

EN – Instruction for use

Q Path[®] FIXATIVE FORMALDEHYDE



According to Regulation (EU) 2017/746, Annex I, EN ISO 15223-1:2021 and EN ISO 20417:2021.

PRODUCT NAME

Formaldehyde 4% Q Path[®]

APPLICABLE PRODUCTS

Description	Pack Size	Cat. No.
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 50 items	87213.0060
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 100 items	10.02010WH0001
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 50 items	10.06030WH0001
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 50 items	10.07040WH0002
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 1 L	10.1000.0002
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 10 L	10.10000.0001
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 32 items	10.15060RD0001
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 32 items	10.15080RD0001
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 30 items	10.300150WH01
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 5 L	10.5000.0001
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 250 ml	10099464
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 500 ml	10099465
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 12 items	10099473_B
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 16 items	10099474_B
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 20 L	10099476_B
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 5 L	11699404
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 10 L	11699408
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 1 L	11699455
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 102 items	FOR0020AF59001
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 50 items	FOR0060AF59001
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 50 items	FOR0070AF59001
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 10 L	FOR010LAF59001
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 32 items	FOR0150AF59001
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 102 items	10.02005WH0003
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 102 items	10.02010BL0001
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 50 items	10.06025BL0001
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 50 items	10.06025BL0003
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 50 items	10.06025RD0001
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 50 items	10.06025WH0001
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 50 items	10.06025WH0005
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 50 items	10.06025YW0005
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 50 items	10.06025YW0007
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 50 items	10.07040OR0001
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 32 items	10.15080BL0001
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 32 items	10.15080BL0002
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 32 items	10.15080WH0004
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 32 items	10.15080WH0005
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 32 items	10.15080WH0006
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 102 items	FOR0021A75L038
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 102 items	FOR0021A75R044
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 102 items	FOR0021A760164
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 102 items	FOR0021A860022
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 102 items	FOR0021A920241

QTY

REF

Description	Pack Size	Cat. No.
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 102 items	FOR0022A540026
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 102 items	FOR0022A950078
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 50 items	FOR0061A13H065
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 50 items	FOR0061A310434
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 50 items	FOR0061A350078
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 50 items	FOR0061A440396
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 50 items	FOR0061A590528
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 50 items	FOR0061A600053
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 50 items	FOR0061A691044
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 50 items	FOR0061A75R044
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 50 items	FOR0061A760164
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 50 items	FOR0061A780109
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 50 items	FOR0061A820010
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 50 items	FOR0061A860022
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 50 items	FOR0061A920241
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 50 items	FOR0061AB10048
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 50 items	FOR0061AB10141
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 50 items	FOR0061AB11045
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 50 items	FOR0061AB11048
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 50 items	FOR0061AB40010
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 50 items	FOR0062A540026
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 50 items	FOR0062A950078
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 50 items	FOR0062AB80004
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 50 items	FOR0062AB88018
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 50 items	FOR0071A800003
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 32 items	FOR0151A440396
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 32 items	FOR0151A75R044
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 32 items	FOR0151A800004
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 32 items	FOR0151A820010
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 32 items	FOR0152A540026
Formaldehyde 4% Q Path / FORMALINE 10%	1 * 32 items	FOR0152A950078

PRODUCT DESCRIPTION

Formaldehyde 4% (formalin 10%) solution, buffered, various volumes.

INTENDED PURPOSE

- Reagent for fixation and preservation of specimens derived from the human body for histopathological analysis.
- Used in the pre-analytical phase of the histological process.
- For in vitro diagnostic use.
- For professional use.

WARNINGS AND PRECAUTIONS



- Reagent is ready for use.
- For single use only.
- It is recommended to always close the cap tightly.
- The histological specimen must be immersed as quickly as possible to stabilize the tissue.
- Do not use this product after its expiry date which is clearly indicated on the vial.
- Use a respiratory protection and appropriate personal protective equipment.
- Dispose according to local legislation. Consult the appropriate local waste disposal expert about waste disposal. Further, this information is also available under the header Disposal.
- Avoid inhalation.
- Avoid contact with eyes and skin.
- Use extractor hood (laboratory).
- If handled uncovered, arrangements with local exhaust ventilation have to be used.
- If local exhaust ventilation is not possible or not sufficient, the entire working area must be ventilated by technical means.
- **Hazard statements**
 - H302+H312+H332: Harmful if swallowed, in contact with skin or if inhaled.
 - H317: May cause an allergic skin reaction.
 - H341: Suspected of causing genetic defects.
 - H350: May cause cancer.
- **Precautionary statements**
 - P201: Obtain special instructions before use.
 - P280: Wear protective gloves/protective clothing/eye protection/face protection.
 - P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
 - P302+P352: IF ON SKIN: Wash with plenty of water.
 - P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.
 - P308+P313: IF exposed or concerned: Get medical advice/attention.
 - Over or under fixation results in unreliable or unreproducible immunohistochemistry outcome.
 - Further immunohistochemistry analysis may require the use of antigen retrieval techniques, which reverse the cross-links and facilitate antigen detection.
 - Tissue stored indefinitely in formalin, does not yield good antigen and hence may give false negative results. It is always useful to store the necessary tissue as paraffin blocks.
 - Formaldehyde should be replaced with fresh solution after hours if the specimen requires longer fixation before processing.
 - A ratio of specimen to formaldehyde less than 5:1 is considered inadequate.
 - Clean up spillages. Use an absorbent such as sand, "kitty litter" or a commercial product to collect spills and contain spread.
 - **First aid:** Obtain medical advice (first aid officer, doctor, poisons information centre, ambulance) immediately if major exposure occurs.

- **First aid:** Eye wash station, safety shower and first aid kits should be standard facilities in a laboratory.
- **Inhalation:** Remove from exposure into fresh air. If not breathing, apply artificial respiration.
- **Ingestion:** Rinse mouth thoroughly with water. Do not induce vomiting. Give water or milk to drink.
- **Eye contact:** Immediately hold eyes open and flood with water. Continue for at least 15 minutes.
- **Skin contact:** Wash affected area thoroughly with water and mild soap. Remove contaminated clothing and wash thoroughly or discard.
- Formalin fixation may lead to less efficient complementary deoxyribonucleic (cDNA) synthesis and reverse transcription quantitative polymerase chain reaction (RT-qPCR) reactions.
- Pregnant women: Formaldehyde exposure is detrimental to the developing foetus.
- The fixation time on a tissue of 5 mm should be between 12 hours and 24 hours. This fixation duration is in most case reasonable for an appropriate penetration and fixation.

For further information please refer to Safety Data Sheet.

INTENDED USER

Intended for laboratory professional use.

INTENDED PATIENT POPULATION

Intended for patients in need of histological specimen examination.

USE ENVIRONMENT

The Q Path® Fixative Formaldehyde is intended to be used in professional healthcare environments, for example clinical and diagnostic laboratories.

COMPOSITION

- Formaldehyde (4% m/V)
- Methanol
- Phosphate buffer (40 mmol/L)
- pH at 20 °C: 6.8 - 7.2

STORAGE AND SHELF LIFE

This product should be stored upright in a tightly closed container, at a temperature between +5 °C and +25 °C, away from direct light and in a properly ventilated location.

Before and after first opening, the contents can be used until the stated expiry date when stored at a temperature between +5 °C and +25 °C.

- The bottles must be kept tightly closed at all times.
- Protect from moisture.

ADDITIONAL MATERIALS AND SPECIAL EQUIPMENT REQUIRED BUT NOT PROVIDED

- Suitable vials with lids and label for product provided in bulk packaging. Such vials must be compatible with 4% solution of formaldehyde.

SPECIMENS

- **Type of specimen:** Histological specimens obtained by microsurgical procedure or macroscopic section.
- **Special conditions for specimens:** Fresh specimens that must be immersed as quickly as possible into the fixative.
- **Pre-treatment:** None.
- **Storage conditions:** Keep at room temperature between +5 °C and +25 °C.

PROTOCOL

Preparation of material from bulk packaging (i.e., all pack sizes > 150 ml):

1. Take a suitably sized empty bottle.
2. Remove the cap.
3. Pour a sufficient volume of Formalin so that the specimen shall be totally immersed in the fixative solution (the volume of fixative should be at least 10 times the volume of the specimen).

General mode of operation

1. Take the specimen.
2. Immerse the specimen into the bottle.
3. Screw the cap back on. The bottle must be tightly closed.
4. Put the patient's identification on the label of the bottle.
5. Send the bottle to the laboratory.

METHODOLOGY

Principle of the method

Fixing by formaldehyde solution allows the conservation of tissue structures in a state which is similar to the normal state. It blocks autolysis due to protein degradation and inhibits bacterial growth.

Fixing must be done immediately after extraction, by immersion of the specimen in a large volume of fixative liquid. The time required for fixing depends on the volume of specimen (e.g., from a few hours for a simple biopsy to several weeks for an entire human brain).

Method characteristics and performance limitations

- The fixed histological sample can not be cut as a frozen tissue, and not be cut with a vibratome.
- The fixative penetration speed is on average from 0.8 to 1 mm / hour.
- The histological sample should be totally submerged, the volume of fixative should be at least 10 times that of the sample.
- For any other methods please refer to the instructions of the used technique (e.g., biochemistry, immuno-histo-chemistry, molecular biology) to know the limits of performances.

REAGENT PREPARATION

Fixative solution is ready for use. Products packaged in bulk volume must be aliquoted or poured into bottles of appropriate size for specimen fixation.

DISPOSAL

Handle contaminated packages in the same way as the substance itself.

Dispose according to local legislation. Consult the appropriate local waste disposal expert about waste disposal.

NOTICE FOR THE USER

Any serious incident that has occurred in relation to this product must be reported to the manufacturer and the Competent Authority of the Member State in which the user and/or the patient is established. Please contact your local VWR partner through the **vwr.com** website.






We pay the utmost attention to the quality of our products. In case of any malfunction or dissatisfaction please use the complaints form on the contact page of your local **vwr.com** website and indicate the reference and batch number of the product concerned.






This instruction for use was established in May 2024 and cancels all previous instructions. The information is based on our knowledge and our experience this day. The attention of the users is drawn to the eventual risks when the product is used for a different use than it is dedicated. The user is not exempt to know and implement all the texts regulating their activity. They will take under their responsibility the precautions bound in the use that they make of the product.

Modifications to instructions for use in revision 13:

- Modified intended purpose.
- Addition of intended user and use environment.
- Update of warnings and precautions.
- Addition of description of symbols used.
- Minor updates and corrections.

SYMBOLS USED (EN ISO 15223-1:2021)

Symbol	Symbol title and description
	In vitro diagnostic medical device: Indicates a medical device that is intended to be used as an in vitro diagnostic medical device.
	Catalogue number: Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Do not re-use: Indicates a medical device that is intended for one single use only.
	Batch code: Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Caution: To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.

Symbol	Symbol title and description
	Manufacturer: Indicates the medical device manufacturer.
	Consult instructions for use or consult electronic instructions for use: Indicates the need for the user to consult the instructions for use.
	Keep dry: Indicates a medical device that needs to be protected from moisture.
	Use-by date: Indicates the date after which the medical device is not to be used.
	Made in Poland

CONTACT 
VWR International S.A.S.
 Immeuble Estréo, 1-3 rue d'Aurion
 93110 Rosny-sous-Bois, France
 +33 (0) 145 14 85 00