ZytoLight® SPEC TP53/ATM Dual Color Probe

CE IVD

Background

The ZytoLight® SPEC TP53/ATM Dual Color Probe (PL115) is intended to be used for the qualitative detection of deletions involving the human TP53 gene as well as the human ATM gene in cytologic specimens by fluorescence *in situ* hybridization (FISH). The probe is intended to be used in combination with the ZytoLight® FISH-Cytology Implementation Kit (Prod. No. Z-2099-20).

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.

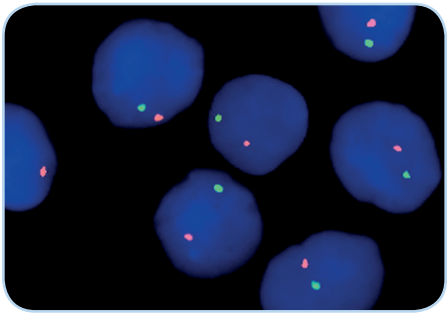
Probe Description

The ZytoLight® SPEC TP53/ATM Dual Color Probe is composed of:

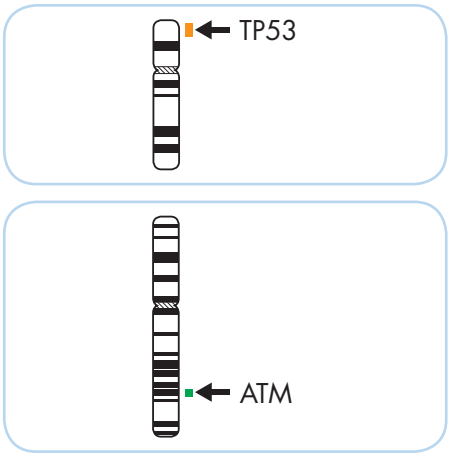
- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~4.5 ng/µl), which target sequences mapping in 17p13.1** (chr17:7,495,749-7,663,022) harboring the TP53 gene region.
- ZyGreen (excitation 503 nm/emission 528 nm) labeled polynucleotides (~10.0 ng/µl), which target sequences mapping in 11q22.3** (chr11:107,957,618-108,380,921) harboring the ATM gene region.
- Formamide based hybridization buffer

Results

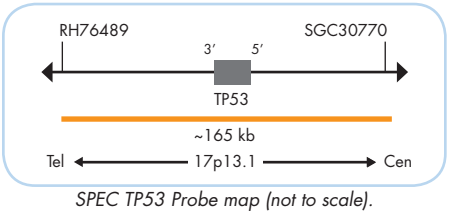
Using the SPEC TP53/ATM Dual Color Probe in a normal interphase nucleus, two orange and two green signals are expected. In a cell with deletions affecting the TP53 gene locus, a reduced number of orange signals will be observed. Deletions affecting only parts of the TP53 locus might result in a normal signal pattern with orange signals of reduced size. In a cell with ATM gene deletions, a reduced number of green signals will be observed. Deletions affecting only parts of the ATM locus might result in a normal signal pattern with green signals of reduced size.



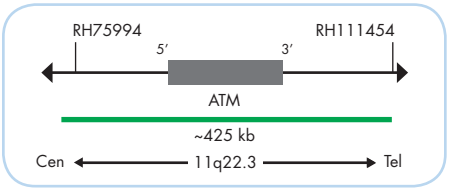
Example of an aberrant signal pattern: SPEC TP53/ATM Dual Color Probe hybridized to bone marrow biopsy with deletions of the ATM and the TP53 genes as indicated by one green and one orange signal in each nucleus.



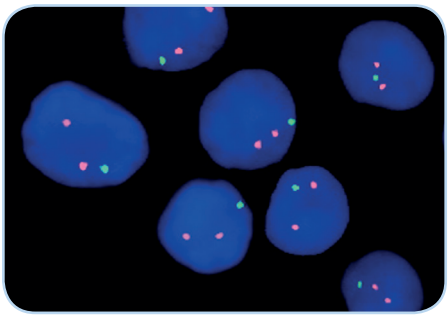
Ideograms of chromosomes 17 (above) and 11 (below) indicating the hybridization locations.



SPEC TP53 Probe map (not to scale).



SPEC ATM Probe map (not to scale).



Example of an aberrant signal pattern: SPEC TP53/ATM Dual Color Probe hybridized to bone marrow smear with deletion of the ATM gene as indicated by one green signal in each nucleus.

Prod. No.	Product	Label	Tests* (Volume)
Z-2159-50	ZytoLight SPEC TP53/ATM Dual Color Probe CE IVD	●/●	5 (50 µl)
Z-2159-200	ZytoLight SPEC TP53/ATM Dual Color Probe CE IVD	●/●	20 (200 µl)
Related Products			
Z-2099-20	ZytoLight FISH-Cytology Implementation Kit CE IVD Incl. Cytology Pepsin Solution, 4 ml; 20x Wash Buffer TBS, 50 ml; 10x $MgCl_2$, 50 ml; 10x PBS, 50 ml; Cytology Stringency Wash Buffer SSC, 500 ml; Cytology Wash Buffer SSC, 500 ml; DAPI/DuraTect-Solution, 0.8 ml		20

** 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*