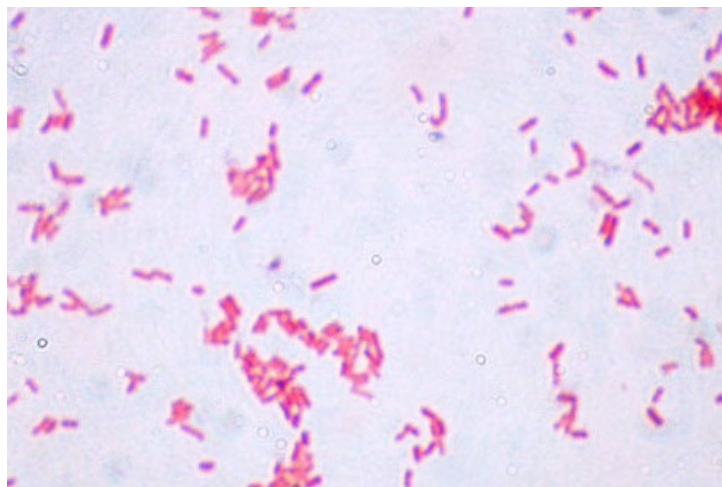




GRAM

For microbiology



Gram-negative bacteria

CODE	DESCRIPTION	TESTS NUMBER
04-100803	Gram for microbiology	N.A.



In Vitro Diagnostic – medical device
EMDN: W0104010899
IVD in **Class A**, Reg. UE 2017/746
UDI-DI: 08033976231064
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

Gram - positive bacteria and yeast cells retain crystal violet and stain blue. Gram-negative organisms allow crystal violet to wash out in decolorization and subsequently take up counterstain safranin and stain pink.

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 (Safranin 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) Safranin 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	The product is intended for professional laboratory use for healthcare professionals. 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. In the event of a serious accident, we recommended that you immediately inform Bio-Optica Milano S.p.A and the competent authorities.	
	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