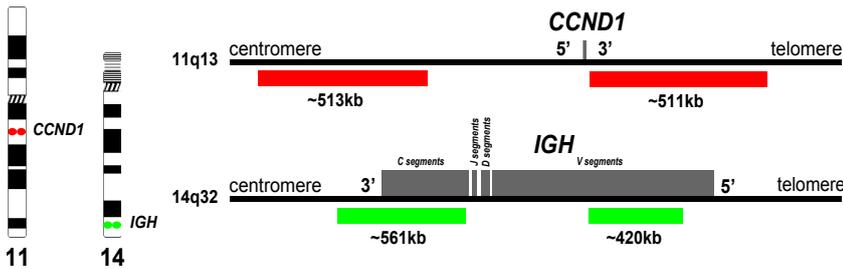


Intended Use

The *CCND1/IGH* DNA-FISH Probe is designed to detect the translocation between the *CCND1* gene located on 11q13 and the *IGH* gene located on 14q32 by fluorescence *in situ* hybridization (FISH). The translocation between the *CCND1* and *IGH* gene is designated as t(11;14)(q13;q32) and is the cytogenetic hallmark of mantle cell lymphoma (MCL), which distinguishes it from other non-Hodgkin lymphomas.^[1,2] The t(11;14) also has been detected in light chain amyloidosis, monoclonal gammopathy of undetermined significance (MGUS), and multiple myeloma (MM) cases.^[3,4] The presence of t(11;14)(q13;q32) in MM patients is associated with an improved survival.^[5]



Schematic of the *CCND1/IGH* DNA-FISH Probe:

Horizontal red and green bars indicate the regions covered by the probes (approximate to scale, GRCh37/Hg19/2009). The directly labeled *CCND1* (red) probe flanks the gene and the *IGH* (green) probe flanks the most common breakpoints within the *IGH* gene.

Signal Interpretation

In normal diploid metaphase and interphase nucleus, two red and two green signals would be observed corresponding to the two normal homologous chromosomes 11 and 14, respectively (Figures 1 and 2). Upon translocation, the most commonly observed pattern is a single red and green signal, representing the normal chromosomes 11 and 14, and two fusion signals (red/green or yellow) representing the translocated chromosomes (Figure 3). It is recommended to confirm variant pattern or atypical signal patterns by metaphase analysis whenever possible.

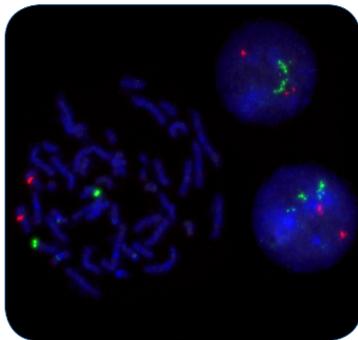


Figure 1: Normal diploid metaphase and interphase nuclei (from normal peripheral blood specimen) with 2 red (*CCND1*) and 2 green (*IGH*) sig-

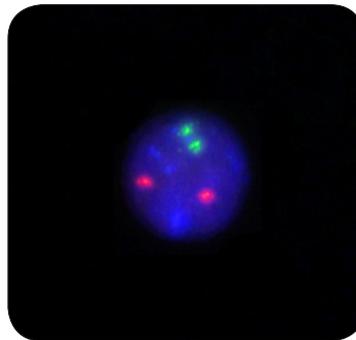


Figure 2: Normal diploid interphase nuclei (from bone marrow specimen) with 2 red (*CCND1*) and 2 green (*IGH*) signals.

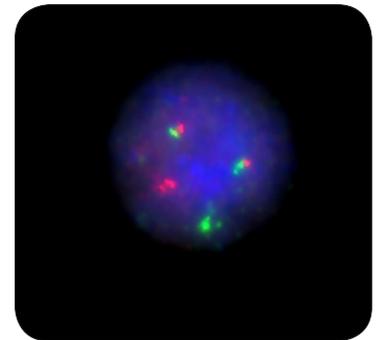


Figure 3: Interphase nucleus with 1 red (*CCND1*), 1 green (*IGH*), and 2 fusion (red/green or yellow) signals.

References

1. Heim, S., Mitelman, F. (Ed). Cancer Cytogenetics, 2009 (3rd Edition). Wiley-Blackwell, New Jersey. P. 313-315.
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Fluorescence Microscopy Filter Requirements

| Fluorophore | Excitation _{max} | Emission _{max} |
|-------------|---------------------------|-------------------------|
| Green | 496 nm | 520 nm |
| Red | 580 nm | 603 nm |
| DAPI | 360 nm | 460 nm |

Instructions for use are available at www.cancergeneticsitalia.com