D13S319 (13q14.2) Orange FISH Probe

Control Number: 901-7267-012218



Catalog Number:	HFI7267A
Description:	D13S319 (13q14.2) Orange FISH Probe
Dilution:	Ready-to-use
Volume:	100 µL

Intended Use:

For In Vitro Diagnostic Use.

D13S319 (13q14.2) Orange FISH Probe is intended to hybridize to the 13q14.2 region on chromosome 13. 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.

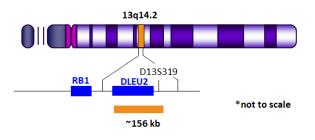
FOR DISTRIBUTION OUTSIDE THE UNITED STATES ONLY

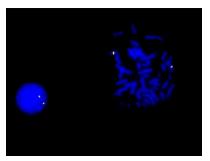
Summary and Explanation:

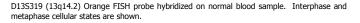
Loss of the 13q region or even the whole of chromosome 13 is very common in cases of multiple myeloma (MM). Deletions of the DS13S319 gene are common in a variety of hematological malignancies including chronic lymphocytic leukemia (CLL), acute myelocytic leukemia (AML) and MM^{1,2}.

Principle of Procedure:

The D13S319 (13q14.2) Probe is approximately 156 kb in size and is designed to provide coverage of the 13q14.2 region of chromosome 13.







Species Reactivity: Human

Known Application:

Fluorescence In-Situ Hybridization (FISH) on hematological samples.

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:

- 1. Apply 10 µl of probe mix to the selected target area of the slide.
- 2. Cover with an 18 mm x 18 mm cover glass and seal with rubber cement.
- Place sealed slide on thermal cycler designed to perform denaturation and hybridization steps in slide-based FISH procedures (please see manufacturer's operating instructions).
- 4. Denature probe at 72°C for 2 minutes and hybridize at 37°C between 12-18 hours.
- 5. Remove cover glass and wash slides using the following conditions:
 - 5.1. Wash 1: 0.4x 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 guidance only and it is the responsibility of the operator to determine optimal conditions. The clinical interpretation of any positive or





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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.

Quality Control:

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

Precautions:

- 1. This product contains formamide, which may be toxic. Formamide 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).
- 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:

- Comprehensive genetic characterization of CLL: a study on 506 cases analysed with chromosome banding analysis, interphase FISH, IgV(H) status and immunophenotyping. Haferlach C, Dicker F, Schnittger S, Kern W, Haferlach T. Leukemia 2007, 21:2442-2451
- Monoallelic and Biallelic Deletions of 13q14 in a Group of 36 CLL Patients Investigated by CGH Haematological Cancer and SNP Array (8x60K).B. Grygalewicz, R. Woroniecka, J. Rygier, K. Borkowska, A. Labak, B. Nowakowska, B. Pienkowska-Grela. International Science Index Vol:2, No:9, 2015
- 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.







The Netherlands