

# CCND1 (11q13) FISH Probe

Control Number: 901-7260-012218

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**Catalog Number:** HFI7260A  
**Description:** CCND1 (11q13) Orange FISH Probe  
**Dilution:** Ready-to-use  
**Volume:** 100 µL

**Intended Use:**  
For In Vitro Diagnostic Use.

CCND1 (11q13) Orange FISH Probe is intended to hybridize to the 11q13 region on chromosome 11. 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.

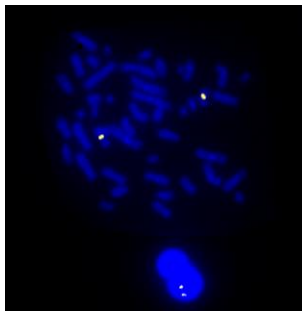
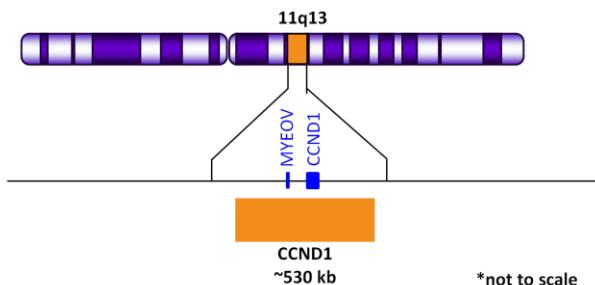
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### Summary and Explanation:

A fusion event involving CCND1 and IGH has been widely reported in many hematologic tumors such as mantle cell lymphoma (MCL), chronic lymphocytic leukemia (CLL), prolymphocytic leukemia, multiple myeloma, and plasma cell leukemia<sup>1</sup>. It is often thought of as a signpost marker for MCL, the frequency of t(11;14) for this type of lymphoma has been reported as 50-70%<sup>2,3</sup>.

### Principle of Procedure:

The CCND1 (11q13) Probe is approximately 530 kb in size and is designed to provide coverage of the 11q13 region of chromosome 11.



CCND1 (11q13) Orange FISH probe hybridized on normal blood sample. Interphase and metaphase cellular states are shown.

**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.
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).
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

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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.

Approved Guideline-Fourth Edition CLSI document M29-A4 Wayne, PA 2014.

## Quality Control:

Fluorescence In-Situ Hybridization (FISH) Methods for Clinical Laboratories; Approved Guidelines – Second edition (MM07-A2). CLSI, Wayne, PA ([www.clsi.org](http://www.clsi.org)). 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).
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 water<sup>4</sup>.
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:

1. Amplification of IGH/CCND1 fusion gene in a primary plasma cell leukemia case. Ishigaki T, Sasaki K, Watanabe K, Nakamura N, Toyota S, Kobayashi H, Tohda S. Cancer Genet Cytogenet. 2010 Aug;201(1):62-5.
2. The ultrastructure of mantle cell lymphoma and other B-cell disorders with translocation t(11;14)(q13;q32). Resnitzky P, Matutes E, Hedges M, Morilla R, Brito-Babapulle V, Khokhar T, Catovsky D. British journal of haematology. 1996 ; 94 (2) : 352-361.
3. Insertion of the CCND1 gene into the IgH locus in a case of leukaemic small cell mantle lymphoma with normal chromosomes 11 and 14. A Aventín, J Nomdedéu, J Briones, I Espinosa, R Bordes, J Sierra. J Clin Pathol 2003;56:798-800
4. Clinical and Laboratory Standards Institute (CLSI). Protection of Laboratory workers from occupationally Acquired Infections;