ZytoDot® 2C SPEC NTRK1 Break Apart Probe

CE IVD

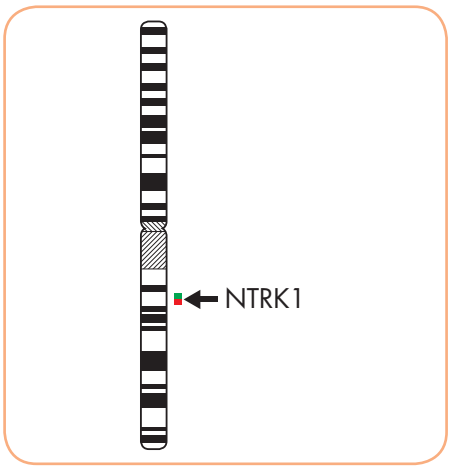
Background

The ZytoDot® 2C SPEC NTRK1 Break Apart Probe (PD57) is intended to be used for the qualitative detection of translocations involving the human NTRK1 gene at 1q23.1 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 alone.

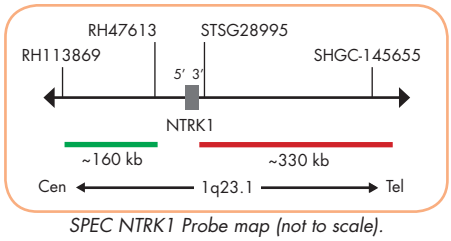
Probe Description

The ZytoDot® 2C SPEC NTRK1 Break Apart Probe is composed of:

- Digoxigenin-labeled polynucleotides (~0.50 ng/µl), which target sequences mapping in 1q23.1** (chr1:156,621,188-156,781,745) proximal to the NTRK1 breakpoint region.
- Dinitrophenyl-labeled polynucleotides (~0.75 ng/µl), which target sequences mapping in 1q23.1** (chr1:156,854,527-157,186,293) distal to the NTRK1 breakpoint region.
- Formamide based hybridization buffer



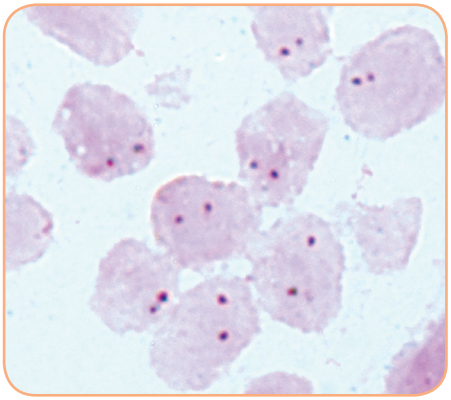
Ideogram of chromosome 1 indicating the hybridization locations.



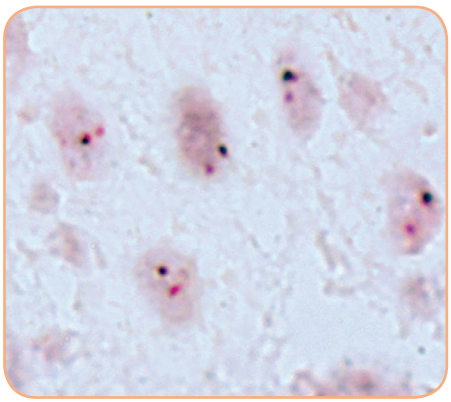
SPEC NTRK1 Probe map (not to scale).

Results

In an interphase nucleus of a normal cell lacking a translocation involving the 1q23.1 band, using the ZytoDot® 2C CISH Implementation Kit, two red/green fusion signals are expected representing two normal (non-rearranged) 1q23.1 loci. A signal pattern consisting of one red/green fusion signal, one red signal, and a separate green signal indicates one normal 1q23.1 locus and one 1q23.1 locus affected by a translocation. Isolated red signals are the result of deletions proximal to the NTRK1 breakpoint region or are due to unbalanced translocations affecting this chromosomal region.



SPEC NTRK1 Break Apart Probe hybridized to normal interphase cells as indicated by two red/green fusion signals per nucleus.



Example of an aberrant signal pattern: Spindle cell sarcoma tissue section with rearrangement of the NTRK1 gene as indicated by isolated red signals.

Prod. No.	Product	Label	Tests* (Volume)
C-3078-100	ZytoDot 2C SPEC NTRK1 Break Apart Probe CE IVD	DIG/DNP	10 (100 µl)
Related Products			
C-3044-10	ZytoDot 2C CISH Implementation Kit CE IVD 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, 0.2 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		10

** 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*