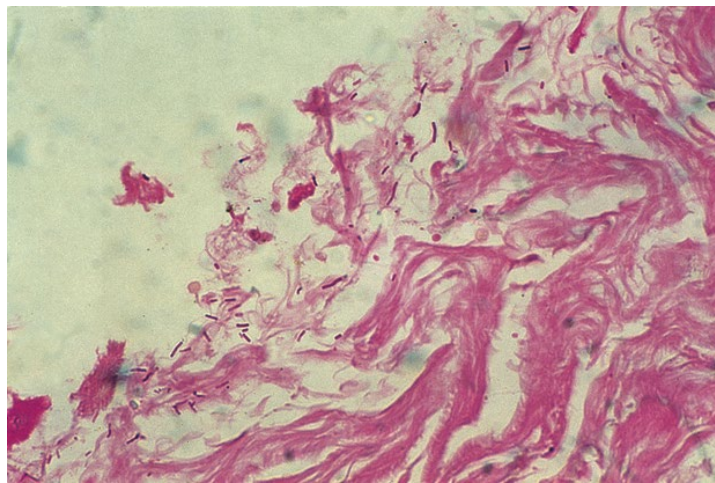




GRAM



Femoral artery

CODE	DESCRIPTION	TESTS NUMBER
04-100802	Gram	100 test



In Vitro Diagnostic – medical device
IVD in **Class A**, Reg. UE 2017/746
UDI-DI: 08033976231040
Basic UDI: 080339762W01030799Y5



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

Product for the preparation of cyto-histological samples for optical microscopy.
To differentiate between Gram-positive and Gram-negative bacteria in tissue sections.

PRINCIPLE

Gram staining is the most important method to differentiate bacteria species. Two dyes are used one after the other: crystal violet and fuchsin. Crystal violet solution precipitates through oxidation with an iodine solution. The deriving complex attaches to bacteria cell walls with bonds of varying nature and intensity. The differentiating solution removes the crystal violet-iodine complex from the walls of some bacteria, but it does not act on others. These retain the primary dye and are called Gram-positive. Decolorized bacteria are then counterstained with a red dye; they are called Gram-negative. Gram-positive bacteria's capacity to retain the dye-iodine complex is usually ascribed to the bond which develops between the complex and a molecule only Gram-positive possess, namely magnesium ribonucleate.

METHOD

- 1) Bring section to distilled water.
- 2) Pour the content of bottle A in a Coplin Jar, introduce the slide and incubate at 56-58°C for 15 minutes; pour back the solution in bottle A filtering through filter paper.
- 3) Wash in distilled water.
- 4) Put on the section 10 drops of reagent B: leave to act 3 minutes.
- 5) Drain the slide without washing and put on the section 10 drops of reagent C: leave to act 3 minutes.
- 6) Wash in distilled water and dry the slide in filter paper then in the air for 10 minutes.
- 7) Pour the content of bottle D in a Coplin Jar: shake the slide for 1 minute; pour back the solution in bottle D filtering through filter paper.
- 8) Repeat step 7 with reagent E.
- 9) Clear in xylene and mount.



The picture is for illustrative purposes only

Technical details

Method specifications	Procedure time	40 minutes	
	Complementary equipment	Coplin Jar n. 3, funnel, filter, oven	
	Results	Gram-positive bacteria:	Blue
		Gram-negative bacteria:	Red
Nuclei:		Red	
Components	A) Phloxine B solution	100 ml	
	B) Crystal violet solution	30 ml	
	C) Gram's iodine solution	30 ml	
	D) Acetone - Limonene	100 ml	
	E) Acetone - Limonene	100 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