Instructions For Use
ENGLISH

ONPG Test

Rapid test for the detection of β-galactosidase activity.

INTENDED PURPOSE

Test for the detection of bacterial β-galactosidase. This test is intended as an aid in the diagnosis, requiring further tests to complete the diagnostic results.

DESCRIPTION

ONPG Test are filter paper discs impregnated with a reagent for differentiation and microbial identification, particularly of Gram-negative bacteria, based on the presence of enzyme β-galactosidase, which allows bacteria to metabolize lactose.

KIT CONTENT

- 5 cartridges of 50 discs

METHOD PRINCIPLE

The ability of bacteria to ferment lactose depends on two enzymes: permease and beta-galactosidase. Permease regulates the movement of lactose across the bacterial cell wall. Once lactose is inside the cell, it is broken down into the individual components, glucose and galactose, by β-galactosidase. Some *Enterobacteriaceae* such as *E. coli*, *Klebsiella* spp. and *Enterobacter* spp., produce both β-galactosidase and permease, while late lactose fermenting organisms, like *Citrobacter* spp. and *Arizona* spp. produce only β-galactosidase. True lactose non-fermenters do not possess either of these enzymes (e.g. species of *Salmonella*, *Shigella*, *Proteus*, *Providencia* and *Morganella*). The colourless ONPG (ortho-nitrophenyl-β-D-galactopyranoside) is hydrolyzed by microorganisms that produce the enzyme β-galactosidase with the formation of o-nitrophenol, a yellow compound. In addition, ONPG is able to enter the bacterial cell more easily than lactose as it is not dependent on the presence of the permease enzyme.

MATERIALS REQUIRED BUT NOT PROVIDED

Standard microbiological supplies and equipment such as: inoculating loop, pipettes, physiological solution (0.85% sterile saline), culture media, quality control organisms.

REAGENTS

- Each disc is impregnated with a solution of ortho-nitrophenyl-galactopyranoside (ONPG).

SPECIMEN

Collect specimens in sterile containers or with sterile swabs and transport to the laboratory. Process each specimen using procedures appropriate for that sample. This product is recommended for use only with pure cultures.

Refer to specific guidelines for more detailed information.

TEST PROCEDURE

1. Allow product to reach room temperature before use, for minimizing condensation on the disc.
2. Place one ONPG Test disc into a sterile tube.
3. Add 0.2 mL of physiological solution to the tube.
4. With a sterile loop pick up one or more than one well isolated colony from a fresh culture plate (18-24 hours old) and emulsify in the tube.
5. Incubate tubes at 35 ± 2°C for up to 24 hours.
6. Examine for colour reactions after 4 h and for up to 24 h.

Note: Positive and negative controls should be run simultaneously with the organism to be tested (see QUALITY CONTROL).

INTERPRETING RESULTS

A positive ONPG reaction is indicated by development of a yellow colour.

No color change is a negative test, indicating the absence of β -galactosidase activity.

STORAGE

Store at 2-8°C away from light. Do not use the product beyond its expiry date on the label or if product shows any evidence of contamination or any sign of deterioration.

SHELF LIFE

1 year.

QUALITY CONTROL

Control strain		Characteristic reactions
Escherichia coli	ATCC® 25922	Positive reaction: Colour change to yellow
Citrobacter freundii	ATCC® 8090	
Proteus mirabilis	ATCC® 25923	Negative reaction: No color change
Salmonella Enteritidis	ATCC® 13076	

PERFORMANCE CHARACTERISTICS

Performance testing of ONPG Test was carried out using the QC strains listed above. The results obtained met the established criteria.

LIMITATIONS

Cultures which naturally yield yellow colour cannot be tested in this media.

Inoculation of test organism should be done only from lactose-containing medium.

The reaction speed depends on the size of the inoculum.

WARNING AND PRECAUTIONS

1) **For *in vitro* diagnostic use (IVD).**
2) **For laboratory professional use only**.
3) Operators must be trained and have certain experience. Please read the instructions carefully before using the product. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this document.
4) Consult the Safety Data Sheet (SDS) for information regarding hazards and safe handling practices.
5) Do not use if the product or packaging appears to be damaged.
6) Follow standard precautions. All patient specimens should be considered potentially infectious and handled accordingly.
7) Handle all specimens as if infectious using safe laboratory procedures. Dispose of hazardous or biologically contaminated materials according to the practices of your institution.
8) Avoid cross-contamination of samples by using disposable tips and changing them after each sample.
9) Do not mix reagents of different batches. Please use the product within the validity period.
10) Do not eat, drink, smoke, apply cosmetics or handle contact lenses in areas where reagents and human specimens are handled.
11) Results should be interpreted by a trained professional in conjunction with the patient's history and clinical signs and symptoms, and epidemiological risk factors.
12) Ensure laboratory equipment is calibrated and maintained in accordance with the laboratory's procedure.
13) When test results are transmitted from the laboratory to an informatics centre, attention has to be done to avoid erroneous data transfer.

DISPOSAL OF WASTE

Disposal of waste must be carried out according to national and local regulations in force.

BIBLIOGRAPHY

See the references at the end of this document.

TABLE OF SYMBOLS

See the table of symbols at the end of this document.

ORDER INFORMATION

Product	Packaging	Ref.
ONPG Test Disc	5 x 50 discs	88105

Revision History

Revision	Release Date	Change Summary
1	2024-09-16	Added notice to report any malfunction, defect or incident.
0	2023-05-15	Updated layout and content in compliance with IVDR 2017/746, version reset to revision 0

In case of malfunctions or defects, contact immediately Liofilchem (*) or the local representative.

In case of incident associated with the device, notify immediately Liofilchem (*) or its local representative and the National Competent Authority.

*Please login to https://www.liofilchemstore.it/login.php (user ID and password required) and click on Complaint.

This IFU document and the SDS are available from the online Support Center:

liofilchem.com/ifu-sds