PTEN (10q23) Orange

FISH Probe 901-7321-120517

В		0	С	A	R	E
Μ	Е	D	Ι	С	А	L

Catalog Number:	PFI7321V
Description:	PTEN (10q23) Orange FISH Probe
Dilution:	Ready-to-use
Volume:	25 μL

Intended Use:

For In Vitro Diagnostic Use.

PTEN (10q23) Orange FISH Probe is intended to hybridize to the 10q23 region on chromosome 10. The clinical interpretation of any positive or negative hybridization events should be complemented by the use of appropriate controls and other diagnostic tests where appropriate. Evaluation should be carried out within the context of the patient's clinical history by a qualified pathologist.

FOR DISTRIBUTION OUTSIDE THE UNITED STATES ONLY

Summary and Explanation:

The PTEN (Phosphatase and Tensin) gene is involved in the regulation of DNA repair, genomic instability, stem cell self-renewal,

cellular senescence, and cell migration. Research has shown that deletions of PTEN occur at a very high frequency in prostate cancer. The presence of PTEN genomic losses are frequent at diagnosis and are a significant prognostic marker for the subsequent development of clinically advanced disease¹. Other studies have demonstrated an association between decreased PTEN protein expression and a higher Gleason grade and advanced tumor stage².

The PTEN (10q23) Probe is approximately 177 kb in size and is designed to provide coverage of the 10q23 region of chromosome 10.





PTEN (10q23.31) Orange FISH probe hybridized on FFPE tissue.

Principle of Procedure:

Biocare Medical 60 Berry Drive Pacheco, CA 94553 USA

Fluorescent in situ hybridization (FISH) is used to detect specific sequences of chromosomal DNA by using probes, or short fragments, of complementary DNA that have been fluorescently labeled. The hybridization between the probe and its target DNA sequence can be detected under a fluorescent microscope.

Species Reactivity: Human

Known Application:

Fluorescence In-Situ Hybridization (FISH) on formalin-fixed paraffinembedded (FFPE) tissues.

Supplied As: Probe in hybridization buffer.

Storage and Stability:

Store probe at -20°C and away from light. The product is stable to the expiration date printed on the label, when stored under these conditions. Do not use after expiration date.

Protocol Recommendations:

- Apply 10 µl of probe mix to the selected target area of the slide. 1.
- Cover with an 18 mm x 18 mm cover glass and seal with rubber 2. cement.
- 3. Place sealed slide on thermal cycler designed to perform denaturation and hybridization steps in slide-based FISH procedures (please see manufacturer's operating instructions).
- Denature probe at 83°C for 5 minutes and hybridize at 37°C 4. between 12-18 hours.
- Remove cover glass and wash slides using the following 5. conditions:
 - 5.1. Wash 1: 2x SSC/0.3% Nonident-P40 at 72°C±1°C for 2 minutes
 - 5.2. Wash 2: 2x SSC/0.1% Nonident-P40 at room temperature for 2 minutes
- 6 Apply 10 µl of a DAPI nuclear counterstain directly to the target area of the slide; cover area using a 24 mm x 50 mm cover glass.
- 7. Slides are ready for visualization using a fluorescent microscope.

Technical Note:

Biocare Medical FISH probes are optimized to provide the best signal performance using optical filters that can accommodate the excitation/emission wavelengths specified below. Using filters outside these spectral specifications may produce sub-optimal results.

Fluorophore	Excitation (nm)	Emission (nm)	
AQUA	432	472	
GREEN	498	521	
ORANGE	546	575	
RED	593	618	

Limitations:

The optimum probe dilution and protocols for specific applications may vary. These include, but are not limited to; sample preparation, hybridization conditions and incubation times, post hybridization washes and microscope filter specifications and illumination conditions. The recommended hybridization times and wash conditions are for



Œ IVD

Rev: 062117 Tel: 800-799-9499 | www.biocare.net | Fax: 925-603-8080

*not to scale

PTEN (10q23) Orange

FISH Probe 901-7321-120517

guidance only and it is the responsibility of the operator to determine optimal conditions. The clinical interpretation of any positive or negative hybridization events should be evaluated within the context of clinical presentation, morphological and/or cytogenetic criteria by a suitably qualified practitioner. These findings should be complemented by the use of appropriate controls and other diagnostic tests where appropriate.

Ouality Control:

Fluorescence In-Situ Hybridization (FISH) Methods for Clinical Laboratories; Approved Guidelines - Second edition (MM07-A2). CLSI, Wayne, PA (<u>www.clsi.orq</u>). 2013.

Precautions:

- This product contains formamide, which may be toxic. Formamide 1. may cause serious eye damage or reproductive toxicity. It may also cause irritation by inhalation or skin contact. Avoid any direct contact exposure to reagent. Take appropriate protective measures (use disposable gloves, protective glasses, and lab garments).
- 2. Specimens, before and after fixation, and all materials exposed to them should be handled as if capable of transmitting infection and disposed of with proper precautions. Never pipette reagents by mouth and avoid contacting the skin and mucous membranes with reagents and specimens. If reagents or specimens come in contact with sensitive areas, wash with copious amounts of water3.
- 3. The SDS is available upon request and is located at http://biocare.net/.

Troubleshooting:

Follow the FISH probe specific protocol recommendations according to data sheet provided. If atypical results occur, contact Biocare Medical's Technical Support at 1-800-542-2002.

References:

- Yoshimoto M, Cutz J-C, Nuin PAS, Joshua AM, Bayani J, Evans AJ, 1. Zielenska M, Squire JA. Interphase FISH Analysis of PTEN in Histologic Sections Shows Genomic Deletions are Present in 68% of Primary Prostate Cancer and 23% of High-Grade Prostatic Intra-Epithelial Neoplasia. Cancer Genetics and Cytogenetics 169:128-37, 2006.
- Loss of PTEN expression in paraffin-embedded primary prostate 2. cancer correlates with high Gleason score and advanced stage. McMenamin ME, Soung P, Perera S, Kaplan I, Loda M, Sellers WR. Cancer Res 1999, 59: 4291-4296
- 3. Clinical and Laboratory Standards Institute (CLSI). Protection of Laboratory workers from occupationally Acquired Infections; Approved Guideline-Fourth Edition CLSI document M29-A4 Wayne, PA 2014.





BIOCARE

MEDICA

