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DATA SHEET

eFISH Her2/CEN17 Dual color probe

Catalog No.

FP039-10X-100µl- 10 test
FP039-20X-200µl- 20 test

Doc No: 932-FP039 Rev: E
Date of Release: 28-Mar-2024

Material Provided: One vial of eFISH probe in hybridization buffer (RTU).

Recommended detection system (Not supplied):
Either of the following detection system is recommended depending on the automation/manual platform used:

eFISH Kit	Cat #	No of Tests	Description
eFISH Histo	DF500-20XE	20	Xmatrx Automation
eFISH Cyto	DF510-20XE	20	Xmatrx Automation
eFISH Histo	DF520-20X	20	NanoVIP Automation
eFISH Cyto	DF530-20X	20	NanoVIP Automation
eFISH Histo	DF521-50X	50	NanoVIP Automation (Open system)
eFISH Cyto	DF531-50X	50	NanoVIP Automation (Open system)
eFISH Histo	DF522-50X	50	NanoVIP Automation (Closed system)
eFISH Cyto	DF532-50X	50	NanoVIP Automation (Closed system)

Intended Use:
The BioGenex eFISH Her2/CEN17 dual color probe is currently available for **Research use only**. eFISH Her2/CEN17 dual color probe is designed to be used for the detection of chromosome 17 alpha-satellites as well as the human HER2 gene in formalin-fixed paraffin-embedded tissue or cells by fluorescence in situ hybridization (FISH).

Summary and Explanation
BioGenex eFISH Her2/CEN17 dual color probe comes in formamide hybridization buffer. The probe contains orange-labeled polynucleotides (Orange: excitation at 547 nm and emission at 572 nm, similar to rhodamine), which target the alpha-satellite-sequences of the centromere of chromosome 17 and green labeled polynucleotides (Green: excitation at 503 nm and emission at 528 nm, similar to FITC), which target HER2 gene.

Principles of the Procedure
Fluorescence *in situ* hybridization (FISH) is a robust technique of cytogenetic used for the detection of chromosomal aberrations, presence or absence of specific DNA sequence in native context. In this technique florescent probes bind to the target sequence of DNA in chromosome. High specificity and sensitivity coupled rapid and an accurate result has proven role of FISH in both research and diagnosis of solid tumor and hematological malignancies. As technique of cancer cytogenetics, FISH, can be used to identify genetic aberrations viz., deletions, amplification and translocation in tissue sections or within individual cells. FISH is also used for use in genetic counseling, medicine, and species identification. FISH can also be used to detect and localize specific RNA targets in cells, circulating tumor cells, and tissue samples[1,2,3,4,5].

In FISH procedure, fixed tissue sections are pretreated to expose target DNA or mRNA sequences. An appropriately labeled probe is hybridized to the exposed target DNA or mRNA sequences in the cells. Subsequent stringent washing steps remove any probe that is non-specifically bound to the tissue section. Subsequently slides are mounted using DAPI/antifade and can be visualized under fluorescence microscope using appropriate filter set.

Storage and Handling
The BioGenex eFISH Her2/CEN17 dual color probe must be stored at 2-8°C protected from light and is stable through the expiry date printed on the label.

Specimen Collection and Slide Preparation
Tissues fixed in 10% (v/v) formalin are suitable for use prior to paraffin embedding and sectioning.

FISH Staining procedure

(a) The BioGenex eFISH probes are supplied in hybridization buffer and used without further dilution.

(b) Protocol:

Please refer to the eFISH probe specific instruction/protocol for automated or semi-automated FISH processing platform (Xmatrx®-Infinity, Xmatrx®-Nano and Xmatrx®-mini.

Further processing, such as washing and counter-staining, can becompleted according to the user's needs. For a particularly user-friendlyperformance, we recommend the use of a BioGenexeFISH kit.

These systems were also used for the confirmation ofappropriateness of the BioGenex eFISH Her2/CEN17 dual color probe.

Disclaimer: The above information is provided for reference only. Each end-user is responsible for developingand validating optimal testing conditions for use with this product.

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Troubleshooting
Contact BioGenex Technical Service Department at **1-800-421-4149 or your local distributor** to report unusual staining.

Expected Results
The use of eFISH HER2/CEN17 probe in interphase and normal chromosome 17 produces two HER2 signals and two chromosome 17 signals. These signals appear green with hybridized HER2 probe and orange when hybridized to alpha centromeric region of chromosome 17, when appropriate filter sets are used. In cases of increased gene amplification in these regions, an increased number of gene signals are visible.

BioGenex eFISH HER2/CEN17 serves as a internal control as it recognizes the alpha-centromeric sequences of chromosome 17 to prove the integrity of the cellular DNA and the success of hybridization.

However, we recommend the use of a control sample in which the chromosome 17 and HER2 gene region copy number is known to judge the specificity of the signals with each hybridization reaction.

Care should be taken not to evaluate overlapping cells, in order to avoidfalse results, e.g. an amplification of genes. Due to decondensedchromatin, single FISH signals can appear as small signal clusters. Thus,two or three signals of the same size, separated by a distance equal to orless than the diameter of one signal, should be counted as one signal.

Limitations of the Procedure
Correct treatment of tissues prior to and during fixation, embedding, and sectioning is important for obtaining optimal results. Inconsistent results may be due to variations in tissue processing, as well as inherent variations in tissue. The results from *in situ* hybridization must be correlated with other laboratory findings.

Bibliography

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	Temperature Limitation	RUO	Research Use only
	Use By Date	LOT	Batch Code
	Non-Sterile		Consult Instructions for Use
	Manufacturer, BioGenex		