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EC REP

DATA SHEET

eFISH ERG Dual Color Break Apart Probe

Catalog No.
FP195-10XE- 100µl-10 test
FP195-20XE- 200µl-20 test

Doc No: 932-FP195E Rev: A
Date of Release: 21-Mar-2023

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 ERG Dual Color Break Apart Probe is currently available for **Invitro diagnostic use** only. The BioGenex eFISH ERG Dual Color Break Apart Probe is designed to be used for the detection of translocation the human ERG at 21q22.2 in formalin-fixed, paraffin-embedded tissue or cells by fluorescence in situ hybridization (FISH).

Summary and Explanation
BioGenex eFISH ERG Dual Color Break Apart Probe comes in Formamide based hybridization buffer. The probe contains green-labeled polynucleotides (Green: excitation at 503 nm and emission at 528 nm), which target the sequences mapping in 21q22.2* distal to ERG breakpoint region and orange-labeled polynucleotides (Orange: excitation at 547 nm and emission at 572 nm), which target the sequences mapping in 21q22.13-q22.2* proximal to the ERG breakpoint region.

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 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.

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 ERG Dual Color Break Apart 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 be completed according to the user's needs. For a particularly user-friendly performance, we recommend the use of a BioGenex eFISH kit.

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These systems were also used for the confirmation of appropriateness of the BioGenex eFISH ERG Dual Color Break Apart Probe .

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

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

Expected Results
The BioGenex eFISH ERG Dual Color Break Apart Probe is a mixture of an orange fluorochrome probe specific for the sequences proximal to the ERG breakpoint region and a green fluorochrome probe specific for the sequences distal to the ERG breakpoint region at 21q22.2*.

In a normal interphase nucleus, two orange and two green fusion signals are expected. In a cell with translocation of the ERG gene, one orange/green fusion signal, a separate green, and a separate orange signal will be observed. A cell with deletion of ERG gene is indicated by the loss of one green signal. Deletions affecting only parts of the ERG gene region might result in a normal signal pattern with green signals of reduced size.

However, we recommend the use of a control sample in which the 21q22.2* status 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 avoid false results, e.g. an amplification of genes. Due to decondensed chromatin, single FISH signals can appear as small signal clusters. Thus, two or three signals of the same size, separated by a distance equal to or less 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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8°C / 2°C	Temperature Limitation	IVD	In Vitro Diagnostic Medical Device
	Use By Date	LOT	Batch Code
NON STERILE	Non-Sterile		Consult Instructions for Use
EC REP	Representative in the European Community		BioGenex