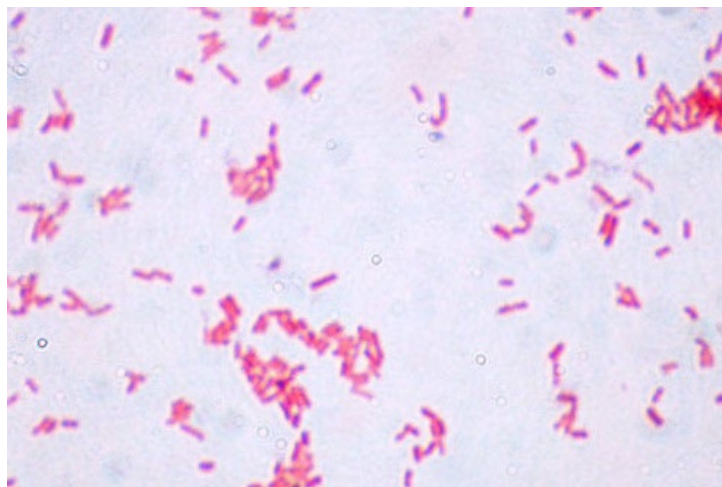




GRAM

For microbiology (with basic fuchsin as counterstain solution)



Gram-negative bacteria

CODE	DESCRIPTION	TESTS NUMBER
04-100804	Gram for microbiology with basic fuchsin	N.A.



In Vitro Diagnostic – medical device
IVD in **Class A**, Reg. UE 2017/746
UDI-DI: 08033976231088
Basic UDI: 080339762W0104010899D7



Manufacturer: Bio-Optica Milano S.p.A.

Product for the preparation of cyto-histological samples for optical microscopy.

Differentiation of gram-positive and gram-negative bacteria in fixed smears. This method is often used to assess suitability of specimen for culture.

PRINCIPLE

The Gram-positive bacteria and yeasts hold back crystal violet and they stain in blue. The Gram-negative bacteria, permeable to the decolourising solution, discolour and are highlighted with a counterstain dye red.

METHOD

- 1) Fix air-dried smears using one of the following techniques:
 - a) Heat fix by passing the slide through a low flame 2-3 times. Cool the slide at room temperature before staining
 - b) Methanol fix, immerse the slide in absolute methanol for 1 - 2 minutes and rinse with distilled water before staining
- 2) Cover specimens with reagent A (Crystal-violet Hucker solution), leave to act 1 minute.
- 3) Drain the slide and flood briefly with reagent B (Lugol solution).
- 4) Cover completely with reagent B (Lugol solution) and leave to act 1 minute.
- 5) Wash with distilled water.
- 6) Cover completely with reagent C (Decolorizing solution): leave to act 1 minute.
- 7) Wash with distilled water
- 8) Cover completely with reagent D (Basic fuchsin solution): Leave to act 1 minute.
- 9) Wash carefully with distilled water
- 10) Air dry



The picture is for illustrative purposes only

Technical details

Method specifications	Procedure time	6 minutes	
	Complementary equipment	Not requested	
	Results	Gram-positive bacteria:	Blue-violet
		Gram-negative bacteria:	Pink-Red
Components	A) Crystal violet solution according to Hucker	500 ml	
	B) Lugol solution	500 ml	
	C) Decolorizing solution	2 x 500 ml	
	D) Basic fuchsin solution	500 ml	
Storage	Storage	Store the preparation at room temperature. Keep the containers tightly closed.	
	Storage temperature	15-25°C	
	Stability	After the first opening, the product is reusable until the expiry date, if correctly stored.	
	Validity	2 years	
Warning	Product classification	<p>The product is intended for professional laboratory use for healthcare professionals.</p> <p>Carefully read the information on the label (danger symbols, risk and safety phrases) and always consult the safety data sheet. Do not use if the primary container is damaged.</p> <p>In the event of a serious accident, we recommended that you immediately inform Bio-Optica Milano S.p.A and the competent authorities.</p>	
	Disposal	Hazardous preparation: observe all state and local environmental regulations regarding waste disposal.	

REVISION n°	REASON	REVISION DATE
001	Regulation adjustment UE 2017/746 - IVDR	16/05/2022