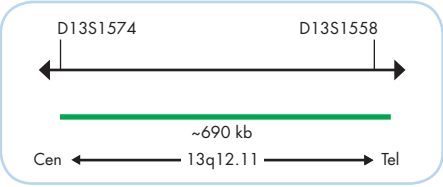
ZytoLight® Aneuploidy Panel X/Y and 13/18/21

CE IVD

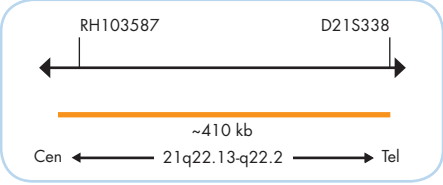
Background

The ZytoLight® Aneuploidy Panel X/Y and 13/18/21 is designed for enumeration of the chromosomes 13, 18, 21, X, and Y. Trisomies of the autosomes 13, 18, or 21 (Down Syndrome) are common genomic aberrations. Aberrant numbers of the gonosomes X and Y are resulting in disorders of sex development (DSD). Diseases such as Ulrich-Turner-Syndrome (45, X) or Triple X Syndrome (47, XXX) may cause severe developmental and metabolic disorders. The prevalence of chromosomal abnormalities detectable in the newborn including chromosomes 13, 18, 21, X, and Y, is about 0.92%.

References
Gillenberg C, (1998) J Autism Dev Disord 28: 415-25.
Jacobs PA, et al. (1992) J Med Genet 29: 103-8.



SPEC 13q12 Probe map (not to scale).



SPEC 21q22 Probe map (not to scale).

Probe Description

The ZytoLight® Aneuploidy Panel X/Y and 13/18/21 is a set comprising two separate probes:

- ZytoLight® CEN X/Yq12 Dual Color Probe (Prod. No. Z-2016-50/200)
- ZytoLight® SPEC 13/CEN 18/SPEC 21 Triple Color Probe (Prod. No. Z-2095-50/200)

The ZytoLight® CEN X/Yq12 Dual Color Probe (PL3) is composed of:

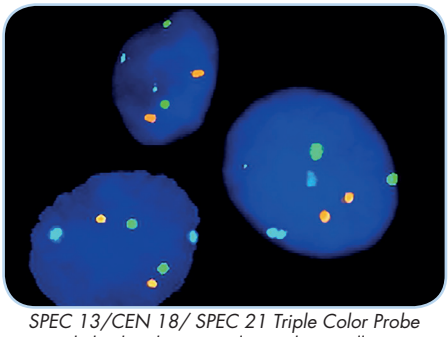
- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~1.5 ng/µl), which target sequences mapping in Xp11.1-q11.1 specific in the alpha satellite centromeric region DXZ1 of chromosome X.
- ZyGreen (excitation 503 nm/emission 528 nm) labeled polynucleotides (~4.5 ng/µl), which target sequences mapping in Yq12 specific in the classical satellite III centromeric region DYZ1 of chromosome Y.
- Formamide based hybridization buffer

The ZytoLight® SPEC 13/CEN 18/SPEC 21 Triple Color Probe (PL54) is composed of:

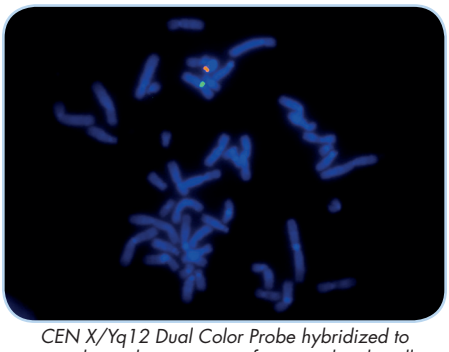
- ZyGreen (excitation 503 nm/emission 528 nm) labeled polynucleotides (~10.0 ng/µl), which target sequences mapping in 13q12.11** (chr13:20,200,365-20,892,494).
- ZyBlue (excitation at 418 nm and emission 467 nm) labeled polynucleotides (~12.0 ng/µl), which target sequences mapping in 18p11.1-q11.1 specific in the alpha satellite centromeric region D18Z1.
- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~4.5 ng/µl), which target sequences mapping in 21q22.13-q22.2** (chr21:39,372,983-39,784,773).
- Formamide based hybridization buffer

Results

In an interphase nucleus, using the ZytoLight® CEN X/Yq12 Dual Color Probe, two orange signals are expected in a normal female cell whereas one single orange and one single green signal is expected in a normal male cell.
In an interphase nucleus of a normal cell, using the ZytoLight® SPEC 13/CEN 18/SPEC 21 Triple Color Probe, two green, two blue, and two orange signals are expected. Other signal patterns indicate numerical aberrations of the respective chromosomes.



SPEC 13/CEN 18/ SPEC 21 Triple Color Probe hybridized to normal interphase cells.



CEN X/Yq12 Dual Color Probe hybridized to metaphase chromosomes of a normal male cell.

Prod. No.	Product	Label	Tests* (Volume)
Z-2104-5/20	ZytoLight Aneuploidy Panel X/Y and 13/18/21 CE IVD Incl. ZytoLight CEN X/Yq12 Dual Color Probe, 0.05/0.2 ml (Z-2016-50/-200); ZytoLight SPEC 13/CEN 18/SPEC 21 Triple Color Probe, 0.05/0.2 ml (Z-2095-50/-200)		5/20 (50/200 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
Z-2028-20	ZytoLight FISH-Tissue Implementation Kit CE IVD Incl. Heat Pretreatment Solution Citric, 500 ml; Pepsin Solution, 4 ml; Wash Buffer SSC, 560 ml; 25x Wash Buffer A, 100 ml; DAPI/DuraTect-Solution, 0.8 ml		20
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*