ZytoDot® 2C SPEC SS18 Break Apart Probe

ZytoDot [®]2^C Products for CISH analysis

Background

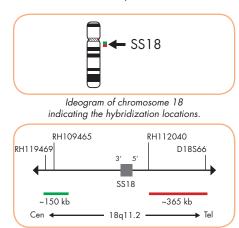
alone.

The ZytoDot® 2C SPEC SS18 Break Apart Probe (PD26) is intended to be used for the qualitative detection of translocations involving the human SS18 gene at 18q11.2 in formalin-fixed, paraffin-embedded specimens by chromogenic in situ hybridization (CISH). The probe is intended to be used in combination with the ZytoDot® 2C CISH Implementation Kit (Prod. No. C-3044-10/-40). 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

Probe Description

The ZytoDot® 2C SPEC SS18 Break Apart Probe is composed of:

- · Digoxigenin-labeled polynucleotides (~0.50 ng/µl), which target sequences mapping in 18q11.2** (chr18:23,109,942-23,262,464) proximal to the SS18 breakpoint region.
- · Dinitrophenyl-labeled polynucleotides (~0.75 ng/µl), which target sequences mapping in 18q11.2** (chr18:23,772,255-24,137,169) distal to the SS18 breakpoint region.
- · Formamide based hybridization buffer

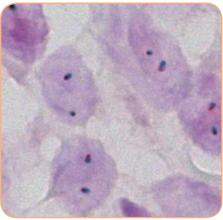


SPEC SS18 Probe map (not to scale).

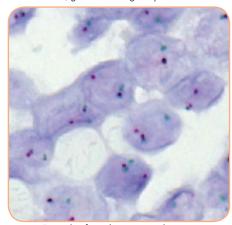
Results

In an interphase nucleus lacking a translocation involving the 18q11.2 band, using the ZytoDot® 2C CISH Implementation Kit two red/green fusion signals are expected representing two normal (non-rearranged) 18g11.2 loci. A signal pattern consisting of one red/green fusion signal, one red signal, and a separate green signal indicates one normal 18q11.2 locus and one 18q11.2 locus affected by an 18q11.2 translocation.

CE IVD



SPEC SS18 Break Apart Probe hybridized to normal interphase cells as indicated by two red/green fusion signals per nucleus.



Example of an aberrant signal pattern: Synovial sarcoma tissue section with translocation affecting the 18q11.2 locus as indicated by one non-rearranged red/green fusion signal, one red signal, and one separate green signal.

Prod. No.	Product	Label	Tests* (Volume)
C-3046-100	ZytoDot 2C SPEC SS18 Break Apart Probe C € 💴	DIG/DNP	10 (100 µl)
Related Prod	ucts		
C-3044-10	ZytoDot 2C CISH Implementation Kit C € IVD		10
	Incl. Heat Pretreatment Solution EDTA, 150 ml; Pepsin Solution, 1 ml; Wash Buffer SSC, 210 ml; 20x Wash Buffer TBS, 50 ml; Anti-DIG/DNP-Mix, 1 ml; HRP/AP-Polymer-Mix,1 ml; AP-Red Solution A, 0.1 ml; AP-Red Solution B, 4 ml; HRP-Green Solution A, 0.2 ml; HRP-Green Solution B, 4 ml; Nuclear Blue Solution, 4 ml; Mounting Solution (alcoholic), 1 ml		

**According to Human Genome Assembly GRCh37/hg19

