ZYTOVISION

Molecular diagnostics simplified

CATALOGUE UPDATE 2021

Dear Valued Customer,

Given the current situation with regard to the coronavirus SARS-CoV-2 pandemic, we have decided on a range of protective measures to maintain the production of our products. Protecting the health of our employees and safeguarding our delivery capability were the priorities for 2020. Therefore, we have decided not to create a new catalogue. Instead, this Catalogue Update informs you about the new products and other product-related changes.

This Catalogue Update introduces new products launched in 2020 and in the beginning of 2021, e.g., for the diagnosis of tumors of hematopoietic and lymphoid tissues. A new multiplex FISH probe for the genetic analysis of different types of lymphoma with the innovative DistinguISH™ probe design is added to the portfolio. DistinguISH™ probes save time and sample material as they allow the simultaneous detection of different genetic markers on only one slide.

Moreover, we are expanding our microdeletion portfolio by introducing the Zyto*Light*® SPEC Williams-Beuren Dual Color Probe. Microdeletion syndromes are characterized as heterogeneous diseases caused by the loss of small chromosomal regions. In general, these genetic aberrations are not visible in classical cytogenetics. FISH can reliably detect these deletions and confirm the diagnosis.

Despite the pandemic and the implemented safety measures, we are striving to maintain our services as far as possible and provide our customers and partners with the usual good service and support.

Stay healthy!

Sincerely,

Your ZytoVision Team

Table of Contents

ZytoLight®

FlexISH®

ZytoMation®

ZytoDot® 2C

VisionArray®

Further Product Changes

Prod. No. M-5050

3

ZytoLight® Bladder Cancer Quadruple Color Probe

CE IVD

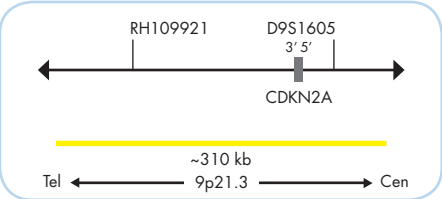
Background

The ZytoLight® Bladder Cancer Quadruple Color Probe is designed to detect CDKN2A (a.k.a. p16) deletions and aneuploidy of chromosomes 3, 7, and 17 in cytology specimens of tumors, e.g., in urine samples from patients with hematuria suspected of having bladder cancer (BC). Moreover, it has been shown that the detection of CDKN2A deletions and/or aneusomies of chromosomes 3, 7, and/or 17 may be used for the surveillance of patients with a history of bladder cancer to early detect possible tumor recurrence. BC represents the ninth most common cancer worldwide. About 430,000 new BC cases and 165,000 BC deaths occurred in 2012. Most of these tumors are non-invasive, well-differentiated, papillary tumors (pTa, low grade) and can be cured by endoscopic transurethral resection. However, up to 70% of pTa and superficially invasive (pT1) tumors recur and of these, 15-30% are characterized by tumor progression. Therefore, a long-term follow-up of patients with BC is necessary. The two standard methods used in the follow-up are either invasive (cystoscopy) or have a low sensitivity (cytology).
BC cells are characterized by typical cytogenetic changes. Homozygous deletion of the CDKN2A gene at 9p21.3 and polysomy of chromosomes 3, 7, and/or 17 are common abnormalities observed in urothelial cell carcinoma, all of which can be detected by FISH.
FISH on cells from urine has been shown to be highly sensitive and specific for detection of tumor cells in urine.

References
Antoni S, et al. (2017) Eur Urol 71: 96-108.
Dimashkieh H, et al. (2013) Cancer Cytopathol 121: 591-7.
Junker K, et al. (2006) Cytogenet Genome Res 114: 279-83.
Placer J, et al. (2002) Eur Urol 42: 547-52.
Sokolova IA, et al. (2000) J Mol Diagn 2: 116-23.

Probe Description

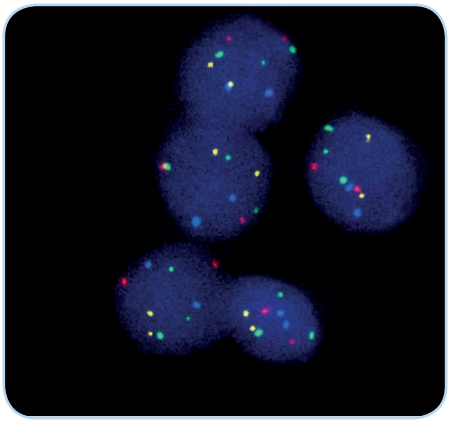
The Bladder Cancer Quadruple Color Probe is a mixture of a gold fluorochrome direct labeled SPEC CDKN2A probe specific for the CDKN2A gene at 9p21.3, a red fluorochrome direct labeled CEN 3 probe specific for the alpha satellite centromeric region of chromosome 3 (D3Z1), a green fluorochrome direct labeled CEN 7 probe specific for the alpha satellite centromeric region of chromosome 7 (D7Z1), and a blue fluorochrome direct labeled CEN 17 probe specific for the alpha satellite centromeric region of chromosome 17 (D17Z1).



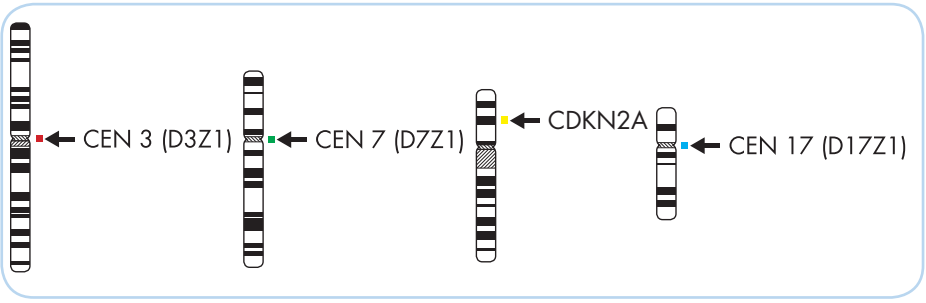
SPEC CDKN2A Probe map (not to scale).

Results

In a normal interphase nucleus, two gold, two red, two green, and two blue signals are expected. In a cell with deletion of the CDKN2A gene locus, a reduced number of gold signals will be observed. In cells with aneusomy of chromosomes 3, 7, or 17 more or less signals of the respective color will be visible.



Interphase tumor cells with trisomy of chromosome 7 as indicated by three green signals in each nucleus.



Ideograms of chromosomes 3, 7, 9, and 17 indicating the hybridization locations.

Prod. No.	Product	Label	Tests* (Volume)
Z-2305-50	ZytoLight Bladder Cancer Quadruple Color Probe CE IVD	●/●/●/●	5 (50 µl)
Z-2305-200	ZytoLight Bladder Cancer Quadruple 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. CE IVD only available in certain countries. All other countries research use only! Please contact your local dealer for more information.*

ZytoLight® SPEC 4p11/CEN 10/17 Triple Color Probe

CE IVD

Background

The ZytoLight® SPEC 4p11/CEN 10/17 Triple Color Probe is designed for the simultaneous enumeration of chromosomes 4, 10, and 17 in tumor cells.

High hyperdiploid childhood acute lymphoblastic leukemia (ALL) is characterized by multiple chromosomal gains (51-67 chromosomes), mainly trisomies but also frequently tetrasomies. The gains may involve any chromosome, but more than 70% of cases have additional copies of some or all of the chromosomes X, 4, 6, 10, 14, 17, 18, and 21.

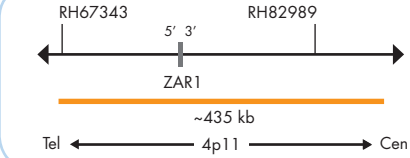
High hyperdiploidy is the most common chromosomal abnormality in childhood B-cell precursor ALL, occurring in 25-30% of such cases. In contrast, modal chromosome numbers of 51-67 are much less common in adult B-lineage ALL. Clinically, high hyperdiploid ALL is associated with age of 3-5 years and a favorable prognosis, with overall survival rates over 90% on current treatment protocols.

Hence, the identification of high hyperdiploidy in patients with pediatric ALL by FISH might be of prognostic and therapeutic relevance.

References
Kaneko Y, et al. (1981) Cancer Genet Cytogenet 4: 227-35.
Lampert F (1967) Klin Wochenschr 45: 763-8.
Paulsson K, et al. (2010) Proc Natl Acad Sci U S A 107: 21719-24.
Paulsson K, et al. (2015) Mol Cell Oncol 3: e1064555.
Paulsson K & Johansson B (2009) Genes Chromosomes Cancer 48: 637-60.

Probe Description

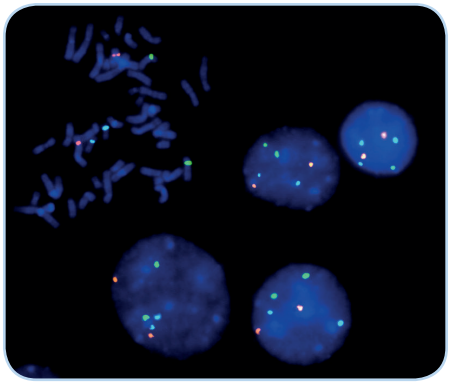
The SPEC 4p11/CEN 10/17 Triple Color Probe is a mixture of an orange fluorochrome direct labeled SPEC 4p11 probe specific for the ZAR1 (zygote arrest 1) gene region in 4p11, a green fluorochrome direct labeled CEN 10 probe specific for the alpha satellite centromeric region of chromosome 10 (D10Z1), and a blue fluorochrome direct labeled CEN 17 probe specific for the alpha satellite centromeric region of chromosome 17 (D17Z1). For an unambiguous enumeration of chromosome 4 the SPEC 4p11 is found to be more suitable.



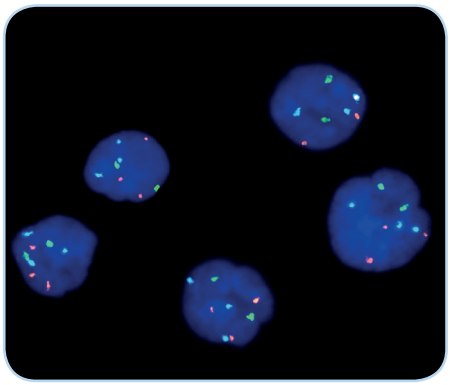
SPEC 4p11 Probe map (not to scale).

Results

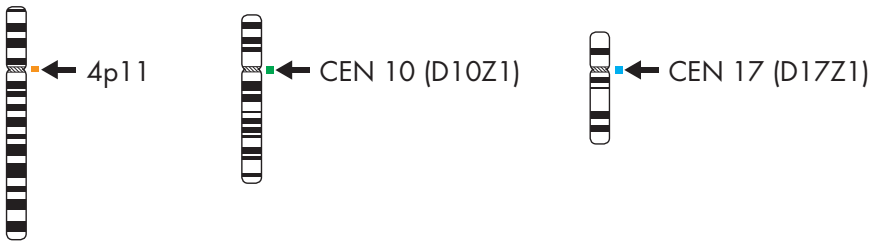
In a normal interphase nucleus, two orange, two green, and two blue signals are expected. In a cell with gain or loss of the chromosomes 4, 10 and/or 17, an increased or a reduced number of signals of the respective color will be observed.



SPEC 4p11/CEN 10/17 Triple Color Probe hybridized to normal interphase cells as indicated by two orange, two green, and two blue signals in each nucleus and to metaphase chromosomes of a normal cell.



Bone marrow smear with trisomy of chromosome 4 and 17 as indicated by three orange and blue signals in each nucleus.



Ideograms of chromosomes 4, 10, and 17 indicating the hybridization locations.

Prod. No.	Product	Label	Tests* (Volume)
Z-2307-50	ZytoLight SPEC 4p11/CEN 10/17 Triple Color Probe CE IVD	●/●/●	5 (50 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. CE IVD only available in certain countries. All other countries research use only! Please contact your local dealer for more information.*

ZytoLight® SPEC IKZF1/CEN 7 Dual Color Probe

CE IVD

Background

The ZytoLight® SPEC IKZF1/CEN 7 Dual Color Probe is designed for the detection of deletions affecting the IKZF1 (IKAROS family zinc finger 1, a.k.a. ZNFN1A1, IKAROS) gene.

The IKZF1 gene is located on 7p12.2 and encodes a zinc finger transcription factor, which is required for normal hematopoietic differentiation and proliferation, particularly in lymphoid lineages.

Genomic deletions affecting the IKZF1 gene are found in approximately 15% of pediatric and ~40% of adult B-cell precursor acute lymphoblastic leukemia (B-ALL) cases. The frequency is remarkably high in BCR-ABL1-positive (~70%) and BCR-ABL1-like (~40%) pediatric B-ALL.

IKZF1 deletions were also identified in the progression of chronic myeloid leukemia to lymphoid blast crisis.

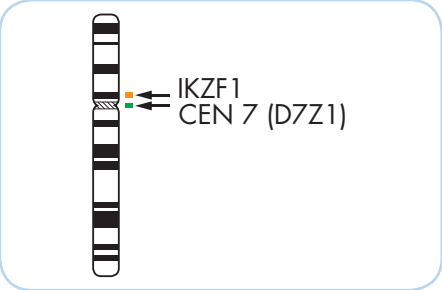
The most frequent deletions in B-ALL affect the whole gene or exons 4 to 7. Deletions affecting other exons (i.e., exons 2 to 7, exons 2 to 8, and exons 4 to 8) were also observed.

IKZF1 deletions are associated with poor prognosis and high risk of relapse in cases of B-ALL. Hence, the detection of IKZF1 deletions by FISH may help in predicting the clinical outcome in patients with B-ALL.

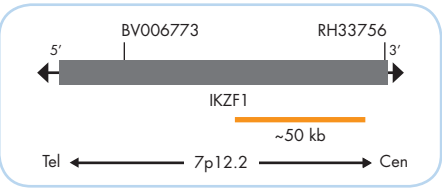
References
Boer JM, et al. (2016) Leukemia 30: 32-8.
Hashiguchi J, et al. (2018) J Mol Diagn 20: 446-54.
Iacobucci I, et al. (2009) Blood 114: 2159-67.
Meyer C, et al. (2013) Am J Blood Res 3: 165-73.
Mullighan CG, et al. (2008) Nature 453: 110-4.

Probe Description

The SPEC IKZF1/CEN 7 Dual Color Probe is a mixture of an orange fluorochrome direct labeled SPEC IKZF1 probe specific for exons 4 to 7 of the IKZF1 gene at 7p12.2 and a green fluorochrome direct labeled CEN 7 probe specific for the alpha satellite centromeric region of chromosome 7 (D7Z1).



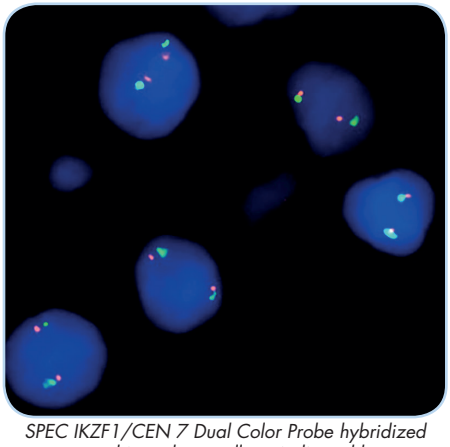
Ideogram of chromosome 7 indicating the hybridization locations.



SPEC IKZF1 Probe map (not to scale).

Results

In a normal interphase nucleus, two orange and two green signals are expected. In a cell with an IKZF1 deletion, one or no copy of the orange signal will be observed.



SPEC IKZF1/CEN 7 Dual Color Probe hybridized to normal interphase cells as indicated by two orange and two green signals in each nucleus.

Prod. No.	Product	Label	Tests* (Volume)
Z-2304-50	ZytoLight SPEC IKZF1/CEN 7 Dual Color Probe CE IVD	●/●	5 (50 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. CE IVD only available in certain countries. All other countries research use only! Please contact your local dealer for more information.*

ZytoLight® SPEC Williams-Beuren Dual Color Probe

CE IVD

Background

The ZytoLight® SPEC Williams-Beuren Dual Color Probe is designed to detect deletions affecting the chromosomal region 7q11.23 harboring the ELN (elastin, a.k.a. WBS) gene.

The Williams-Beuren syndrome (WBS) is a genetic disorder caused by a hemizygous contiguous gene deletion on chromosome 7q11.23. The estimated prevalence of the disease ranges between 1/7,500 and 1/20,000 newborns.

The WBS deletion region (~1.5-1.8 Mb) consists of a single copy gene region containing app. 28 genes, including the ELN gene that is flanked by repetitive sequences known as low-copy repeats (LCRs).

The deletions arise as a consequence of misalignment of these repetitive sequences during meiosis and a following unequal crossing over due to high similarity of LCRs. Usually, WBS occurs sporadically, but some parents of WBS patients were shown to carry a paracentric inversion of the WBS locus. Presence of this inversion predisposes to chromosomal mispairing in meiosis.

WBS patients clinically display a characteristic pattern of symptoms including vascular stenosis, weakness of connective tissue, a typical face, short stature, overfriendliness, and mental retardation.

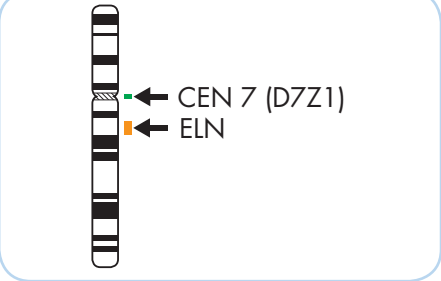
FISH analysis can be performed to confirm WBS diagnosis in patients with vascular stenosis together with mental retardation.

References

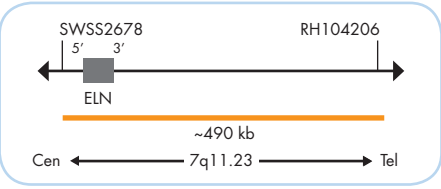
Bayés M, et al. (2003) Am J Hum Genet 73: 131-51.
Beuren AJ, et al. (1964) Am J Cardiol 13: 471-83.
Schubert C (2009) Cell Mol Life Sci 66: 1178-97.
Sugayama SM, et al. (2003) Arq Bras Cardiol 81: 462-73.
Williams JC, et al. (1961) Circulation 24: 1311-8.

Probe Description

The SPEC Williams-Beuren Dual Color Probe Probe is a mixture of an orange fluorochrome direct labeled SPEC ELN probe specific for the ELN gene at 7q11.23 and a green fluorochrome direct labeled CEN 7 probe specific for the alpha satellite centromeric region of chromosome 7 (D7Z1).



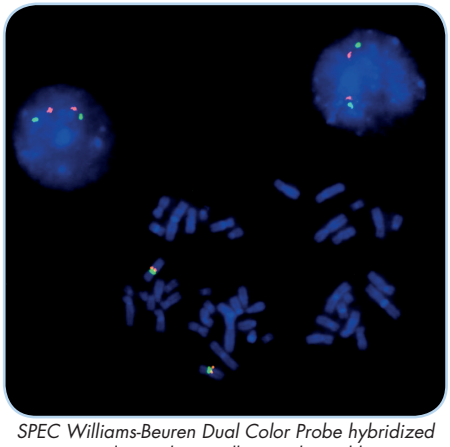
Ideogram of chromosome 7 indicating the hybridization locations.



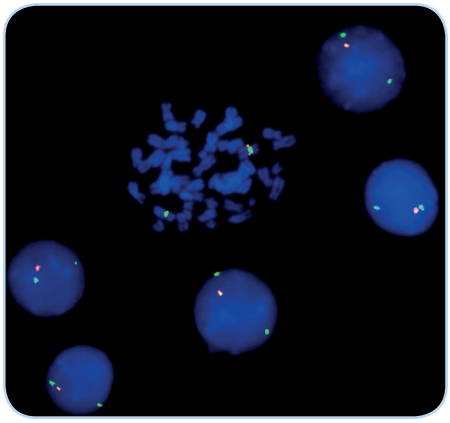
SPEC ELN Probe map (not to scale).

Results

In a normal interphase nucleus, two orange and two green signals are expected. In a cell with deletion of the ELN gene locus, a reduced number of orange signals will be observed.



SPEC Williams-Beuren Dual Color Probe hybridized to normal interphase cells as indicated by two orange and two green signals in each nucleus and to metaphase chromosomes of a normal cell.



Lymphocytes and metaphase chromosomes from a Williams-Beuren syndrome case showing an ELN deletion as indicated by the loss of one orange signal.

Prod. No.	Product	Label	Tests* (Volume)
Z-2302-50	ZytoLight SPEC Williams-Beuren Dual Color Probe CE IVD	●/●	5 (50 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. CE IVD only available in certain countries. All other countries research use only! Please contact your local dealer for more information.*

FlexISH® IGK/IGL DistinguISH™ Probe

CE IVD

Background

The FlexISH® IGK/IGL DistinguISH™ Probe is designed to detect rearrangements affecting the chromosomal region 2p11.2 and 22q11.22 harboring the IGK (immunoglobulin kappa locus, a.k.a. IGK@, IGκ) and IGL (immunoglobulin lambda locus, a.k.a., IGλ) gene cluster region, respectively. Translocations involving the immunoglobulin (IG) genes are recurring events of B-cell oncogenesis. In all of these translocations, an oncogene is activated and overexpressed by juxtaposition to IG regulatory sequences. Burkitt lymphoma (BL) is characterized by reciprocal translocations involving the MYC gene and one of the IG loci. The majority of translocations involve the immunoglobulin heavy chain (IGH) locus while a minor part involves the immunoglobulin light chain loci, either the kappa light chain (IGK) or the lambda light chain (IGL). IGK and IGL rearrangements have been detected in up to 25% of BL cases.

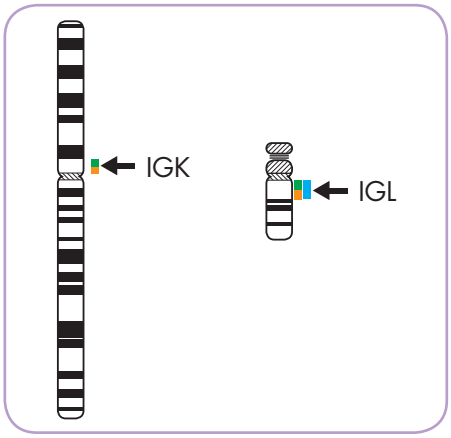
IG translocations have been reported in several other malignancies including non-Hodgkin lymphoma, atypical Burkitt/Burkitt-like lymphoma, diffuse large B-cell lymphoma, follicular lymphoma, mantle cell lymphoma, and multiple myeloma. Other rearrangement events involve the IGK and IGL gene with the BCL2 and BCL6 oncogenes as translocation partners. Large B-cell lymphoma patients with MYC-IG have shorter overall survival compared with both MYC translocation with non-IG translocation partner gene as well as absence of MYC translocation. Thus, the detection of MYC translocation partner by FISH may prove a valuable diagnostic and prognostic tool.

References
Cario G, et al. (2000) Br J Haematol 110: 537-46.
Copie-Bergman C, et al. (2015) Blood 126: 2466-74.
Einerson RR, et al. (2006) Leukemia 20: 1790-9.
Henglein B, et al. (1989) Mol Cell Biol 9: 2105-13.
Martín-Subero JI, et al. (2002) Int J Cancer 98: 470-4.
Pedersen MØ, et al. (2014) Eur J Haematol 92: 42-8.
Poulsen TS, et al. (2002) Leukemia 16: 2148-55.

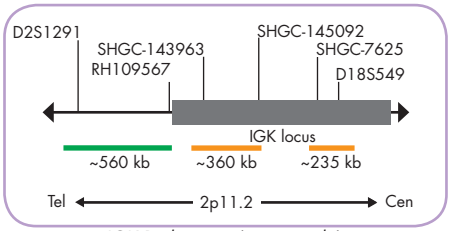
Probe Description

The FlexISH® IGK/IGL DistinguISH™ Probe is a mixture of five direct labeled probes hybridizing to the 2p11.2 and 22q11.21-q11.23 bands. The orange fluorochrome direct labeled probes hybridize proximal to the IGK and distal to the IGL breakpoint regions, the green fluorochrome direct labeled probes hybridize distal to the IGK and proximal to the IGL breakpoint regions. The blue fluorochrome direct labeled probe hybridizes distal and proximal to the IGL breakpoint region.

Due to homologous sequence segments proximal to the IGK breakpoint region, the orange probe, which hybridizes to the IGK locus, has two hybridization regions in close proximity.



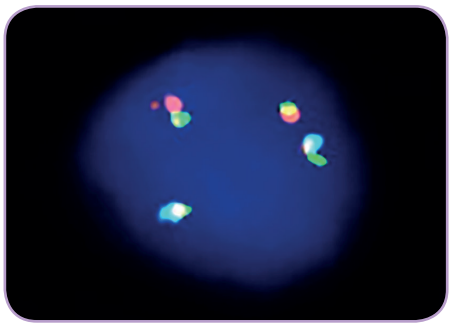
Ideograms of chromosomes 2 (left) and 22 (right) indicating the hybridization locations.



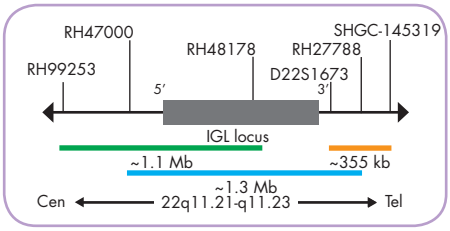
IGK Probe map (not to scale).

Results

In an interphase nucleus without IGK or IGL rearrangements, two IGK specific green/orange fusion signals and two IGL specific green/orange/blue fusion signals are expected. An IGK rearrangement is indicated by one separate green and one separate orange signal, both not co-localizing with blue signals. Due to the two hybridization regions of the orange probe hybridizing to the IGK locus, IGK-specific orange signals may appear as paired signal dots. An IGL rearrangement is indicated by one separate green and one separate orange signal, both co-localizing with blue signals.



FlexISH IGK/IGL DistinguISH™ Probe on a normal interphase cell with non-rearranged IGK loci (two green/orange fusion signals) and non-rearranged IGL loci (two green/orange/blue fusion signals). Orange signals of the IGK locus may appear as paired signal dots.



IGL Probe map (not to scale).

Prod. No.	Product	Label	Tests* (Volume)
Z-2295-50	FlexISH IGK/IGL DistinguISH Probe CE IVD	●/●/●	5 (50 µl)
Related Products			
Z-2182-5	FlexISH-Tissue Implementation Kit CE IVD Incl. Heat Pretreatment Solution Citric, 150 ml; Pepsin Solution, 1 ml; 5x FlexISH Wash Buffer, 150 ml; DAPI/DuraTect-Solution, 0.2 ml		5

** Using 10 µl probe solution per test. CE IVD only available in certain countries. All other countries research use only! Please contact your local dealer for more information.*

ZytoMation® BCL2 Dual Color Break Apart FISH Probe

CE IVD

Background

The ZytoMation® BCL2 Dual Color Break Apart FISH Probe is designed to detect translocations involving the chromosomal region 18q21.33 harboring the BCL2 gene.

The BCL2 (BCL2 apoptosis regulator, a.k.a. PPP1R50) gene encodes a mitochondrial membrane protein that regulates apoptosis and is expressed in B-cells.

Translocations involving the BCL2 gene are commonly identified in B-cell lymphomas. In particular, the translocation t(14;18)(q32.3;q21.3) has been identified in about 80% of follicular lymphoma (FL), in 20% to 30% of diffuse large B-cell lymphoma (DLBCL), and rarely in B-cell chronic lymphocytic leukemia (B-CLL).

In FL this translocation is considered to be a cytogenetic hallmark. As a result of this rearrangement, the BCL2 gene is juxtaposed to IGH (immunoglobulin heavy locus) at 14q32.33 which leads to overexpression of the anti-apoptotic protein BCL2, and finally to progression to lymphoma.

Alternative BCL2 translocations to immunoglobulin light chain genes as well as non-IG translocation events have been reported.

In DLBCL, BCL2 gene overexpression has been implicated in conferring resistance to chemotherapy and has been associated with poor prognosis.

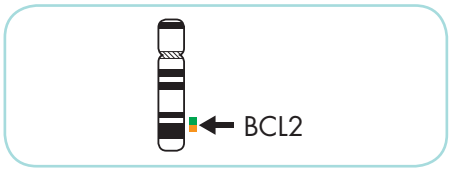
Hence, detection of BCL2 translocations by FISH may be of diagnostic and prognostic relevance.

References

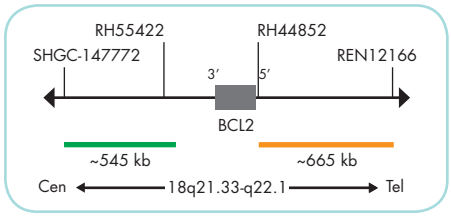
Da Cunha Santos G, et al. (2011) Cancer Cytopathol 119: 254-62.
Dyer MJ, et al. (1994) Blood 83: 3682-8.
Gu K, et al. (2008) Arch Pathol Lab Med 132: 1355-61.
Hockenbery D, et al. (1990) Nature 348: 334-6.
Impera L, et al. (2008) Oncogene 27: 6187-90.
López-Guillermo A, et al. (1999) Blood 93: 3081-7.
Nelson BP, et al. (2007) Am J Clin Pathol 128: 323-32.
Tibiletti MG, et al. (2009) Hum Pathol 40: 645-52.
Tomita N, et al. (2009) Haematologica 94: 935-43.
Weinberg OK, et al. (2007) J Mol Diagn 9: 530-7.

Probe Description

The BCL2 Dual Color Break Apart FISH Probe is a mixture of two direct labeled probes hybridizing to the 18q21.33-q22.1 band. The orange fluorochrome direct labeled probe hybridizes distal to the BCL2 breakpoint region at 18q21.33-q22.1, the green fluorochrome direct labeled probe hybridizes proximal to the BCL2 breakpoint region at 18q21.33.



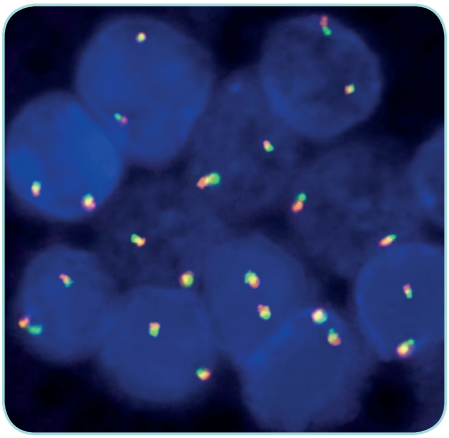
Ideogram of chromosome 18 indicating the hybridization locations.



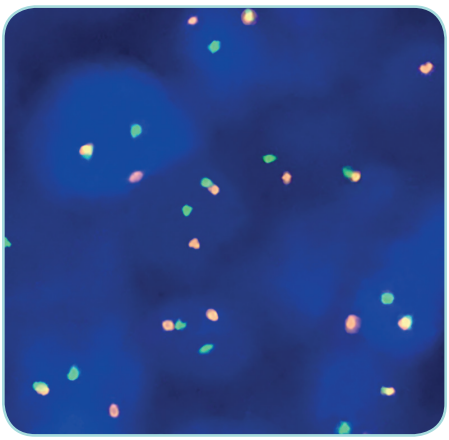
BCL2 Probe map (not to scale).

Results

In an interphase nucleus lacking a translocation involving the 18q21.33-q22.1 band, two orange/green fusion signals are expected representing two normal (non-rearranged) 18q21.33-q22.1 loci. A signal pattern consisting of one orange/green fusion signal, one orange signal, and a separate green signal indicates one normal 18q21.33-q22.1 locus and one 18q21.33-q22.1 locus affected by a translocation.



BCL2 Dual Color Break Apart FISH Probe hybridized to normal interphase cells as indicated by two orange/green fusion signals per nucleus.



Follicular lymphoma tissue section with translocation of the BCL2 gene as indicated by one non-rearranged orange/green fusion signal, one orange and one separate green signal.

Prod. No.	Product	Label	Tests* (Volume)
Z-2306-5.1ML	ZytoMation BCL2 Dual Color Break Apart FISH Probe CE IVD	●/●	up to 20 (5.1 ml)

** Using 240 µl probe solution per test. CE IVD only available in certain countries. All other countries research use only! Please contact your local dealer for more information.*

ZytoDot® 2C SPEC NTRK1 Break Apart Probe

CE IVD

Background

The ZytoDot® 2C SPEC NTRK1 Break Apart Probe is designed to detect translocations involving the chromosomal region 1q23.1 harboring the NTRK1 (neurotrophic receptor tyrosine kinase 1, a.k.a. TRKA or TRK) gene.

The neurotrophic tyrosine receptor kinase genes (NTRK1, NTRK2, and NTRK3) encode a family of receptor tyrosine kinases that serve important roles in cell survival, proliferation, and cellular differentiation in healthy human cells.

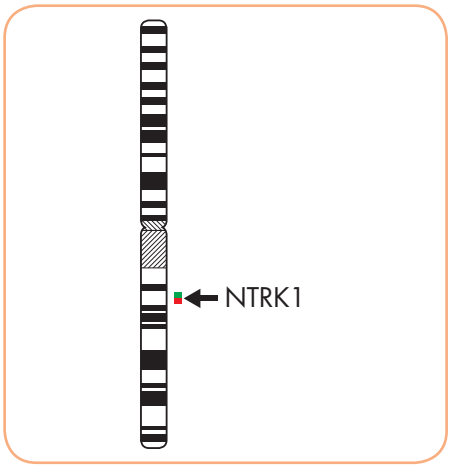
NTRK gene rearrangements were found to occur in many different tumor types. They result in the fusion of the 3′ end of the NTRK gene, encoding the NTRK kinase domain, with the 5′ end of various activating genes. The product of the fusion is a chimeric oncoprotein characterized by ligand-independent constitutive activation of the NTRK kinase. More than 40 different 5′ gene partners of NTRK1 have been described in a diverse range of human tumor types including, e.g., papillary thyroid carcinoma (PTC), lung cancer, sarcomas, and spitzoid neoplasms.

NTRK1 rearrangements were shown to be involved in thyroid carcinogenesis. Several studies showed that NTRK1 rearrangements may be associated with a worse clinical course when compared with NTRK1 rearrangement-negative PTCs.

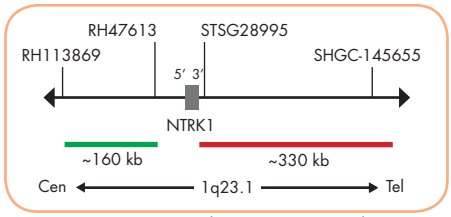
The treatment of patients with NTRK fusion-positive cancers with a NTRK inhibitor, such as the FDA-approved drugs larotrectinib or entrectinib, is associated with high response rates, regardless of NTRK gene, fusion partner, and tumor type. Hence, detection of NTRK1 rearrangements by *in situ* Hybridization may be of prognostic and therapeutic significance.

Probe Description

The ZytoDot® 2C SPEC NTRK1 Break Apart Probe is a mixture of a Digoxigenin-labeled and a Dinitrophenyl-labeled probe hybridizing to the 1q23.1 band. The DNP-labeled probe hybridizes distal to the NTRK1 gene breakpoint region at 1q23.1, the DIG-labeled probe hybridizes proximal to the NTRK1 gene breakpoint region.



Ideogram of chromosome 1 indicating the hybridization locations.



SPEC NTRK1 Probe map (not to scale).

References
Cocco E, et al. (2018) Nat Rev Clin Oncol 15: 731-47.
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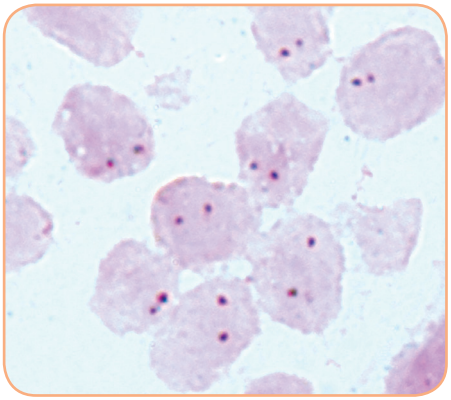
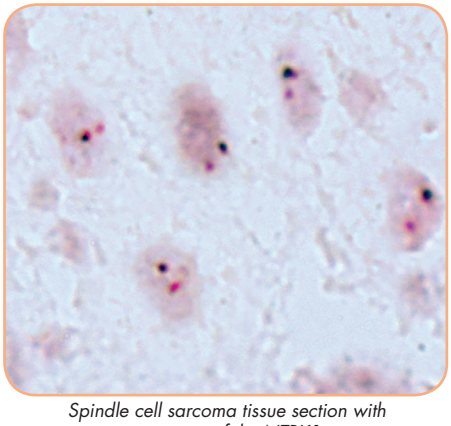
Martin-Zanca D, et al. (1986) Nature 319: 743-8.
Musholt TJ (2000) Surgery 128: 984-93.
Russell JP, et al. (2000) Oncogene 19: 5729-35.
Solomon JP & Hechtman JF (2019) Cancer Res 79: 3163-8.
Vaishnavi A, et al. (2013) Nat Med 19: 1469-72.

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.



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. CE IVD only available in certain countries. All other countries research use only! Please contact your local dealer for more information.*

VisionArray® MYCO Chip 2.0

CE IVD

Introduction

The VisionArray® MYCO Chip 2.0 is intended to be used with a VisionArray® Analysis Package for the qualitative detection and identification of PCR amplificates of the genera *Mycobacterium, Mycobacteroides, Mycolicibacillus, Mycolicibacter,* and *Mycolicibacterium* as well as several clinically relevant mycobacterial species that have been produced with the help of the VisionArray® MYCO PreCise Master Mix 2.0.

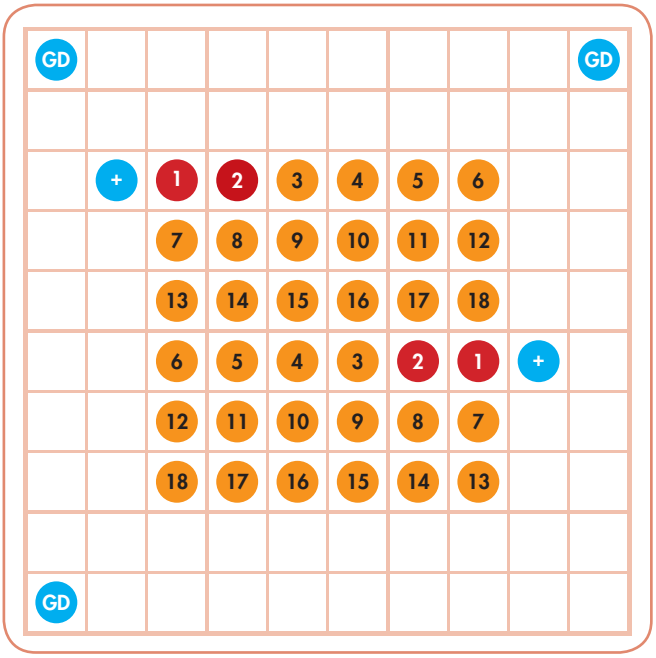
The mycobacterial genera comprise more than 140 species, which, for the purpose of diagnosis and treatment, have been grouped into three categories: *M. tuberculosis complex* (MTC), *M. leprae*, and non-tuberculous mycobacteria (NTM).

The majority of the *Mycobacterium* species belongs to the NTM group and can be found in different environments. Many of these bacteria cause life-threatening infections in humans and in recent years, the mortality and morbidity associated with NTM has increased especially in immunocompromised patients worldwide. Treatment of NTM is specific to each species and therefore a clear distinction between the present species is of extreme importance.

Reliable and rapid molecular diagnostics are the basis of an adequate therapy that is given by the VisionArray® MYCO Chip 2.0.

Chip Description

The VisionArray® MYCO Chip 2.0 is designed to detect several clinically relevant mycobacterial species. All capture sequences and the positive control are set up on the Chip as duplicates and the guide dots as triplicates. The signals are visible on the Chip as dark blue areas. The automated evaluation of the results is performed by a VisionArray® Analyzer Software.



GD Guide Dot + Positive Control

M. tuberculosis (MTC) complex

1	M. tuberculosis complex (ITS Region)
2	M. tuberculosis complex (IS6110 Region)

Nontuberculous Mycobacteria (NTM)

3	M. abscessus	11	M. kansasii
4	M. avium / M. intracellulare complex	12	M. malmoense
5	M. chelonae	13	M. marinum / M. ulcerans
6	M. chimaera NEW SPECIES	14	M. scrofulaceum / M. parascrofulaceum
7	M. fortuitum	15	M. simiae
8	M. genavense	16	M. smegmatis
9	M. gordonae NEW SPECIES	17	M. szulgai
10	M. haemophilum	18	M. xenopi

References
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Gupta RS, et al. (2018) Front Microbiol 9: 67.
Oren A & Carrity GM (2019) Int J Syst Evol Microbiol 69: 597-9.
Perez-Martinez I, et al. (2013) BMC Res Notes 6: 531.
Simons S, et al. (2011) Emerg Infect Dis 17: 343-9.
Tortoli E (2009) Clin Microbiol Infect 15: 906-10.

Prod. No.	Product	Tests
VA-0005-10	VisionArray MYCO Chip 2.0 Incl. 10 pieces CE IVD NEW SPECIES	10
VA-0005-50	VisionArray MYCO Chip 2.0 Incl. 5x 10 pieces CE IVD NEW SPECIES	50

CE IVD *only available in certain countries. All other countries research use only! Please contact your local dealer for more information.*

VisionArray® DNA Extraction, PCR, and Detection

VisionArray® Detection Kit

For hybridization and detection of PCR products on VisionArray® Chips

Prod. No.	Product	Tests
VK-0003-50	VisionArray Detection Kit CE IVD Incl. Hybridization Solution, 1 ml; Detection Solution, 5 ml; Blue Spot Solution, 5 ml; 100x Wash Buffer, 250 ml	50

VisionArray® DNA Extraction Kits

For isolation of genomic DNA from FFPE as well as liquid based cytology specimens

Prod. No.	Product	Tests
VI-0001-50	VisionArray FFPE DNA Extraction Kit Incl. Paraffin Dissolver; Tissue Lysis Buffer; Decrosslink Buffer; DNA Wash Buffer; Proteinase K; Proteinase K Buffer; Elution Buffer; Columns; Collection Tubes	50
VI-0002-50	VisionArray Cytology DNA Extraction Kit Incl. Pre-Lysis Buffer; Cell Lysis Buffer; DNA Wash Buffer; Proteinase K; Proteinase K Buffer; Elution Buffer; Columns; Collection Tubes	50

VisionArray® PCR Reagents

For contamination-free amplification and biotinylation of target sequences with a high quality heat stable Taq polymerase

Prod. No.	Product	Tests
ES-0007-50	VisionArray HPV PreCise Master Mix CE IVD Containing HPV Primer Mix 2.0; dNTP/dUTP Solution; VisionArray PreCise Taq DNA Polymerase; PCR-Buffer; $MgCl_2$; VisionArray Uracil-DNA Glycosylase	50
ES-0008-50	VisionArray MYCO PreCise Master Mix 2.0 CE IVD MODIFIED Containing MYCO Primer Mix 2.0; dNTP/dUTP Solution; VisionArray PreCise Taq DNA Polymerase; PCR-Buffer; $MgCl_2$; VisionArray Uracil-DNA Glycosylase	50
PR-0003-50	VisionArray MYCO Sequencing Primers NEW	50

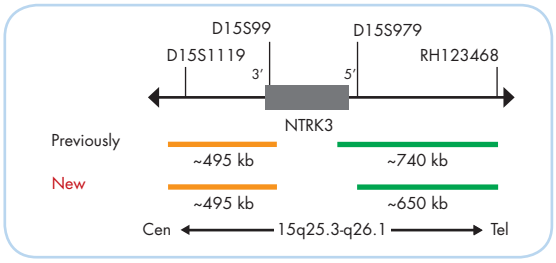
Slide Centrifuge

Prod. No.	Product
E-4051-1	Mini Slide Centrifuge Incl. 2 place slide rotor; two slide holders

CE IVD only available in certain countries. All other countries research use only! Please contact your local dealer for more information.

ZytoLight® SPEC NTRK3 Dual Color Break Apart Probe

The green-labeled probe of the ZytoLight® SPEC NTRK3 Dual Color Break Apart Probe now hybridizes further upstream of the NTRK3 gene, allowing the detection of further breakpoints.

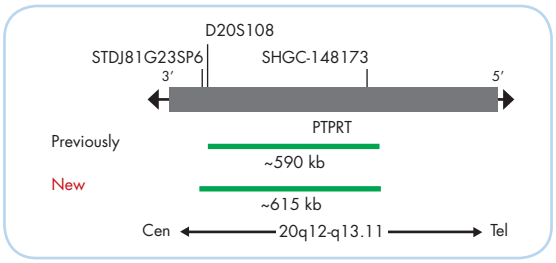


SPEC NTRK3 Probe map (not to scale).

Prod. No.	Product	Label	Tests* (Volume)
Z-2206-50	ZytoLight SPEC NTRK3 Dual Color Break Apart Probe CE IVD	●/●	5 (50 µl)
Z-2206-200	ZytoLight SPEC NTRK3 Dual Color Break Apart Probe CE IVD	●/●	20 (200 µl)

ZytoLight® SPEC PTPRT/20q11 Dual Color Probe

The green fluorochrome direct labeled SPEC PTPRT probe, hybridizing in the minimal common deleted region at 20q12, was extended proximally in order to additionally cover the STS marker D20S108.



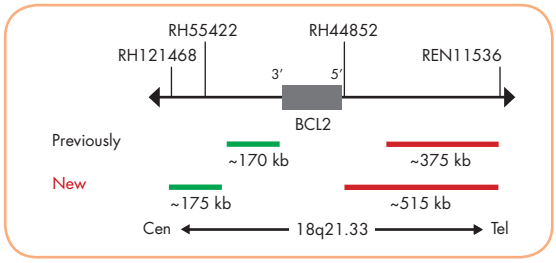
SPEC PTPRT Probe map (not to scale).

Prod. No.	Product	Label	Tests* (Volume)
Z-2213-50	ZytoLight SPEC PTPRT/20q11 Dual Color Probe CE IVD	●/●	5 (50 µl)

** Using 10 µl probe solution per test. CE IVD only available in certain countries. All other countries research use only! Please contact your local dealer for more information.*

ZytoDot® 2C SPEC BCL2 Break Apart Probe

The DIG-labeled probe of the ZytoDot® 2C SPEC BCL2 Break Apart Probe now hybridizes further downstream of the BCL2 gene, allowing the detection of further breakpoints.

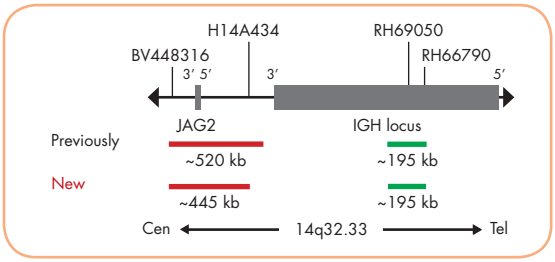


SPEC BCL2 Probe map (not to scale).

Prod. No.	Product	Label	Tests* (Volume)
C-3073-100	ZytoDot 2C SPEC BCL2 Break Apart Probe CE IVD	DIG/DNP	10 (100 µl)

ZytoDot® 2C SPEC IGH Break Apart Probe

The DNP-labeled probe of the ZytoDot® 2C SPEC IGH Break Apart Probe now hybridizes further downstream of the IGH locus, allowing the detection of further breakpoints.



SPEC IGH Probe map (not to scale).

Prod. No.	Product	Label	Tests* (Volume)
C-3071-100	ZytoDot 2C SPEC IGH Break Apart Probe CE IVD	DIG/DNP	10 (100 µl)

** Using 10 µl probe solution per test. CE IVD only available in certain countries. All other countries research use only! Please contact your local dealer for more information.*

New reaction vessels, protocol, and filling volume

The components of the below listed Kits or Sets, AP-Red Solution A and HRP-Green Solution A, are now provided in a reaction vessel instead of a dropper bottle. As indicated in the current version of the instruction for use, preparation of the working solution should be performed **by pipetting** the appropriate volume of AP-Red Solution A and HRP-Green Solution A into AP-Red Solution B and HRP-Green Solution B, respectively.

In addition, AP-Red Solution A is now available in new filling volumes (0.2 ml and 0.5 ml) which replace the previous volume sizes (0.1 ml and 0.4 ml). AP-Red Solution A is a component of the below listed Zyto*Dot* ® Kits and the Zyto*Dot* ® AP-Red Solution Set and is not available as a single sales product.

Prod. No.	Product	Tests
C-3044-10/-40	Zyto*Dot* 2C CISH Implementation Kit CE IVD	10/40
C-3028-40	Zyto*Dot* 2C CISH Polymer Detection Kit CE IVD	40
C-3022-10/-40	Zyto*Dot* 2C SPEC ERBB2/CEN 17 Probe Kit CE IVD	10/40
C-3038-100	Zyto*Dot* AP-Red Solution Set CE IVD	40
C-3039-100	Zyto*Dot* HRP-Green Solution Set CE IVD	40
T-1105-40	Zyto*Fast* human Ig-kappa/Ig-lambda Permanent CISH Kit CE IVD	40

Withdrawn Products

The products listed below were withdrawn from the ZytoVision portfolio.

Withdrawn Products		Alternative Products	
Prod. No.	Product	Prod. No.	Product
AB-0001-30	Mouse-anti-DIG CE IVD	AB-0001-4	Mouse-anti-DIG CE IVD
VA-0003-10/-50	Vision*Array* MYCO Chip 1.0 * CE IVD	VA-0005-10/-50	Vision*Array* MYCO Chip 2.0 CE IVD
VE-0001-100	Vision*Array* PreCise Taq DNA Polymerase CE IVD	ES-0007-50	Vision*Array* HPV PreCise Master Mix CE IVD
		ES-0008-50	Vision*Array* MYCO PreCise Master Mix 2.0 CE IVD
VE-0002-100	Vision*Array* Uracil-DNA Glycosylase CE IVD	ES-0007-50	Vision*Array* HPV PreCise Master Mix CE IVD
		ES-0008-50	Vision*Array* MYCO PreCise Master Mix 2.0 CE IVD
VP-0001-50	Vision*Array* HPV Primer Kit 2.0 CE IVD	ES-0007-50	Vision*Array* HPV PreCise Master Mix CE IVD
VP-0002-50	Vision*Array* MYCO Primer Kit 1.0 CE IVD	ES-0008-50	Vision*Array* MYCO PreCise Master Mix 2.0 CE IVD

** The VisionArray® MYCO Chip 1.0 will be no longer a catalogue item as of January 1, 2021. For customers who need the MYCO Chip 1.0 it will probably remain available for the first half of the year 2021.*

CE IVD only available in certain countries. All other countries research use only! Please contact your local dealer for more information.

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Molecular diagnostics simplified

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