Zyto Dot ® 2C SPEC IGH Break Apart Probe



Background

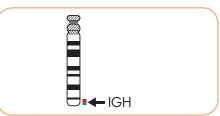
The ZytoDot® 2C SPEC IGH Break Apart Probe (PD51) is intended to be used for the qualitative detection of translocations involving the human IGH locus at 14q32.33 in formalin-fixed, paraffin-embedded specimens by chromogenic *in situ* hybridization (CISH). The probe is intended to be used in combination 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.

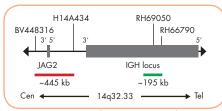
Probe Description

The Zyto*Dot* ® 2C SPEC IGH Break Apart Probe is composed of:

- Digoxigenin-labeled polynucleotides (~0.50 ng/µl), which target sequences mapping in 14q32.33** (chr14:106,690,778-106,883,535) distal to the IGH breakpoint region.
- · Dinitrophenyl-labeled polynucleotides (~0.75 ng/µl), which target sequences mapping in 14q32.33** (chr14:105,462,169-105,909,611) proximal to the IGH breakpoint region.
- · Formamide based hybridization buffer



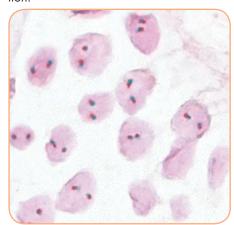
Ideogram of chromosome 14 indicating the hybridization locations.



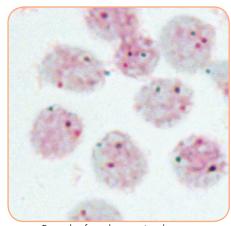
SPEC IGH Probe map (not to scale).

Results

In an interphase nucleus of a normal cell lacking a translocation involving the 14q32.33 band, using the ZytoDot® 2C CISH Implementation Kit, two red/green fusion signals are expected representing two normal (non-rearranged) 14q32.33 loci. A signal pattern consisting of one red/green fusion signal, one red signal, and a separate green signal indicates one normal 14q32.33 locus and one 14q32.33 locus affected by a translocation.



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



Example of an aberrant signal pattern:
Burkitt lymphoma tissue section with translocation
affecting the 14q32.33 locus as indicated by
one red/green fusion (non-rearranged) signal,
one red signal, and one separate green signal.

| Prod. No. | Product | Label | Tests* (Volume) |
|--------------|--|---------|-----------------|
| C-3071-100 | ZytoDot 2C SPEC IGH Break Apart Probe C € 0124 IVD | DIG/DNP | 10 (100 µl) |
| Related Prod | ucts | | |
| C-3044-10 | Zyto Dot 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; | | |

^{*} 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

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

