

# Central Drugs Standard Control Organization

Directorate General of Health Services

Government of India

(Medical Device Division)

Food & Drugs Administration Bhavan,  
Kotla Road, New Delhi

File No: 1/B-1N/2010-DC (01) End 04

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## DIAGNOSTIC KIT ALERT

### Product

BBL™ MGIT™ Mycobacteria Growth Indicator Tube (Lot No. 3042467)

### BACKGROUND

BBL™ MGIT™ Mycobacteria Growth Indicator Tube supplemented with BACTEC™ MGIT™ growth supplement and BBL™ MBIT™ PANTA™ antibiotic mixture is intended for detection and recovery of mycobacteria using the BACTEC™ MGIT™ 960 and BACTEC™ MGIT™ 320 systems. Acceptance specimen types are digested and decontaminated clinical (except urine) and sterile body fluid(except blood)

### PROBLEM

Voluntary recall of the BBL™ MGIT™ Mycobacteria Growth Indicator Tube ( Lot No. 3042467) due to a portion of the tubes of the product contain an incorrect prefix on the barcode label. The incorrect prefix begins with "43 02" instead of the required "43 01". The instrument BACTEC™ MGIT may report an incorrect result for growth and detection function.

### ACTION BY

- Medical directors/ Healthcare Professionals
- Staff involved in the management of patients
- Diagnostics Labs

#### **ACTION**

- Do not use the BBL™ MGIT™ Mycobacteria Growth Indicator Tube (Lot No. 3042467)
- Return all unused product to the manufacturer.

#### **ADVERSE EFFECTS**

The BACTEC™ MGIT™ instrument may report an incorrect result for growth and detection function.

11800 pieces of BBL™ MGIT™ Mycobacteria Growth Indicator Tube has been imported in India. Out of which 7100 pieces been recalled by the M/s Becton & Dickinson till 13-sep-2013.

#### **CONTACTS**

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