ZytoLight® SPEC C19MC/19p13 Dual Color Probe

CE IVD

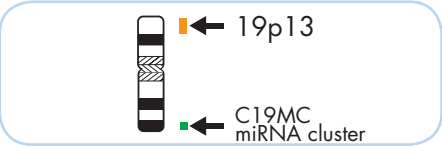
Background

The ZytoLight® SPEC C19MC/19p13 Dual Color Probe (PL230) is intended to be used for the qualitative detection of amplifications involving the C19MC locus as well as the detection of chromosome 19p13 specific sequences in formalin-fixed, paraffin-embedded specimens by fluorescence *in situ* hybridization (FISH).
The probe is intended to be used in combination with the ZytoLight® FISH-Tissue Implementation Kit (Prod. No. Z-2028-5/-20).
The product is intended for professional use only. All tests using the product should be performed in a certified, licensed anatomic pathology laboratory under the supervision of a pathologist/human geneticist by qualified personnel.
The probe is intended to be used as an aid to the differential diagnosis of various cancers and therapeutic measures should not be initiated based on the test result alone.

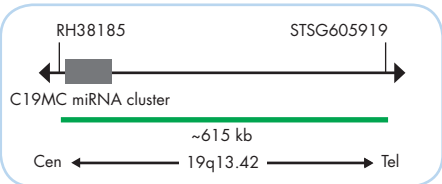
Probe Description

The ZytoLight® SPEC C19MC/19p13 Dual Color Probe is composed of:

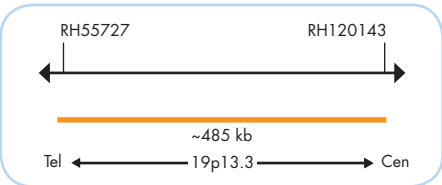
- ZyGreen (excitation 503 nm/emission 528 nm) labeled polynucleotides (~10.0 ng/µl), which target sequences mapping in 19q13.42** (chr19:54,156,239-54,768,983) harboring the C19MC locus.
- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~4.5 ng/µl), which target sequences mapping in 19p13.3** (chr19:658,555-1,144,465).
- Formamide based hybridization buffer



Ideogram of chromosome 19 indicating the hybridization locations.



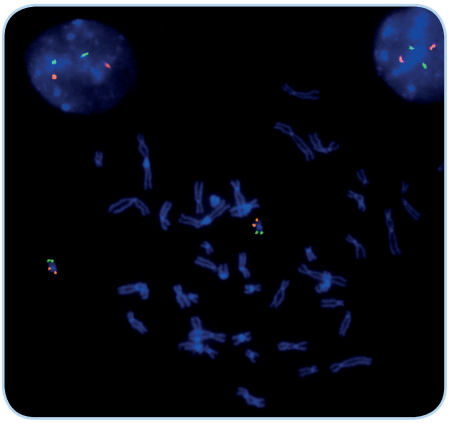
SPEC C19MC Probe map (not to scale).



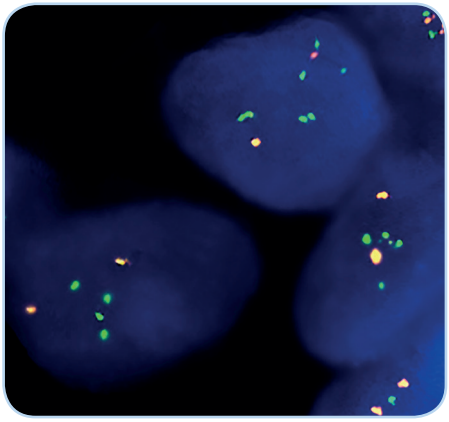
SPEC 19p13 Probe map (not to scale).

Results

In a normal interphase nucleus, two orange and two green signals are expected. In a cell with amplification of the C19MC region, multiple copies of the green signal or green signal clusters will be observed.



SPEC C19MC/19p13 Dual Color Probe hybridized to normal interphase cells as indicated by two orange and two green signals per nucleus and to metaphase chromosomes of a normal cell.



Example of an aberrant signal pattern: Primitive neuroectodermal tumor tissue section with amplification of the C19MC miRNA cluster as indicated by multiple green signals.

Specimen kindly provided by Hannu Haapasalo, MD, PhD, Fimlab Laboratories, Finland.

Prod. No.	Product	Label	Tests* (Volume)
Z-2274-50	ZytoLight SPEC C19MC/19p13 Dual Color Probe CE IVD	●/●	5 (50 µl)
Related Products			
Z-2028-5	ZytoLight FISH-Tissue Implementation Kit CE IVD Incl. Heat Pretreatment Solution Citric, 150 ml; Pepsin Solution, 1 ml; Wash Buffer SSC, 210 ml; 25x Wash Buffer A, 50 ml; DAPI/DuraTect-Solution, 0.2 ml		5

** Using 10 µl probe solution per test. IVD labeled products are only available in certain countries. All other countries research use only! Please contact your local dealer for more information.*
***According to Human Genome Assembly GRCh37/hg19*