



# Microbact™ Reagent Set D

**REF** MB1082A Microbact™ Reagent Set D ..... 10ml

## 1. INTENDED USE

The Microbact Reagent Set D is a set of reagents for use as an aid in qualitative procedures for the detection of Gram-negative Bacilli in biochemical tests. The device is used in a diagnostic workflow to aid clinicians in the treatment options for patients suspected of having bacterial infections.

The device is not automated, is for professional use only and is not a companion diagnostic.

## 2. PRINCIPLE OF THE TEST

Microbact Reagent TDA, Microbact Reagents VP I and VP II, Microbact Reagents Nitrate A and Nitrate B and Microbact Reagent Indole-Kovacs are required for specific biochemical reactions.

Tests used in systems, such as the Microbact GNB Identification System, are based on microbial degradation of specific substrates detected by various indicators, which can require the addition of these reagents. The reactions employed are conventional biochemical reactions.

### Microbact Reagent TDA:

One drop of TDA reagent is added to the well. Intracellular enzymes collectively called "tryptophanases" mediate the degradation of tryptophan to produce indolepyruvate and other metabolic end products. Indolepyruvate can be detected by the addition of ferric chloride which forms a brown colour with indolepyruvate.

### Microbact Reagents VP I and VP II:

The VP test is a two-step process. One drop of VP I reagent and one drop of VP II reagent are added to the well. Production of a pink-red complex indicates the production of acetoin from glucose has occurred.

### Microbact Reagents Nitrate A and Nitrate B:

The nitrate reduction test is a two-step process. One drop of Nitrate A reagent and one drop of Nitrate B reagent are added to the ONPG well (only after reading the ONPG result). Production of a red colour indicates that nitrate reduction to nitrite (NO<sup>2</sup>) has occurred. A small amount of zinc powder should be added to those wells which exhibit a yellow colour, after the addition of the nitrate reagents. This will determine whether nitrate has been reduced completely to nitrogen gas (N<sup>2</sup>), which would result in a yellow colour.

### Microbact Reagent Indole-Kovacs:

Two drops of Indole-Kovacs reagent are added to the well. Intracellular enzymes collectively called "tryptophanases" mediate the degradation of tryptophan to produce indole and other metabolic end products. Indole can be detected by the addition of dimethylaminobenzaldehyde which forms a pink-red complex with indole.

## 3. KIT CONTENTS, PREPARATION FOR USE AND STORAGE

**REF** MB0180A **Microbact Reagent TDA** - One 10 mL Wheaton dropper bottle with nozzle and cap. Hydrochloric acid (HCL)10%, Ferric Chloride anhydrous.

**REF** MB0181A **Microbact Reagent VP I** - One 10 mL Wheaton dropper bottle with nozzle and cap. Reverse Osmosis (RO) water. Ethanol denatured 95%, α-naphthol (1-naphthol).

**REF** MB0184A **Microbact Reagent VP II** - One 10 mL Wheaton dropper bottle with nozzle and cap. RO water, Potassium hydroxide, Creatine.

**REF** MB0186A **Microbact Reagent Nitrate A** - One 10 mL Wheaton dropper bottle with nozzle and cap. RO water, Acetic acid, Sulphanilic acid.

**REF** MB0187A **Microbact Reagent Nitrate B** - One 10 mL Wheaton dropper bottle with nozzle and cap. RO water, Acetic acid, Dimethyl naphthylamine.

**REF** MB0209A **Microbact Reagent Indole-Kovacs** - One 10 mL Wheaton dropper bottle with nozzle and cap. Iso-amyl alcohol. Dimethylaminobenzaldehyde. HCL 36%.

This product is ready for use and no further preparation is necessary. Store product in its original container at 2-8°C until expiry date.

## 4. PRECAUTIONS

This product is for *in vitro* diagnostic use and should be used by properly trained individuals. Precautions should be taken against the dangers of microbiological hazards by properly sterilizing specimens, containers, and media after use. Directions should be read and followed carefully.

Avoid contact with skin, eyes or clothing. Wear personal protective equipment/face protection. Ensure adequate ventilation. Avoid ingestion or inhalation.

Discard used material into a suitable waste container or disinfectant.

Do not use the product beyond its stated expiry date.

Do not use if there is evidence of contamination, or other signs of deterioration.

Do not use if packaging is damaged.

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

In the event of malfunction do not use device.

### MB0180A - Microbact Reagent TDA

DANGER	
H290	May be corrosive to metals
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H318	Causes serious eye damage
P302 + P352	IF ON SKIN: Wash with plenty of soap and water
P332 + P313	If skin irritation occurs: Get medical advice/attention
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P310	Immediately call a POISON CENTER or doctor/physician
P280	Wear protective gloves/protective clothing/eye protection/face protection



### MB0181A - Microbact Reagent VP I

DANGER	
H225	Highly flammable liquid and vapor
H318	Causes serious eye damage
P280	Wear eye protection/ face protection
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P310	Immediately call a POISON CENTER or doctor/physician
P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking



### MB0184A - Microbact Reagent VP II

DANGER	
H302	Harmful if swallowed
H314	Causes severe skin burns and eye damage
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P310	Immediately call a POISON CENTER or doctor/physician
P280	Wear protective gloves/protective clothing/eye protection/face protection
P301 + P330 + P331	IF SWALLOWED: Rinse mouth. Do NOT induce vomiting
P303 + P361 + P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower



### MB0209A - Microbact Reagent Indole Kovacs

DANGER	
H226	Flammable liquid and vapor
H290	May be corrosive to metals
H332	Harmful if inhaled
H314	Causes severe skin burns and eye damage
H335	May cause respiratory irritation
EUH066	Repeated exposure may cause skin dryness or cracking
P280	Wear protective gloves/protective clothing/eye protection/face protection
P301 + P330 + P331	IF SWALLOWED: Rinse mouth. Do NOT induce vomiting
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P310	Immediately call a POISON CENTER or doctor/physician
P303 + P361 + P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower
P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking



**MB0186A - Microbact Reagent Nitrate A**

**MB0187A - Microbact Reagent Nitrate B**

**DANGER**



H226	Flammable liquid and vapor
H314	Causes severe skin burns and eye damage
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P310	Immediately call a POISON CENTER or doctor/physician
P280	Wear protective gloves/protective clothing/eye protection/face protection
P301 + P330 + P331	IF SWALLOWED: Rinse mouth. Do NOT induce vomiting
P303 + P361 + P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower
P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking

**5. SPECIMEN COLLECTION, STORAGE, AND TRANSPORT**

Specimens should be collected and handled following recommended guidelines.

Refer to procedure notes with associated biochemical tests for details of specimen handling.

**6. MATERIALS REQUIRED BUT NOT SUPPLIED**

The reagents are intended for use as an aid in qualitative procedures with biochemical tests, such as the Thermo Scientific™ Oxoid™ Microbact™ GNB Identification System.

Refer to procedure notes with associated biochemical tests for details on required materials.

**7. QUALITY CONTROL**

Quality control should be run with each shipment and new lot number received. Each laboratory should follow their State and local requirements.

	Indole-Kovacs	VPI/II	Nitrate A/B	TDA
<i>Escherichia coli</i> (ATCC® 25922™)	Positive	Negative	Positive	Negative
<i>Klebsiella aerogenes</i> (ATCC® 13048™)	Negative	Positive	Positive	Negative
<i>Proteus mirabilis</i> (ATCC® 12453™)	Negative	Negative	Positive	Positive
<i>Moraxella catarrhalis</i> (ATCC® 8716™)	Negative	Negative	Negative	Negative

Do not use the test if the reactions of the control organisms are incorrect.

**8. PROCEDURE**

Refer to procedure notes with associated biochemical tests for details on use.

**9. SYMBOL LEGEND**

<b>REF</b>	Catalogue Number
<b>IVD</b>	In Vitro Diagnostic Medical Device
	Consult instructions for use or consult electronic instructions for use
	Temperature Limitations (Storage temp.)
	Do not use if package is damaged
	Not for near patient testing
<b>LOT</b>	Batch Code (Lot Number)
	Use By (Expiration Date)
	To indicate the entity importing the medical device into the locale. Applicable to the European Union
<b>EC REP</b>	Authorized representative in the European Community/European Union
<b>Made in Australia</b>	Made in Australia
<b>UK CA</b>	UK Conformity Assessed
<b>CE</b>	European Conformity Assessment
	Manufacturer



For technical information contact your local distributor.

Oxoid Ltd Wade Road Basingstoke Hampshire, RG24 8PW UK

Version	Date of modifications introduced
1.0	December 2023 Initial document

Printed in the UK