven days. The most common causes of QC failures during the external evaluation were over-inoculated PZA Sets and contaminated QC cultures.

VIII. RESULTS

The **BACTEC MGIT** 960 instrument will monitor AST sets until a susceptible or resistant determination is made. Once the set testing is completed, the results are reported by the **BACTEC MGIT** 960 instrument (refer to the **BACTEC MGIT** 960 User's Manual, AST Instructions). The **BACTEC MGIT** 960 instrument will report an AST Set result as an Error ("X"), no susceptibility interpretation, when certain conditions occur that may affect the test results. Conditions that may result in an Error ("X") result are described in the AST Instructions,
Section 6 – Troubleshooting of the **BACTEC MGIT** 960 User's Manual.

It is important to include the test method, drug name and concentration when reporting results. The Pulmonary and/or Infectious Disease specialist in TB control should be consulted concerning the appropriate therapeutic regimen and dosages.

Mono-resistance to pyrazinamide is uncommon, therefore in the event of unexpected resistant results, verify purity and identification of the isolate tested as *M. tuberculosis.* Guidelines for mycobacterial purity checks can be found in the NCCLS M24 standard.[2]

BACTEC MGIT 960 PZA result reporting

Drug (concentration)	MGIT 960 result	Recommended Report	Action
PZA (100 µg/mL)	Susceptible	Isolate tested with **BACTEC MGIT** 960 [PZA/100 µg/mL] and result is susceptible.	No action.
	Resistant	Isolate tested with **BACTEC MGIT** 960 [PZA/100 µg/mL] and result is resistant.	If isolate is mono-resistant to PZA, confirm that isolate tested is a pure culture of *Mycobacterium tuberculosis.*
	Error "X"	No report.	Repeat test.

IX. LIMITATIONS OF THE PROCEDURE

The **BACTEC MGIT** 960 PZA susceptibility test does not interpret the degree of susceptibility of the isolate being tested. Results are reported as either susceptible or resistant.

The **BACTEC MGIT** 960 PZA susceptibility test can only be performed using the **BACTEC MGIT** 960 instrument. The PZA Sets cannot be read manually.

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

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

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

Failure to use a 1:10 dilution of the organism suspension for the inoculation of the Growth Control tube may give inaccurate results or cause an AST Set error.

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

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

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

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

Failure to use the **BACTEC MGIT** 960 PZA Supplement in the PZA AST set may give inaccurate results. DO NOT add **BACTEC MGIT** 960 SIRE Supplement or **BACTEC MGIT** 960 Growth Supplement to the PZA AST set.

Failure to use **BACTEC MGIT** PZA Medium for the PZA AST set may give inaccurate results. DO NOT substitute **BBL MGIT** 7 mL Mycobacteria Growth Indicator Tubes for **BACTEC MGIT** PZA Medium.

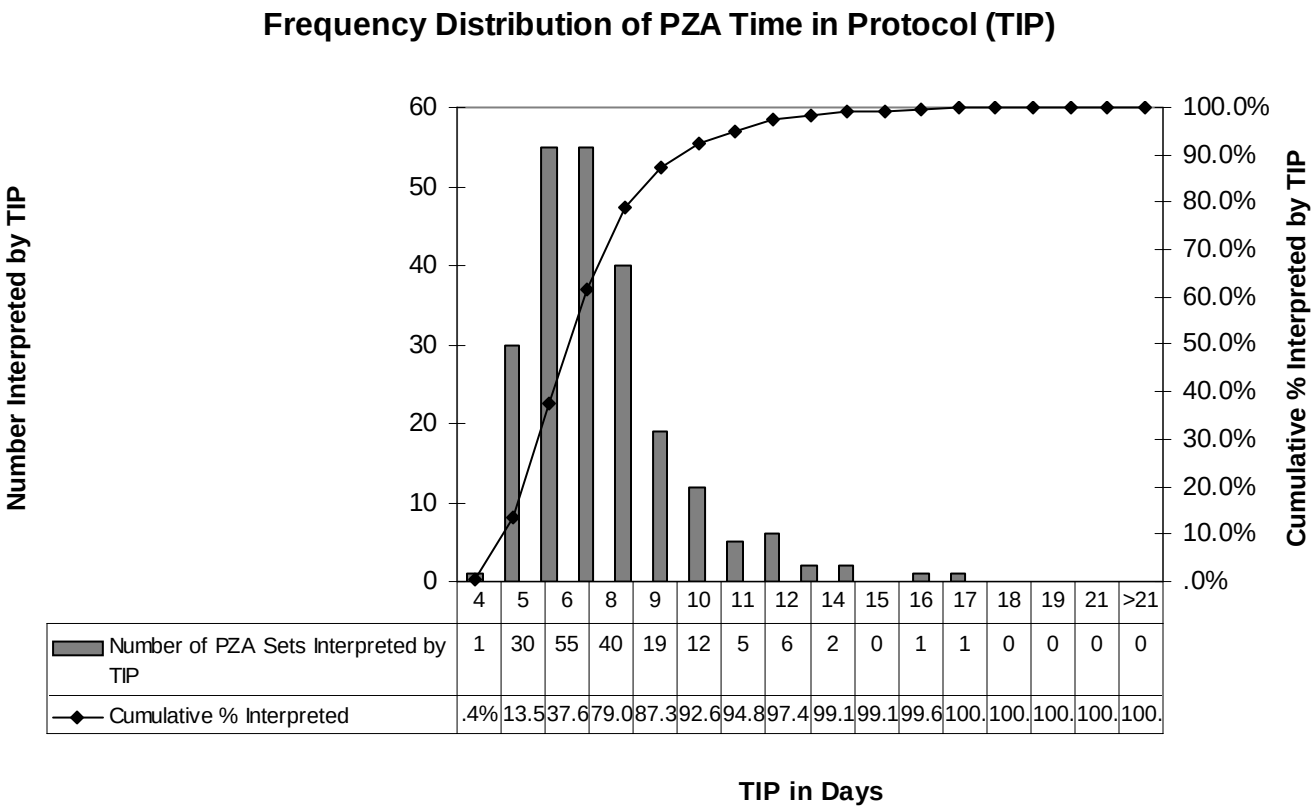
X. EXPECTED VALUES

A total of 118 clinical isolates of *M. tuberculosis* were tested with the **BACTEC MGIT** 960 PZA susceptibility test at four geographically diverse sites. The testing included both fresh clinical and subcultured isolates from both liquid and solid culture sources. A total of 228 PZA susceptibility tests (liquid and solid) were performed.

During the external evaluation of the **BACTEC MGIT** 960 PZA Kit, there were nine PZA tests from clinical trial isolates that required repeat testing due to contamination (six isolates) or over-inoculation/procedural errors (three isolates).

The average time-to-result for the **BACTEC MGIT** 960 PZA susceptibility test is seven days with a range from four to seventeen days. The data are shown in Figure 1.

Figure 1: Distribution of **BACTEC MGIT** 960 PZA AST Time to Result



TIP	4	5	6	8	9	10	11	12	14	15	16	17	18	19	21	>21
Number of PZA Sets Interpreted by TIP	1	30	55	40	19	12	5	6	2	0	1	1	0	0	0	0
Cumulative % Interpreted	.4%	13.5	37.6	79.0	87.3	92.6	94.8	97.4	99.1	99.1	99.6	100.	100.	100.	100.	100.

XI. PERFORMANCE CHARACTERISTICS

Analytical Studies

Liquid and Solid Media AST Inoculum Ranges:

Liquid media - The recommended procedure for preparing a PZA Set from a positive **MGIT** 7 mL tube uses a direct inoculum on Day 1 and Day 2 post-positivity and a dilute (1:5) inoculum on Day 3 to Day 5 post-positivity. Internal studies show that inocula prepared from a Day 1 to Day 5 positive **MGIT** 7 mL tube range between 2.0×10^4 to 7.5×10^6 CFU/mL.

Solid media - The recommended procedure for preparing a PZA Set from growth on solid media (up to 14 days after first visible growth is seen) uses a 1:5 dilution of an organism suspension equivalent to a 0.5 McFarland Standard. Internal studies show that inocula prepared from solid medium culture range between 2.1×10^5 to 3.9×10^6 CFU/mL.

Lot Reproducibility:

Lot reproducibility was evaluated using twenty-five *M. tuberculosi*s strains (including three ATCC™ strains). Each strain was tested in triplicate with the **BACTEC MGIT** 960 PZA susceptibility test. Each replicate represented a separate test condition differentiated by lot of PZA drug, PZA Supplement and PZA medium used (three lots each).

Observed results were compared to the expected results. The overall reproducibility for the **BACTEC MGIT** 960 PZA susceptibility test is 96.8%.

CDC Challenge Panel Testing:

The performance of the **BACTEC MGIT** 960 PZA susceptibility test was evaluated using a panel of challenge strains obtained from the Centers for Disease Control and Prevention (CDC), Atlanta, GA, USA. The panel consisted of nine strains of *M. tuberculosis* with known susceptibility patterns (using **BACTEC** 460TB). The panel was tested in triplicate with the **BACTEC MGIT** 960 PZA susceptibility test. The **BACTEC MGIT** 960 PZA results were compared to the CDC expected results. The overall agreement with CDC expected results for the **BACTEC MGIT** 960 PZA test is 98.7%.

Clinical Evaluation

The **BACTEC MGIT** 960 PZA susceptibility test was evaluated at four geographically diverse clinical sites composed of regional reference centers and university hospital-based laboratories, including two ex-US sites. The **BACTEC MGIT** 960 PZA susceptibility test was compared to the **BACTEC** 460TB PZA susceptibility test method.

Reproducibility Testing:

The reproducibility of the **BACTEC MGIT** 960 PZA susceptibility test was evaluated at the clinical sites using a panel of five qualified strains. The **BACTEC MGIT** 960 PZA test results were compared to the expected results. The overall reproducibility for the **BACTEC MGIT** 960 PZA susceptibility test is 94%.

CDC Challenge Panel Testing:

The performance of the **BACTEC MGIT** 960 PZA susceptibility test was evaluated at each of the four clinical sites using a panel of challenge strains obtained from the Centers for Disease Control and Prevention (CDC), Atlanta, GA, USA. The panel consisted of nine strains of *M. tuberculosis* with known susceptibility patterns (using **BACTEC** 460TB). Of the thirty-six PZA results collected with the **BACTEC MGIT** 960 PZA susceptibility test, thirty-three agreed with the CDC expected results. The calculated percent agreement to the CDC expected results for the **BACTEC MGIT** 960 PZA susceptibility test is 91.7%.

Clinical Isolate Testing:

A total of 118 clinical isolates of *M. tuberculosis* were tested with the **BACTEC MGIT** 960 PZA susceptibility test and the **BACTEC** 460TB PZA susceptibility test. This included testing of both fresh clinical and subcultured isolates from both liquid and solid culture sources. This generated a total of 228 test results.

Table 1 presents the results from clinical isolate testing for PZA drug at 100 µg/mL from liquid source cultures, from solid source cultures and both source cultures combined.

Table 1: Clinical Isolate Results – BACTEC MGIT 960 PZA test Compared to BACTEC 460TB test

		BACTEC 460TB System		BACTEC MGIT 960 System			
		Expected PZA Results		Susceptible Results		Resistant Results	
Source	# Tests	S	R	# agree	Category agreement % (95% CI)	# agree	Category agreement % (95% CI)
LIQUID	112	89	23	88	98.9% (93.9-100)	22	95.7% (78.1-99.9)
SOLID	113*	90	23	88	97.8% (92.2-99.7)	20	87.0% (66.4-97.2)
ALL	225*	179	46	176	98.3% (95.2-99.7)	42	91.3% (79.2-97.6)

*Three **BACTEC** 460TB borderline results are not included in this table.

All isolates with discordant **BACTEC MGIT** 960 PZA results were tested using the **BACTEC** 460TB PZA susceptibility test at two independent sites. Discordant results were those strains where the **BACTEC MGIT** 960 PZA result differed from the **BACTEC** 460TB PZA result. Borderline results are not included in the performance calculations for the **BACTEC MGIT** 960 PZA Kit.

Of the four discordant PZA susceptible (S-**MGIT** 960, R-**BACTEC** 460TB) isolates tested, one had susceptible results from both independent sites and the other three had resistant results from both independent sites. Of the three discordant PZA resistant (R-**MGIT** 960, S-**BACTEC** 460TB) isolates tested, all isolates had susceptible results from both independent sites.

Two of the three **BACTEC** 460TB borderline PZA results (S-**MGIT** 960, B-**BACTEC** 460TB) had susceptible results from both independent sites. One of the three **BACTEC** 460TB borderline PZA results (R-**MGIT** 960, B-**BACTEC** 460TB) had one independent site determine a susceptible result. The other independent site determined a borderline result.

XII. AVAILABILITY

Cat. No.	Description
245128	**BACTEC™ MGIT™** 960 PZA Kit, carton of 2 lyophilized drug vials and 6 PZA Supplements.
245115	**BACTEC™ MGIT™** PZA Medium, carton of 25 tubes.

XIII. REFERENCES

1. Barenfanger, J. 1993. Making your lab safe against multi-drug resistant *Mycobacterium tuberculosis*. Clin. Microbiol. Newsl. *15*: 76-80.
2. National Committee for Clinical Laboratory Standards. 2001. Approved standard: M24-A. Susceptibility testing of mycobacteria, *Nocardia,* and other aerobic actinomycetes . NCCLS, Wayne, Pa.
3. Butler, W.R. and Kilburn. 1982. Improved method for testing susceptibility of *Mycobacterium tuberculosis* to pyrazinamide. J.Clin.Microbiol. *16*:1106-1109.
4. Heifets, L.B. and Iseman, M.D. 1985. Radiometric method for testing susceptibility of *Mycobacterium tuberculosis* to pyrazinamide in 7H12 broth. J.Clin.Microbiol. *21*:200-204.
5. BD Diagnostic Systems. **BACTEC**™ 460TB System Product and Procedure Manual.
6. Salfinger, M. et al. 1989. Rapid radiometric method for pyrazinamide susceptibility testing of *Mycobacterium tuberculosis*. Res. Microbiol 1989. *140*:301-309.
7. National Committee for Clinical Laboratory Standards. 2002. Approved Guideline M29-A2. Protection of laboratory workers from occupationally acquired infections. NCCLS, Wayne, Pa.
8. Garner, J.S. 1996. Hospital Infection Control Practices Advisory Committee, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. Guideline for isolation precautions in hospitals. Infect. Control Hospital Epidemiol. *17*:53-80.
9. U.S. Department of Health and Human Services. 1999. Biosafety in microbiological and biomedical laboratories, HHS Publication (CDC) 4th ed. U.S. Government Printing Office, Washington, D.C.
10. Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC). Official Journal L262, 17/10/2000, p. 0021-0045.

XIV. TECHNICAL INFORMATION

In the United States, telephone Technical Services, toll free (800) 638-8663.

Approved by:

Supervisor:_____ Date:_____

Director:_____ Date:_____

Effective Date:_____

Reviewed by Date:

PI Rev 07/02

Rev 07/02

Date: 25.09.2018

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Kit Components

Kit Product No.	Kit Product Description
245128	Kit Drug Pza Mgit

Kit Component(s)	Kit Component(s) Description
8019891	MGIT PZA
WP245128JAA	SUPPLEMENT PZA

IMDG

Special precautions for user: Not regulated.

IATA

Special precautions for user: Not regulated.

Please note: If a listed component does not have a corresponding document included, this means that the product is not hazardous and does not require a Safety Data Sheet.

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SAFETY DATA SHEET

1. Identification

Product identifier

Product No.:	Product name:	Common name(s), synonym(s)
8019891	MGIT PZA	

Other means of identification
SDS number: 088100156805

Recommended use and restriction on use
Recommended use: Laboratory Chemicals
Restrictions on use: None known.

Manufacturer/Importer/Supplier/Distributor Information

Manufacturer

Company Name: BD Diagnostic Systems
Address: 7 Loveton Circle
21152 Sparks, MD USA
Telephone: 1 410 771 0100 or 1 800 638 8663
Fax:
Contact Person: Tech Services

Emergency telephone number: ChemTrec 1 800 424 9300

2. Hazard(s) identification

Hazard Classification
Not classified

Label Elements

Hazard Symbol: No symbol

Signal Word: No signal word.

Hazard Statement: Not applicable
Precautionary Statements Not applicable

Other hazards which do not result in GHS classification: None.

3. Composition/information on ingredients

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Mixtures

Composition Comments: The components are not hazardous or are below required disclosure limits.

4. First-aid measures

General information: Get medical attention if symptoms occur.

Ingestion: Get medical attention if symptoms occur.

Inhalation: Provide fresh air, warmth and rest, preferably in comfortable upright sitting position.

Skin Contact: Wash contact areas with soap and water. Remove contaminated clothing. Launder contaminated clothing before reuse.

Eye contact: Flush thoroughly with water. If irritation occurs, get medical assistance.

Most important symptoms/effects, acute and delayed

Symptoms: No data available.

Indication of immediate medical attention and special treatment needed

Treatment: No data available.

5. Fire-fighting measures

General Fire Hazards: Extinguish all ignition sources. Avoid sparks, flames, heat and smoking. Ventilate. Use water spray to keep fire-exposed containers cool.

Suitable (and unsuitable) extinguishing media

Suitable extinguishing media: Water spray, fog, CO2, dry chemical, or alcohol resistant foam.

Unsuitable extinguishing media: None known.

Specific hazards arising from the chemical: None known.

Special protective equipment and precautions for firefighters

Special fire fighting procedures: No unusual fire or explosion hazards noted.

Special protective equipment for fire-fighters: Firefighters must use standard protective equipment including flame retardant coat, helmet with face shield, gloves, rubber boots, and in enclosed spaces, SCBA.

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6. Accidental release measures

Personal precautions, protective equipment and emergency procedures: No special precautionary health measures should be needed under anticipated conditions of use.

Methods and material for containment and cleaning up: No specific clean-up procedure noted.

Environmental Precautions: Avoid release to the environment.

7. Handling and storage

Precautions for safe handling: When using do not eat, drink or smoke. Read and follow manufacturer's recommendations. Use personal protective equipment as required.

Conditions for safe storage, including any incompatibilities: Store in a cool, dry place. Keep container tightly closed.

8. Exposure controls/personal protection

Control Parameters

Occupational Exposure Limits

None of the components have assigned exposure limits.

Appropriate Engineering Controls No special requirements under ordinary conditions of use and with adequate ventilation.

Individual protection measures, such as personal protective equipment

General information: Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing to remove contaminants. Discard contaminated footwear that cannot be cleaned.

Eye/face protection: Wear safety glasses with side shields (or goggles).

Skin Protection

Hand Protection: Chemical resistant gloves Suitable gloves can be recommended by the glove supplier. Wash hands after contact.

Other: Wear a lab coat or similar protective clothing.

Respiratory Protection: Respiratory protection not required.

Hygiene measures: Observe good industrial hygiene practices.

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9. Physical and chemical properties

Appearance	
Physical state:	solid
Form:	solid
Color:	According to product specification.
Odor:	Characteristic
Odor threshold:	No data available.
pH:	No data available.
Melting point/freezing point:	No data available.
Initial boiling point and boiling range:	No data available.
Flash Point:	No data available.
Evaporation rate:	No data available.
Flammability (solid, gas):	No data available.
Upper/lower limit on flammability or explosive limits	
Flammability limit - upper (%):	No data available.
Flammability limit - lower (%):	No data available.
Explosive limit - upper (%):	No data available.
Explosive limit - lower (%):	No data available.
Vapor pressure:	No data available.
Vapor density:	No data available.
Relative density:	No data available.
Solubility(ies)	
Solubility in water:	No data available.
Solubility (other):	No data available.
Partition coefficient (n-octanol/water):	No data available.
Auto-ignition temperature:	No data available.
Decomposition temperature:	No data available.
Viscosity:	No data available.

10. Stability and reactivity

Reactivity:	Stable under normal temperature conditions and recommended use.
Chemical Stability:	Material is stable under normal conditions.
Possibility of hazardous reactions:	Not known.
Conditions to avoid:	Avoid exposure to high temperatures or direct sunlight.
Incompatible Materials:	Strong oxidizers.

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Hazardous Decomposition Products: Not known.

11. Toxicological information

General information: No data on possible toxicity effects have been found.

Information on likely routes of exposure

Ingestion: No harmful effects expected in amounts likely to be ingested by accident.

Inhalation: Limited inhalation hazard at normal work temperatures.

Skin Contact: Negligible irritation to skin at ambient temperatures.

Eye contact: Do not get in eyes.

Symptoms related to the physical, chemical and toxicological characteristics

Ingestion: No data available.

Inhalation: No data available.

Skin Contact: No data available.

Eye contact: No data available.

Information on toxicological effects

Acute toxicity (list all possible routes of exposure)

Oral
Product: No data available.

Dermal
Product: No data available.

Inhalation
Product: No data available.

Repeated dose toxicity
Product: No data available.

Skin Corrosion/Irritation
Product: No data available.

Serious Eye Damage/Eye Irritation
Product: No data available.

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Respiratory or Skin Sensitization
Product: No data available.

Carcinogenicity
Product: No data available.

IARC Monographs on the Evaluation of Carcinogenic Risks to Humans:
No carcinogenic components identified

US. National Toxicology Program (NTP) Report on Carcinogens:
No carcinogenic components identified

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050):
No carcinogenic components identified

Germ Cell Mutagenicity

In vitro
Product: No data available.

In vivo
Product: No data available.

Reproductive toxicity
Product: No data available.

Specific Target Organ Toxicity - Single Exposure
Product: No data available.

Specific Target Organ Toxicity - Repeated Exposure
Product: No data available.

Aspiration Hazard
Product: No data available.

Other effects: None known.

12. Ecological information

Ecotoxicity:

Acute hazards to the aquatic environment:

Fish
Product: No negative effects on the aquatic environment are known.

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Aquatic Invertebrates
Product: No negative effects on the aquatic environment are known.

Chronic hazards to the aquatic environment:

Fish
Product: No negative effects on the aquatic environment are known.

Aquatic Invertebrates
Product: No negative effects on the aquatic environment are known.

Toxicity to Aquatic Plants
Product: No negative effects on the aquatic environment are known.

Persistence and Degradability

Biodegradation
Product: Expected to be readily biodegradable.

BOD/COD Ratio
Product: No data available.

Bioaccumulative potential
Bioconcentration Factor (BCF)
Product: No data available.

Partition Coefficient n-octanol / water (log Kow)
Product: No data available.

Mobility in soil: No data available.

Known or predicted distribution to environmental compartments

Other adverse effects: The product is not expected to be hazardous to the environment.

13. Disposal considerations

General information: Dispose of waste and residues in accordance with local authority requirements.

Disposal instructions: No specific disposal method required.

Contaminated Packaging: No data available.

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14. Transport information

DOTUN Number:	Not regulated.
UN Proper Shipping Name:	Not regulated.
Transport Hazard Class(es)	
Class:	Not regulated.
Label(s):	Not regulated.
Packing Group:	Not regulated.
Marine Pollutant:	Not regulated.
Limited quantity	Not regulated.
Excepted quantity	Not regulated.
Special precautions for user:	Not regulated.

IMDG

UN Number:	Not regulated.
UN Proper Shipping Name:	Not regulated.
Transport Hazard Class(es)	
Class:	Not regulated.
Subsidiary risk:	Not regulated.
EmS No.:	Not regulated.
Packing Group:	Not regulated.
Environmental Hazards	
Marine Pollutant:	Not regulated.
Special precautions for user:	Not regulated.

IATA

UN Number:	Not regulated.
Proper Shipping Name:	Not regulated.
Transport Hazard Class(es):	
Class:	Not regulated.
Subsidiary risk:	Not regulated.
Packing Group:	Not regulated.
Environmental Hazards	
Marine pollutant:	Not regulated.
Special precautions for user:	Not regulated.

15. Regulatory information

US Federal Regulations

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)
None present or none present in regulated quantities.

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)
None present or none present in regulated quantities.

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CERCLA Hazardous Substance List (40 CFR 302.4):
None present or none present in regulated quantities.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories
Not classified
Not classified

SARA 302 Extremely Hazardous Substance
None present or none present in regulated quantities.

SARA 304 Emergency Release Notification
None present or none present in regulated quantities.

SARA 311/312 Hazardous Chemical

None present or none present in regulated quantities.

SARA 313 (TRI Reporting)
None present or none present in regulated quantities.

Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3)
None present or none present in regulated quantities.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130):
None present or none present in regulated quantities.

US State Regulations

US. California Proposition 65
No ingredient regulated by CA Prop 65 present.

US. New Jersey Worker and Community Right-to-Know Act
No ingredient regulated by NJ Right-to-Know Law present.

US. Massachusetts RTK - Substance List
No ingredient regulated by MA Right-to-Know Law present.

US. Pennsylvania RTK - Hazardous Substances
No ingredient regulated by PA Right-to-Know Law present.

US. Rhode Island RTK
No ingredient regulated by RI Right-to-Know Law present.

16.Other information, including date of preparation or last revision

Issue Date: 07/17/2018

Version #: 1.0

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Revision Information:	No data available.
Further Information:	No data available.
Disclaimer:	Disclaimer: The information contained herein has been obtained from various sources and is believed to be correct as of the date issued. However, neither BD nor any of its subsidiaries assumes any liabilities whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability for a particular use of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist. BD provides SDS in electronic form so the information may be more easily accessed. Due to the possibility of errors during transmission, BD makes no representations as to the completeness or accuracy of the information.

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SAFETY DATA SHEET

1. Identification

Product identifier

Product No.:	Product name:	Common name(s), synonym(s)
WP245128JAA	SUPPLEMENT PZA	

Other means of identification
SDS number: 088100177573

Recommended use and restriction on use
Recommended use: Laboratory Chemicals
Restrictions on use: None known.

Manufacturer/Importer/Supplier/Distributor Information

Manufacturer

Company Name: BD Diagnostic Systems
Address: 7 Loveton Circle
21152 Sparks, MD USA
Telephone: 1 410 771 0100 or 1 800 638 8663
Fax:
Contact Person: Tech Services

Emergency telephone number: ChemTrec 1 800 424 9300

2. Hazard(s) identification

Hazard Classification
Not classified

Label Elements

Hazard Symbol: No symbol

Signal Word: No signal word.

Hazard Statement: Not applicable
Precautionary Statements Not applicable

Other hazards which do not result in GHS classification: None.

3. Composition/information on ingredients

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Mixtures

Chemical Identity	Common name and synonyms	CAS number	Content in percent (%)*
Ethanol		64-17-5	0.9177%

* All concentrations are percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

4. First-aid measures

General information: Get medical attention if symptoms occur.

Ingestion: Get medical attention if symptoms occur.

Inhalation: Provide fresh air, warmth and rest, preferably in comfortable upright sitting position.

Skin Contact: Wash contact areas with soap and water. Remove contaminated clothing. Launder contaminated clothing before reuse.

Eye contact: Flush thoroughly with water. If irritation occurs, get medical assistance.

Most important symptoms/effects, acute and delayed

Symptoms: No data available.

Indication of immediate medical attention and special treatment needed

Treatment: No data available.

5. Fire-fighting measures

General Fire Hazards: Extinguish all ignition sources. Avoid sparks, flames, heat and smoking. Ventilate. Use water spray to keep fire-exposed containers cool.

Suitable (and unsuitable) extinguishing media

Suitable extinguishing media: Water spray, fog, CO2, dry chemical, or alcohol resistant foam.

Unsuitable extinguishing media: None known.

Specific hazards arising from the chemical: None known.

Special protective equipment and precautions for firefighters

Special fire fighting procedures: No unusual fire or explosion hazards noted.

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Special protective equipment for fire-fighters: Firefighters must use standard protective equipment including flame retardant coat, helmet with face shield, gloves, rubber boots, and in enclosed spaces, SCBA.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures: No special precautionary health measures should be needed under anticipated conditions of use.

Methods and material for containment and cleaning up: No specific clean-up procedure noted.

Environmental Precautions: Avoid release to the environment.

7. Handling and storage

Precautions for safe handling: When using do not eat, drink or smoke. Read and follow manufacturer's recommendations. Use personal protective equipment as required.

Conditions for safe storage, including any incompatibilities: Store in a cool, dry place. Keep container tightly closed.

8. Exposure controls/personal protection

Control Parameters

Occupational Exposure Limits

Chemical Identity	Type	Exposure Limit Values	Source
Ethanol	TWA	1,000 ppm 1,900 mg/m3	US. OSHA Table Z-1-A (29 CFR 1910.1000) (1989)
	TWA	1,000 ppm 1,900 mg/m3	US. Tennessee. OELs. Occupational Exposure Limits, Table Z1A (06 2008)
	AN ESL	1,000 ppb	US. Texas. Effects Screening Levels (Texas Commission on Environmental Quality) (12 2010)
	ST ESL	10,000 ppb	US. Texas. Effects Screening Levels (Texas Commission on Environmental Quality) (12 2010)
	AN ESL	1,880 µg/m3	US. Texas. Effects Screening Levels (Texas Commission on Environmental Quality) (12 2010)
	ST ESL	18,800 µg/m3	US. Texas. Effects Screening Levels (Texas Commission on Environmental Quality) (12 2010)
	TWA PEL	1,000 ppm 1,900 mg/m3	US. California Code of Regulations, Title 8, Section 5155. Airborne Contaminants (08 2010)
	STEL	1,000 ppm	US. ACGIH Threshold Limit Values (12 2010)
	REL	1,000 ppm 1,900 mg/m3	US. NIOSH: Pocket Guide to Chemical Hazards (2005)

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	PEL	1,000 ppm 1,900 mg/m3	US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000) (02 2006)

Appropriate Engineering Controls No special requirements under ordinary conditions of use and with adequate ventilation.

Individual protection measures, such as personal protective equipment

General information: Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing to remove contaminants. Discard contaminated footwear that cannot be cleaned.

Eye/face protection: Wear safety glasses with side shields (or goggles).

Skin Protection

Hand Protection: Chemical resistant gloves Suitable gloves can be recommended by the glove supplier. Wash hands after contact.

Other: Wear a lab coat or similar protective clothing.

Respiratory Protection: Respiratory protection not required.

Hygiene measures: Observe good industrial hygiene practices.

9. Physical and chemical properties

Appearance

Physical state: solid
Form: Solid or Flake
Color: According to product specification.
Odor: Characteristic
Odor threshold: No data available.
pH: No data available.
Melting point/freezing point: No data available.
Initial boiling point and boiling range: No data available.
Flash Point: Not applicable
Evaporation rate: No data available.
Flammability (solid, gas): No data available.
Upper/lower limit on flammability or explosive limits
Flammability limit - upper (%): No data available.
Flammability limit - lower (%): No data available.
Explosive limit - upper (%): No data available.
Explosive limit - lower (%): No data available.
Vapor pressure: No data available.
Vapor density: No data available.
Relative density: No data available.

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Solubility(ies)

Solubility in water:	Completely Soluble
Solubility (other):	Water.: No data available.
Partition coefficient (n-octanol/water):	No data available.
Auto-ignition temperature:	No data available.
Decomposition temperature:	No data available.
Viscosity:	Not determined.

10. Stability and reactivity

Reactivity:	Stable under normal temperature conditions and recommended use.
Chemical Stability:	Material is stable under normal conditions.
Possibility of hazardous reactions:	Not known.
Conditions to avoid:	Avoid exposure to high temperatures or direct sunlight.
Incompatible Materials:	Strong oxidizers.
Hazardous Decomposition Products:	Not known.

11. Toxicological information

General information: No data on possible toxicity effects have been found.

Information on likely routes of exposure

Ingestion:	No harmful effects expected in amounts likely to be ingested by accident.
Inhalation:	Limited inhalation hazard at normal work temperatures.
Skin Contact:	Negligible irritation to skin at ambient temperatures.
Eye contact:	Do not get in eyes.

Symptoms related to the physical, chemical and toxicological characteristics

Ingestion:	No data available.
Inhalation:	No data available.
Skin Contact:	No data available.
Eye contact:	No data available.

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Information on toxicological effects

Acute toxicity (list all possible routes of exposure)

Oral
Product: No data available.

Dermal
Product: No data available.

Inhalation
Product: No data available.

Repeated dose toxicity
Product: No data available.

Specified substance(s):
Ethanol — Based on available data, the classification criteria are not met.
LOAEL (Rat(Female, Male), Inhalation, 7,318 - 7,496 h): 1.3 mg/l Inhalation Read-across from supporting substance (structural analogue or surrogate), Weight of Evidence study
NOAEL (Guinea pig, Inhalation, 10.5 Weeks): 3,000 ppm(m) Inhalation Experimental result, Supporting study
LOAEL (Rat(Male), Inhalation, 1 - 6 Weeks): 13.3 mg/l Inhalation Read-across from supporting substance (structural analogue or surrogate), Supporting study
LOAEL (Monkey, Inhalation, 5 - 20 d): 3.99 mg/l Inhalation Read-across from supporting substance (structural analogue or surrogate), Supporting study

Skin Corrosion/Irritation
Product: No data available.

Specified substance(s):
Ethanol
in vivo (Rabbit): Not irritant Experimental result, Key study

Serious Eye Damage/Eye Irritation
Product: No data available.

Specified substance(s):
Ethanol — in vivo (Rabbit, 24 - 72 hrs): Not irritating EU

Respiratory or Skin Sensitization
Product: No data available.

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Specified substance(s):

Ethanol	Based on available data, the classification criteria are not met. Skin sensitization:, in vivo (Guinea pig): Non sensitising

Carcinogenicity

Product:	No data available.
Specified substance(s):	
Ethanol	Based on available data, the classification criteria are not met.

IARC Monographs on the Evaluation of Carcinogenic Risks to Humans:
No carcinogenic components identified

US. National Toxicology Program (NTP) Report on Carcinogens:
No carcinogenic components identified

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050):
No carcinogenic components identified

Germ Cell Mutagenicity

In vitro

Product:	No data available.
Specified substance(s):	
Ethanol	Based on available data, the classification criteria are not met.

In vivo

Product:	No data available.
Specified substance(s):	
Ethanol	Based on available data, the classification criteria are not met.

Reproductive toxicity

Product:	No data available.
Specified substance(s):	
Ethanol	Based on available data, the classification criteria are not met.

Specific Target Organ Toxicity - Single Exposure

Product:	No data available.
Specified substance(s):	
Ethanol	Based on available data, the classification criteria are not met.

Specific Target Organ Toxicity - Repeated Exposure

Product:	No data available.
Specified substance(s):	
Ethanol	Based on available data, the classification criteria are not met.

Aspiration Hazard

Product:	No data available.

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Other effects: None known.

12. Ecological information

Ecotoxicity:

Acute hazards to the aquatic environment:

Fish
Product: No negative effects on the aquatic environment are known.

Aquatic Invertebrates
Product: No negative effects on the aquatic environment are known.

Chronic hazards to the aquatic environment:

Fish
Product: No negative effects on the aquatic environment are known.

Aquatic Invertebrates
Product: No negative effects on the aquatic environment are known.

Toxicity to Aquatic Plants
Product: No negative effects on the aquatic environment are known.

Persistence and Degradability

Biodegradation
Product: Expected to be readily biodegradable.

BOD/COD Ratio
Product: No data available.

Bioaccumulative potential
Bioconcentration Factor (BCF)
Product: No data available.

Specified substance(s):

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Ethanol	Potential to bioaccumulate is low. Cyprinus carpio, Bioconcentration Factor (BCF): 4.5 Aquatic sediment Read-across from supporting substance (structural analogue or surrogate), Supporting study Cyprinus carpio, Bioconcentration Factor (BCF): 3 Aquatic sediment Read-across from supporting substance (structural analogue or surrogate), Supporting study Leuciscus idus, Bioconcentration Factor (BCF): 0.2 Aquatic sediment Read-across from supporting substance (structural analogue or surrogate), Not specified Cyprinus carpio, Bioconcentration Factor (BCF): 1 Aquatic sediment Read-across from supporting substance (structural analogue or surrogate), Supporting study

Partition Coefficient n-octanol / water (log Kow)

Product: Log Kow: No data available.

Mobility in soil: No data available.

Known or predicted distribution to environmental compartments

Ethanol: soil - Very mobile liquid

Other adverse effects: The product is not expected to be hazardous to the environment.

13. Disposal considerations

General information: Dispose of waste and residues in accordance with local authority requirements.

Disposal instructions: No specific disposal method required.

Contaminated Packaging: No data available.

14. Transport information

DOTUN Number:	Not regulated.
UN Proper Shipping Name:	Not regulated.
Transport Hazard Class(es)	
Class:	Not regulated.
Label(s):	Not regulated.
Packing Group:	Not regulated.
Marine Pollutant:	Not regulated.
Limited quantity	Not regulated.
Excepted quantity	Not regulated.
Special precautions for user:	Not regulated.

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IMDG

UN Number:	Not regulated.
UN Proper Shipping Name:	Not regulated.
Transport Hazard Class(es)	
Class:	Not regulated.
Subsidiary risk:	Not regulated.
EmS No.:	Not regulated.
Packing Group:	Not regulated.
Environmental Hazards	
Marine Pollutant:	Not regulated.
Special precautions for user:	Not regulated.

IATA

UN Number:	Not regulated.
Proper Shipping Name:	Not regulated.
Transport Hazard Class(es):	
Class:	Not regulated.
Subsidiary risk:	Not regulated.
Packing Group:	Not regulated.
Environmental Hazards	
Marine pollutant:	Not regulated.
Special precautions for user:	Not regulated.

15. Regulatory information

US Federal Regulations

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)
None present or none present in regulated quantities.

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)
None present or none present in regulated quantities.

CERCLA Hazardous Substance List (40 CFR 302.4):

Chemical Identity	Reportable quantity
Ethanol	100 lbs.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories
Not classified
Not classified

SARA 302 Extremely Hazardous Substance
None present or none present in regulated quantities.

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SARA 304 Emergency Release Notification

Chemical Identity	Reportable quantity
Ethanol	100 lbs.

SARA 311/312 Hazardous Chemical

Chemical Identity	Threshold Planning Quantity
Ethanol	10000 lbs

SARA 313 (TRI Reporting)
None present or none present in regulated quantities.

Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3)
None present or none present in regulated quantities.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130):
None present or none present in regulated quantities.

US State Regulations

US. California Proposition 65

US. New Jersey Worker and Community Right-to-Know Act

Chemical Identity
Ethanol

US. Massachusetts RTK - Substance List
No ingredient regulated by MA Right-to-Know Law present.

US. Pennsylvania RTK - Hazardous Substances
No ingredient regulated by PA Right-to-Know Law present.

US. Rhode Island RTK
No ingredient regulated by RI Right-to-Know Law present.

16.Other information, including date of preparation or last revision

Issue Date: 07/17/2018

Version #: 2.1

Revision Information: No data available.

Further Information: No data available.

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Disclaimer:

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Safety Data Sheet
acc. to OSHA HCS

Date Prepared: 05/10/2016 Reviewed On: 04/28/2016

1 Identification

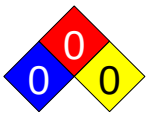
· **Product Identifier:**
· **Product Name:** **BACTEC MGIT 960 PZA Tubes**
· **Catalog Number:** 245115
· **Application of the substance / the mixture** Laboratory Chemicals

· **Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
BD Diagnostic Systems
7 Loveton Circle
Sparks, MD 21152
Telephone: (410) 771 - 0100 or (800) 638 – 8663
Email Address: Technical_Services@bd.com
· **Information Department:** Technical Service
· **Emergency telephone number:**
In case of a chemical emergency, spill, fire, exposure, or accident, contact BD Diagnostic Systems (410) 771-0100 or (800)-638-8663, or ChemTrec at (800) 424-9300.

2 Hazard(s) identification

· **Classification of the substance or mixture**
The product is not classified according to the Globally Harmonized System (GHS).

· **Label elements**
· **GHS label elements** Void
· **Hazard pictograms** Void
· **Signal word** Void
· **Hazard statements** Void
· **NFPA ratings (scale 0-4)**



Health = 0
Flammability = 0
Reactivity = 0

· **HMIS ratings (scale 0-4)**

Health = 0
Flammability = 0
Reactivity = 0

· **Other hazards**
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

(Contd. on page 2)

Safety Data Sheet
acc. to OSHA HCS

Date Prepared: 05/10/2016 Reviewed On: 04/28/2016

Product Name: BACTEC MGIT 960 PZA Tubes

(Contd. of page 1)

3 Composition/information on ingredients

· **Chemical characterization: Mixture**
· **Description:** Mixture consisting of the following components.

· **Dangerous Components:** Void
· **Additional information** Risk phrases refer to section 15.

4 First-aid measures

· **Description of first aid measures**
· **General information** No special measures required.
· **After inhalation** Seek medical treatment in case of complaints.
· **After skin contact** Immediately wash with water and soap and rinse thoroughly.
· **After eye contact**
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
· **After swallowing** If symptoms persist consult doctor.
· **Information for doctor** Show this product label or this SDS.
· **Most important symptoms and effects, both acute and delayed**
No further relevant information available.
· **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire-fighting measures

· **Extinguishing media**
· **Suitable extinguishing agents**
CO2, ABC multipurpose dry chemical or water spray. Fight larger fires with water spray or alcohol resistant foam.
· **Special hazards arising from the substance or mixture**
No further relevant information available.
· **Advice for firefighters**
· **Protective equipment:** No special measures required.

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures** Not required.
· **Environmental precautions:** Wipe up with damp sponge or mop.
· **Methods and material for containment and cleaning up:** No special measures required.
· **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.

(Contd. on page 3)

Safety Data Sheet
acc. to OSHA HCS

Date Prepared: 05/10/2016 Reviewed On: 04/28/2016

Product Name: BACTEC MGIT 960 PZA Tubes

(Contd. of page 2)

See Section 13 for disposal information.

7 Handling and storage

· **Handling**
· **Precautions for safe handling** No special measures required.
· **Information about protection against explosions and fires:**
No special measures required.

· **Conditions for safe storage, including any incompatibilities**
· **Storage**
· **Requirements to be met by storerooms and receptacles:** No special requirements.
· **Information about storage in one common storage facility:**
Store away from oxidizing agents.
· **Further information about storage conditions:**
Store in cool, dry conditions in well sealed containers.
· **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

· **Additional information about design of technical systems:**
No further data; see Section 7.

· **Control parameters**
· **Components with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
· **Additional information:** The lists that were valid during the creation were used as basis.

· **Exposure controls**
· **Personal Protective Equipment**
· **General protective and hygienic measures**
The usual precautionary measures for handling chemicals should be followed.
· **Breathing equipment:** Not required.
· **Protection of hands:**

Chemical resistant gloves (i.e. nitrile, or equivalent).

· **Eye protection:** Safety glasses
· **Body protection:** Protective work clothing (lab coat).

(Contd. on page 4)

Safety Data Sheet
acc. to OSHA HCS

Date Prepared: 05/10/2016 Reviewed On: 04/28/2016

Product Name: BACTEC MGIT 960 PZA Tubes

(Contd. of page 3)

9 Physical and chemical properties

· **Information on basic physical and chemical properties**	
· **General Information**	
· **Appearance:**	
Form:	Liquid
Color:	Clear
· **Odor:**	Characteristic
· **Odor threshold:**	Not determined.
· **pH-value at 20 °C (68 °F):**	5.8
· **Change in condition**	Undetermined
· **Melting point/Melting range:**	Not determined
· **Boiling point/Boiling range:**	Not determined
· **Flash point:**	Not applicable
· **Flammability (solid, gaseous)**	Not applicable.
· **Ignition temperature:**	
Decomposition temperature:	Not determined.
· **Auto igniting:**	Product is not self igniting.
· **Danger of explosion:**	Product does not present an explosion hazard.
· **Explosion limits:**	
Lower:	Not determined.
Upper:	Not determined.
· **Vapor pressure:**	Not determined.
· **Density:**	Not determined
· **Relative density**	Not determined.
· **Vapor density**	Not determined.
· **Evaporation rate**	Not determined.
· **Solubility in / Miscibility with**	
Water:	Soluble
· **Partition coefficient (n-octanol/water):**	Not determined.
· **Viscosity:**	
dynamic:	Not determined.
kinematic:	Not determined.
· **Other information**	No further relevant information available.

(Contd. on page 5)

Safety Data Sheet
acc. to OSHA HCS

Date Prepared: 05/10/2016 Reviewed On: 04/28/2016

Product Name: BACTEC MGIT 960 PZA Tubes

(Contd. of page 4)

10 Stability and reactivity

· **Reactivity** No further relevant information available.
· **Chemical stability**
· **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
· **Possibility of hazardous reactions** No dangerous reactions known
· **Conditions to avoid** No further relevant information available.
· **Incompatible materials:** Incompatible material: strong oxidizers.
· **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological information

· **Information on toxicological effects**
· **Acute toxicity:**
· **Primary irritant effect:**
· **on the skin:** No irritating effect.
· **on the eye:** No irritating effect.
· **Sensitization:** No sensitizing effects known.
· **Additional toxicological information:**
The product shows the following dangers according to internally approved calculation methods for preparations:
The product is not subject to OSHA classification according to internally approved calculation methods for preparations.
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**
None of the ingredients is listed.

· **NTP (National Toxicology Program)**
None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**
None of the ingredients is listed.

12 Ecological information

· **Toxicity**
· **Aquatic toxicity:** No further relevant information available.
· **Persistence and degradability** No further relevant information available.
· **Behavior in environmental systems:**
· **Bioaccumulative potential** No further relevant information available.

(Contd. on page 6)

Safety Data Sheet
acc. to OSHA HCS

Date Prepared: 05/10/2016 Reviewed On: 04/28/2016

Product Name: BACTEC MGIT 960 PZA Tubes

(Contd. of page 5)

· **Mobility in soil** No further relevant information available.
· **Ecotoxical effects:**
· **Other information:**
The ecological effects have not been thoroughly investigated, but currently none have been identified.
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **Other adverse effects** No further relevant information available.

13 Disposal considerations

· **Waste treatment methods**
· **Recommendation**
Smaller quantities can be disposed of with solid waste.
This product is not considered a RCRA hazardous waste.
Dispose of material in accordance with federal (40 CFR 261.3), state and local requirements.

· **Uncleaned packagings:**
· **Recommendation:** Disposal must be made according to state and federal regulations.
· **Recommended cleansing agent:** Water, if necessary with cleansing agents.

14 Transport information

· **UN-Number**	
· **DOT, ADN, IMDG, IATA**	Void
· **UN proper shipping name**	
· **DOT, ADN, IMDG, IATA**	Void
· **Transport hazard class(es)**	
· **DOT, ADN, IMDG, IATA**	
· **Class**	Void
· **Packing group**	
· **DOT, IMDG, IATA**	Void
· **Environmental hazards:**	Not applicable.
· **Special precautions for user**	Not applicable.

(Contd. on page 7)

Safety Data Sheet
acc. to OSHA HCS

Date Prepared: 05/10/2016 Reviewed On: 04/28/2016

Product Name: BACTEC MGIT 960 PZA Tubes

(Contd. of page 6)

· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable.
· **Transport/Additional information:**	Not dangerous according to the above specifications.
· **UN "Model Regulation":**	Void

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**

· **SARA Section 355 (extremely hazardous substances)**

None of the ingredients is listed.

· **SARA Section 313 (specific toxic chemical listings)**

None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act)**

All ingredients are listed.

· **California Proposition 65 - Chemicals known to cause cancer**

None of the ingredients is listed.

· **California Proposition 65 - Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **California Proposition 65 - Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **California Proposition 65 - Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

· **Carcinogenic categories**

· **TLV (Threshold Limit Value established by ACGIH)**

None of the ingredients is listed.

· **GHS label elements** Void
· **Hazard pictograms** Void
· **Signal word** Void
· **Hazard statements** Void
· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

To the best of our knowledge, the information contained herein is accurate. However, neither Becton, Dickinson and Company or any of its subsidiaries assumes any liabilities whatsoever

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Safety Data Sheet
acc. to OSHA HCS

Date Prepared: 05/10/2016 Reviewed On: 04/28/2016

Product Name: BACTEC MGIT 960 PZA Tubes

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for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we can not guarantee that these are the only hazards that exist.

· **Department issuing SDS:**
Environmental, Health & Safety
Created by Michael J. Spinazzola
· **Contact:** Technical Service Representative
· **Date of preparation / last revision** 05/10/2016 / -
· **Abbreviations and acronyms:**
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
ACGIH: American Conference of Governmental Industrial Hygienists
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
NFPA: National Fire Protection Association (USA)
HMIS: Hazardous Materials Identification System (USA)
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
OSHA: Occupational Safety & Health
TLV: Threshold Limit Value
PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
LC50: Lethal concentration, 50 percent
BEI: Biological Exposure Limit