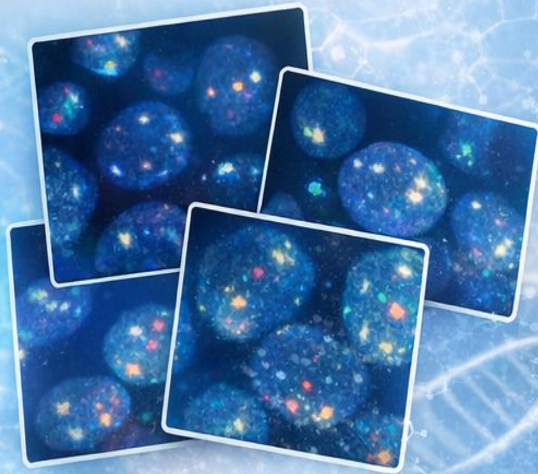
Fast Fluorescence In Situ Hybridization

Probe Kit Catalogue

Comprehensive FISH Probe Kits for Oncology and Genetics



- ✓ **Break-Apart, Dual-Fusion & Locus-Specific Probes**
- ✓ Solid Tumors & Hematological Malignancies
- ✓ Centromeric & **Chromosome Enumeration Probes** (CEPs)
- ✓ High Sensitivity & Fast Hybridization Time

- **Break-Apart, Dual-Fusion & Locus-Specific** Probes
- Solid Tumors & Hematological Malignancies
- Centromeric & Chromosome Enumeration Probes (CEPs)
- **High Sensitivity** & Fast Hybridization Time

- **CE IVD*** and **RUO**** Kits Available

* Labeled for in Vitro Diagnostic Use (MY) where epaitble.
* Research Use Only RUO, Avaailblity depense on your regions reguiatory Regiinerionts.

Fast Hybridization Tine

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CBFB gene break apart probe

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BREAST CANCER

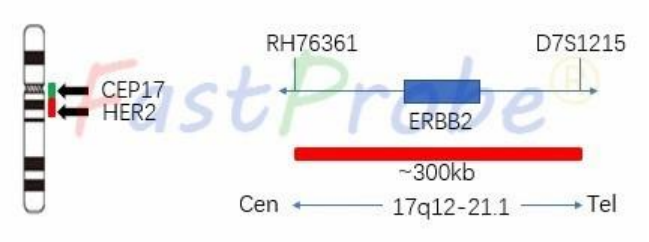
Cat.# FP-001: HER2 gene amplification probe CE-IVD

Background

Human epidermal growth factor receptor 2 (HER2, also known as ERBB2, Neu, ErbB-2, CD340 or p185) is a proto-oncogene HER2/neu located on the long arm 17q12 of human chromosome 17. The coding, which is a member of the epidermal growth factor receptor (EGFR/ErbB) family, has tyrosine kinase activity and is involved in signal transduction of cell growth and differentiation. The oncogenic mechanism of the HER2 oncogene includes inhibition of apoptosis, promotion of cell proliferation, increase of invasiveness of tumor cells, and promotion of tumor vascular and lymphangiogenesis. 20% of breast cancer and 12% of gastric cancer patients showed positive HER2 gene amplification.

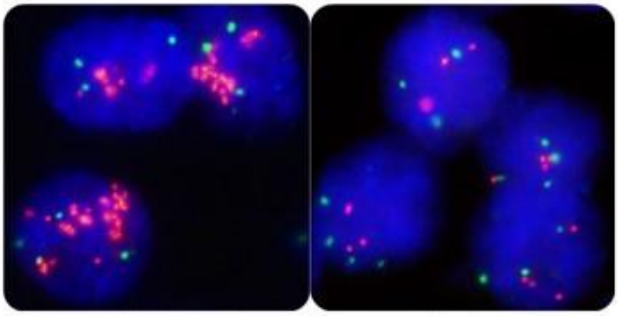
Probe description

The HER2 gene amplification probe uses the orange-red dye to label the HER2 gene region, and the green dye is used to label the chromosome 17 centromere region (CEP17). The HER2 gene marker region is located at 17q12-q21.1, and the CEP17 probe adopts an alpha satellite sequence, which has extremely high specificity and does not hybridize with other chromosome centromeres to produce noisy spots.



Clinical significance

Fluorescence in situ hybridization (FISH) is a clinically recognized “gold standard” for HER2 detection. It can accurately and repeatedly evaluate the status of HER2 gene in cancer cells. Compared with IHC, FISH has higher consistency. The patients with positive HER2 gene amplification were effectively treated with targeted drugs such as monoclonal antibodies Herceptin and Lapatinib. The prognosis of patients with positive HER2 gene amplification was poor, and the disease-free survival and overall survival were significantly shortened.



HER2 amplification [+]　　HER2 amplification [-]

Product name	Cat. No.	Probe name	Specification
Human HER2 gene amplification detection kit	FP-001	HER2/CEP17	100μL/Kit

References

· Sauter G, et al. J Clin Oncol 27:1323-1333, 2009.
· Mass R, et al. Clinical Breast Cancer, Vol 6, No. 3, 240-246, 2005.
· Allison M, Nature Biotechnology 28 (2): 117-119, 2010.
· Press M, et al, Clinical Cancer Research 2005; 11(18) September 15, 2005

Cat.# FP-008: TOP2A gene amplification probe detection kit

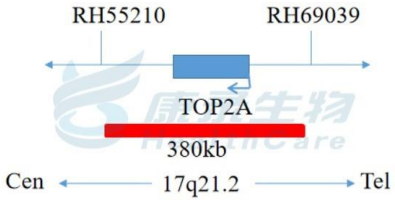
IVD/RUO

Background

TOP2A gene encodes a DNA topoisomerase that participates in processes such as chromosomal concentration, chromatid separation, and release of torsional stress during DNA transcription and replication. The gene encoding this form, TOP2A, is located on chromosome 17, the beta gene located on chromosome 3, and multiple mutations in the TOP2A gene are involved in development.

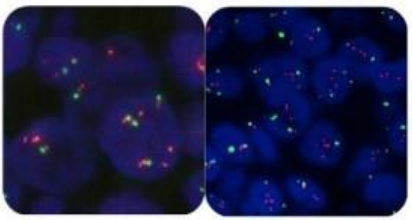
Probe description

TOP2A gene amplification probe uses the orange-red dye to label the TOP2A gene region, and the green dye to label the chromosome 17 centromere region (CEP17). TOP2A gene-labeled region is located at 17q21.2, and the CEP17 probe adopts an alpha satellite sequence, which has extremely high specificity and does not hybridize with other chromosome centromeres to produce noisy spots.



Clinical significance

Patients with abnormal TOP2A gene indicates a shorter recurrence-free survival, and patients with TOP2A gene deletion have a worse prognosis. In the study of advanced breast cancer, it was found that the abnormality of TOP2A gene was significantly correlated with the protein expression and the sensitivity of tumor cells to anthracyclines. Therefore, the detection of TOP2A gene status has guiding significance for the treatment and prognosis of breast cancer.



TOP2A amplification [+] TOP2A amplification [-]

Product name	Cat. No.	Probe name	Specification
TOP2A gene amplification probe detection kit	FP-008	TOP2A/CEP17	100μL/Kit

References

· Brunello E, et al. (2012) Histopathology 60: 482-8.

· Razis E, et al. (2011) Breast Cancer Res Treat 128: 447-56.

Cat.# FP-015: MYC gene amplification probe detection kit

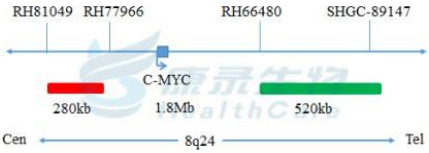
CE-IVD

Background

The MYC proto-oncogene is located on chromosome 8q24 and encodes a transcription factor that regulates cell growth. It is activated mainly by amplification and chromosome translocation rearrangement. MYC gene amplification is associated with the development of a variety of tumors (including breast cancer, colon cancer, lung cancer, hematopoietic tumors, etc.).

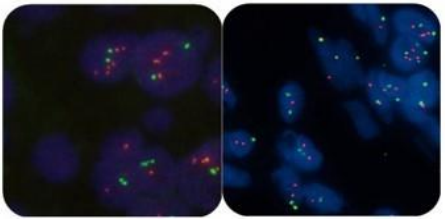
Probe description

MYC gene amplification probe uses orange-red dye to label MYC gene region, and green dye to label chromosome 8 centromere region (CEP8). The MYC gene marker region is located at 8q24.21, and the CEP8 probe is labeled with a specific alpha satellite sequence.



Clinical significance

MYC gene amplification is a common phenomenon in tumors and can be found in a variety of malignant tumors such as breast cancer, nasopharyngeal cancer, and cervical cancer. The prognosis of breast cancer patients with MYC gene amplification is poor.



MYC amplification [+] MYC amplification [-]

Product name	Cat. No.	Probe name	Specification
MYC（8q24）gene amplification probe reagent	FP-015	C-MYC/CEP8	100μL/Kit

E-mail: cs@healthcare-biotech.com

References

- Fromont G, et al. (2013) Hum Pathol 44: 1617-23.
- Mannuci S, et al. (2012) Adv Hematol 2012: 149780.

LUNG CANCER

Cat.# FP-002: Human ALK gene fusion detection probe

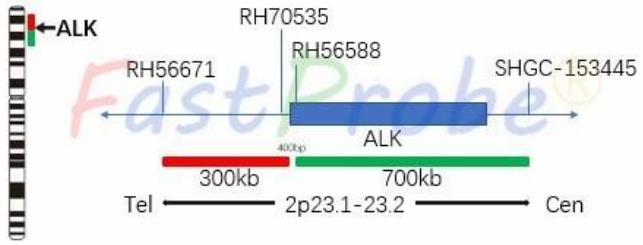
CE-IVD

Background

ALK gene encodes a transmembrane receptor tyrosine kinase (RTK). The ALK-NPM1 fusion protein was first discovered in anaplastic large cell lymphoma (ALCL). It has been found to mutate, amplify or rearrange in other tumors, including neuroblastoma and non-small cell lung cancer. Chromosome rearrangement is the most common cause of ALK and other genes. Fusion, including ALK/EML4, ALK/RANBP2, ALK/ATIC, ALK/TFG, ALK/NPM1, ALK/SQSTM1, ALK/KIF5B, ALK/CLTC, ALK/TPM4 and ALK/MSN.

Probe description

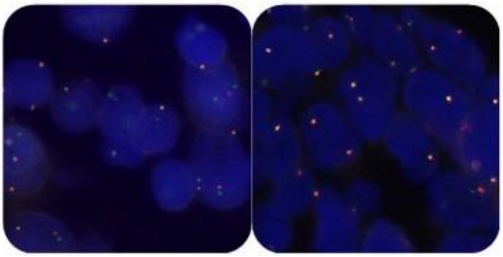
ALK gene break-apart probe uses an orange-red dye to label the 2p23.2 region (3' end), and the green dye to label ALK gene 2p23.1-p23.2 region (5' end). ALK gene break-apart probe detects all ALK gene rearrangements and avoids missed diagnosis by a single fusion gene (such as EML4-ALK).



Clinical significance

According to the 2013 edition of the Chinese consensus of diagnostic experts on anaplastic lymphoma kinase (ALK) positive non-small cell lung cancer, the positive rate of ALK gene is as high as 30%-42% in NSCLC patients with adenocarcinoma, young (< 60 years old), non-smoking and no mutation in EGFR, KRAS, HER2 or P53 genes. Pathological studies suggest that the positive rate of mucinous or solid adenocarcinomas with signet ring cells is higher than that of other types of lung adenocarcinomas.

In 2013, CFDA approved XALKORI (Crizotinib) for targeted therapy of advanced ALK-positive non-small cell lung cancer, and the necessary condition for XALKORI (Crizotinib) drug therapy is FISH for ALK-positive non-small cell lung cancer. Patients with positive ALK gene fusion are sensitive to XALKORI (Crizotinib).



ALK fusion [+] ALK fusion [-]

Product name	Cat. No.	Probe name	Specification
Human ALK gene fusion detection probe	FP-002	ALK	100μL/Kit

References

- Rodig SJ, et al. (2009) Clin Cancer Res 15: 5216-23.
- Sasaki T, et al. (2010) Eur J Cancer 46: 1773-80.
- Von Laffert M, et al. (2013) Lung Cancer 81: 200-6.

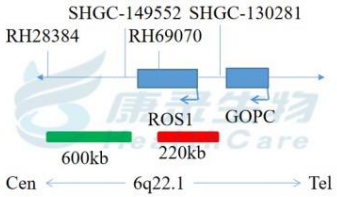
Cat.# FP-06: ROS1 gene break apart probe CE-IVD

Background

C-ros sarcoma ROS-receptor tyrosine kinase (ROS1) is located on chromosome 6q22 and encodes a receptor tyrosine kinase (RTK), which is involved in cell growth and proliferation, differentiation and survival. When the ROS1 gene is rearranged, the extracellular region is lost, and the transmembrane region and the intracellular tyrosine kinase region are retained. The rearrangement site mainly occurs in the 32 to 36 exons of the ROS1 gene. In NSCLC, ROS1 gene is mainly fused with SLC34A2, CD74, EZR, SDC4, etc., and continues to activate ROS1 tyrosine kinase domain and downstream signaling pathway, which leads to tumor development.

Probe description

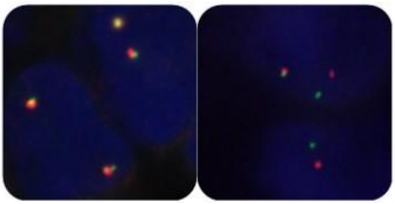
ROS1 gene break-apart probe uses orange-red dye to label the 5' end region of the ROS1 gene, and a green dye to label the 3' end region of the ROS1 gene. ROS1 gene break-apart is able to detect all ROS1 gene rearrangements, avoiding the missed diagnosis caused by a single gene fusion.



Clinical significance

ROS1 gene rearrangement mainly occurs in young, non-smoking patients with lung adenocarcinoma. ROS1 gene rearrangement is different from other mutations such as EGFR, KRAS, ALK and so on. The positive rate of ROS1 rearrangement was 1.0%-3.4% in NSCLC and 5.7% in EGFR, KRAS and ALK negative population.

On March 11, 2016, the FDA approved the indication for XALKORI (Crizotinib) in the treatment of ROS1-positive advanced NSCLC. XALKORI (Crizotinib) indication for ROS1-positive advanced NSCLC have been approved in China. Patients with positive ROS1 rearrangement are sensitive to XALKORI (Crizotinib) drugs.



ROS1 break apart [-] ROS1 break apart [+]

Product name	Cat. No.	Probe name	Specification
6q probe reagent	FP-006	ROS1	100μL/Kit

References

· Brunello E, et al. (2012) Histopathology 60: 482-8.

· Razis E, et al. (2011) Breast Cancer Res Treat 128: 447-56.

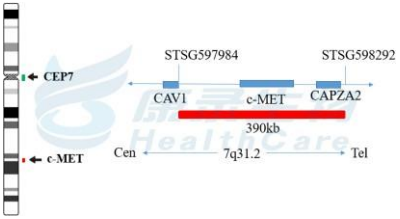
Cat.# FP-046: MET gene amplification probe CE-IVD

Background

MET gene is located on chromosome 7q31.2 and encodes a transmembrane tyrosine kinase receptor. The ligand of MET is hepatocyte growth factor (HGF), which is secreted by mesenchymal cells. The binding of HGF and c-MET can promote cell proliferation, migration, differentiation and morphological changes. The HGF/c-MET signaling pathway is highly regulated and plays an important role in cell proliferation, differentiation and movement.

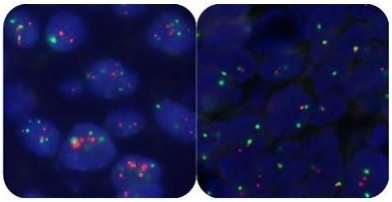
Probe description

MET gene amplification probe uses orange-red dye to label MET gene region, and green dye to label chromosome 7 centromere region (CEP7). MET gene marker region is located at 7q31.2, and the CEP7 probe is labeled with a specific alpha satellite sequence.



Clinical significance

MET gene can be amplified in a variety of tumors such as lung cancer, breast cancer, ovarian cancer, thyroid cancer, gastric cancer, colorectal cancer, etc. It is an independent prognostic factor, and the prognosis of patients with MET gene amplification is poor. In NSCLC, MET gene amplification is closely related to poor prognosis and TKIs drug resistance. MET gene amplification is one of the targets of XALKORI (Crizotinib). Tumors in patients with MET gene amplification can shrink significantly after treatment.



MET amplification [+] MET amplification [-]

Product name	Cat. No.	Probe name	Specification
MET gene amplification probe reagent	FP-046	C-MET/CEP7	100μL/Kit

References

- Lacroix L, et al. (2014) PLoS One 1: e84319.
- Lee D, et al. (2015) Cancer Res Treat 47: 120-5.

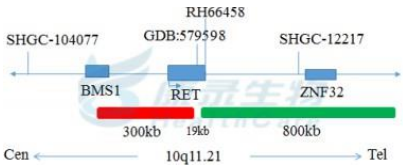
Cat.# FP-059: RET gene amplification probe IVD/RUO

Background

RET gene is located on the long arm of chromosome 10 and encodes a receptor tyrosine kinase. It is expressed in normal neurons, sympathetic and parasympathetic ganglia, thyroid C cells, adrenal myelocytes, genitourinary tract cells, and testicular germ cells. Activation of the RET protein activates downstream signaling pathways (including RAS, MAPK, ERK, PI3K, AKT, etc.), resulting in cell proliferation, migration, and differentiation. Activating mutations in the RET gene are associated with human malignancies, but if the RET gene loses its function, this can lead to gastrointestinal developmental diseases such as the congenital megacolon or Hirschsprung's disease.

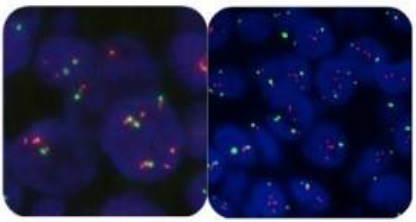
Probe description

The RET gene break-apart probe uses an orange-red dye to label the RET gene (5'-end) region, and a green dye to label the RET gene (3'-end) region. The RET gene break-apart probe detects all RET gene rearrangements, avoiding missed diagnosis by a single gene fusion.



Clinical significance

RET gene fusion in patients with non-small cell lung cancer accounts for 1%-2% of the frequency, and the RET gene is mutually exclusive with other driver genes such as EGFR, KRAS, ALK, HER2 and BRAF, i.e., rarely occurs at the same time, the RET gene is an independent gene for driving non-small cell lung cancer. At present, there are four fusion partner genes of RET gene, namely KIF5B, CCDC6, TRIM33 and NCOA4, of



RET amplification [+] RET amplification [-]

which KIF5B is the most important fusion gene, accounting for 90%.

RET gene fusion is more common in patients who have never smoked or had adenocarcinoma. Screening of 936 patients with non-small cell lung cancer found 13 patients with positive RET fusion genes, 11 of which were adenocarcinomas (85% probability), and other characteristics of the patients included never smoking, and being younger. Moreover, the primary lesions of these patients are often smaller (100%, less than 3 cm).

Product name	Cat. No.	Probe name	Specification
RET gene amplification probe reagent	FP-059	RET	100μL/Kit

References

- Takashi Kohno, et al., Transl Lung Cancer Res. 2015 Apr;4(2):156-64.
- Drilon A, et al., Ann Oncol. 2016 Jul;27(7):1286-91.
- Falchook GS, et al., J Clin Oncol. 2016 May 20;34(15):e141-4

BLADDER CANCER

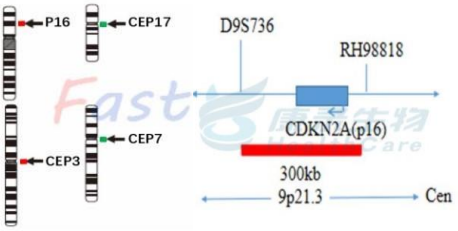
Cat.# FP-009: Bladder cancer detection probe CE-IVD

Background

Bladder cancer is the most common malignant tumor of the urinary system. It is more common in men and the incidence is about 4 times that of women. The average age of onset is 65 years. Seventy-five percent of the new cases are superficial tumors, of which 50-80% will have recurrences one to many times after treatment; 15-25% will progress to invasive cancer. Therefore, patients with superficial bladder cancer need to pay close attention to the recurrence and deterioration of the tumor. Cystoscopy or urine exfoliative cytology is recommended for patients with hematuria over 40 years of age. However, cystoscopy can cause unnecessary pain to the patient, and because of the stimulation of the bladder wall tumor, it will cause the malignant expansion and metastasis of the tumor, which is not suitable for large-scale screening, and the cytological examination is insufficiently sensitive. Fluorescence in situ hybridization detection of urine sediment cells showed strong advantages in early diagnosis and postoperative recurrence of bladder cancer.

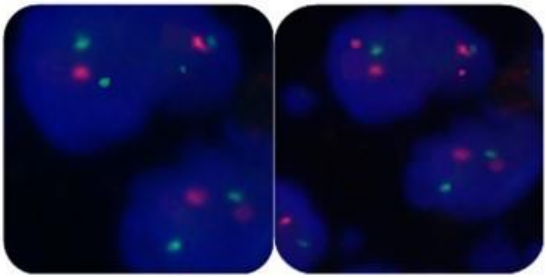
Probe description

Bladder cancer probes consist of two groups of probes. The orange dye is used to label the P16 gene region, the green dye is used to label the centromere region of chromosome 17 (CEP17); the orange dye is used to label the centromere region of chromosome 3 (CEP3), and the green dye is used to label the centromere region of chromosome 7 (CEP7). The P16 gene marker region is located at 9p21.3, and the chromosomal centromere probes are labeled with a specific alpha satellite sequences.



Clinical significance

The most common genetic alteration of urinary transitional epithelial cell carcinoma is the partial or total loss of chromosome 9 (e.g. p16 locus). In addition, the development of urinary transitional epithelial cell carcinoma is closely linked to chromosomal instability. In particular, it is closely related to the aneuploidy of chromosomes 3, 7, and 17. FISH is a non-invasive test, which can detect exfoliated cells in patient’s urine. If there are two or more abnormalities in the above four indicators, or if one of the indicators has a complex abnormality, it can be determined as the urinary system transitional epithelial cell carcinoma.



P16 deletion Chromosome 7 deletion

Product name	Cat. No.	Probe name	Specification
Bladder Cancer Cells chromosome and gene anomaly probe detection kit	FP-009	CEP3/CEP7 P16/CEP17	200μL/Kit

References

- Barocas DA, et al. (2006) BJU Int 99: 290-5.
- Gallucci M, et al. (2005) J Clin Pathol 58: 367-71.

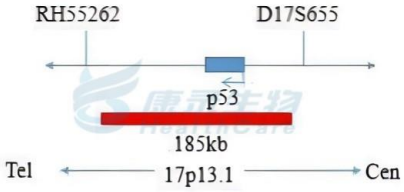
Cat.# FP-014-2: P53 gene probe CE-IVD

Background

The P53 gene is highly correlated with human tumors and is an important tumor suppressor gene. The 53kD protein encoded by the P53 gene plays an important regulatory role in the cell cycle, and has a growth inhibitory effect under normal conditions, and plays an important role in DNA cell damage response, cell death and differentiation in the cell cycle.

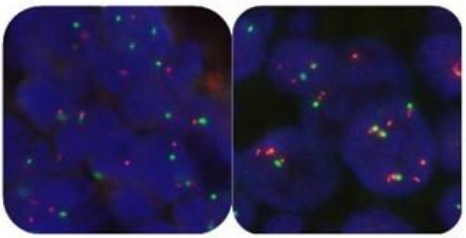
Probe description

P53 gene amplification probe uses an orange-red dye to label the P53 gene region, and a green dye label chromosome 17 centromere region (CEP17). P53 gene marker region is located at 17q13.1, and the CEP17 probe is labeled with a specific alpha satellite sequence.



Clinical significance

P53 gene amplification and deletion indicate tumor poor prognosis, its insensitivity to conventional chemotherapy, and is inclined to metastasis.



P53 amplification [-] P53 amplification [+]

Product name	Cat. No.	Probe name	Specification
CLL chromosome and gene anomaly probe detection kit	FP-014-2	P53/CEP17	100μL/Kit

References

- Chang H, et al. (2010) Am J Clin Pathol 133: 70-4.
- Herrera JC, et al. (2010) Biomedica 30: 390-400.

BRAIN CANCER

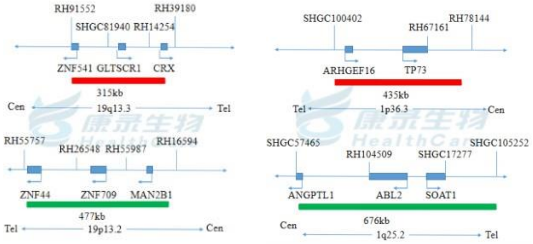
Cat.# FP-045: 1p/19q gene probe CE-IVD

Background

The most common genetic alteration in oligodendroglioma is the loss of heterozygosity in the long arm (19q) of chromosome 19, which occurs between 50% and 80%, and the most common deletion region is 19q13.3. The second most common is the loss of heterozygosity in the short arm (1p) of chromosome 1, which occurs between 40% and 92%.

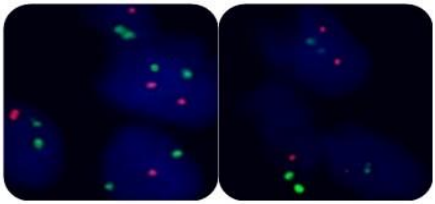
Probe description

1p/19q deletion probe uses an orange dye to label the short arm p36 region of chromosome 1 and a green dye to label the long arm q13 region of chromosome 19.



Clinical significance

The detection of 1p/19q heterozygous deletion has important implications for clinical treatment guidance and prognosis of oligodendroglioma. 100% of patients with heterozygous deletions on chromosome 1p/19q were found sensitive to chemotherapy with PVC regimen, with an average survival of 10 years; the average survival of patients without such genetic alterations was only 2 years. The 1p/19q heterozygous deletion is an independent prognostic factor with significant prognosis, even in recurrent cases. 1p/19q heterozygous deletion is a specific molecular genetic alteration in oligodendroglioma, but it is not the only change, so detection of 1p/19q heterozygous deletion is not recommended for differential diagnosis alone. However, for patients with confirmed oligodendroglioma, detection of 1p/19q heterozygous deletions can provide valuable information to clinicians.

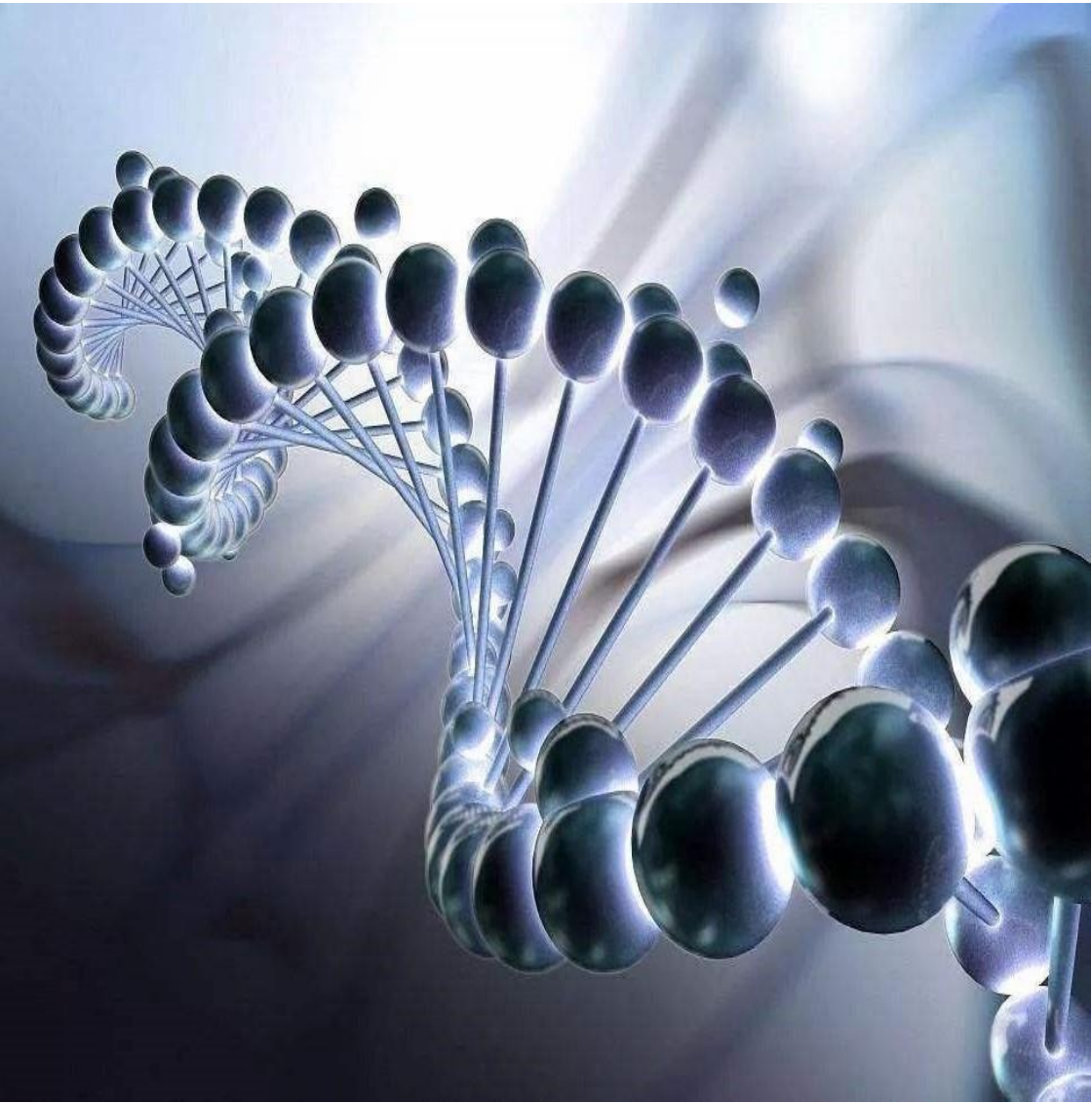


1p deletion [+] 19q deletion [+]

Product name	Cat. No.	Probe name	Specification
1p/19q deletion probe reagent	FP-045	1p36/1q25 19q13/19p13	200μL/Kit

References

- Barocas DA, et al. (2006) BJU Int 99: 290-5.
- Gallucci M, et al. (2005) J Clin Pathol 58: 367-71.

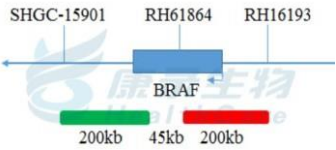


Cat.# FP-016: BRAF gene break apart probe IVD/RUO

Background

BRAF gene is located in the q34 region of chromosome 7 and encodes a protein of 766 amino acid residues. It is a silk/threonine-specific kinase and is an important transduction factor in the RAS /RAF /MEK /ERK signaling pathway which regulates cell proliferation and division. The BRAF gene can be rearranged with multiple genes such as AKAP9, FCHSD1, and BTF3L4, and plays an important role in the development of tumors. KIAA1549 gene is located in the q34 region of chromosome 7, and the KIAA1549/BRAF fusion gene can occur in 60% to 80% of hair cell astrocytoma.

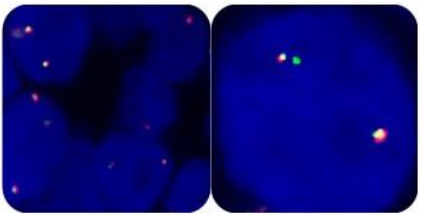
Probe description



BRAF gene break apart probe (KIAA1549/BRAF gene fusion probe) uses an orange dye to mark the 5'end of BRAF gene and a green dye to mark the 3'end of BRAF gene. Because BRAF is close to KIAA1549 (2Mbp) and BRAF gene can be rearranged with multiple genes, conventional BRAF break probe and KIAA1549/BRAF gene fusion probe cannot completely distinguish positive and negative samples. This probe uses non-repetitive sequences probe to design BRAF cleavage probe. When BRAF rearrangement is negative, it shows a 2F signal. When BRAF gene is rearranged with other genes, it shows a typical 1R1G1F signal. When BRAF gene is fused with the KIAA1549 gene, it shows specific 1G2F signal.

Clinical significance

Hairy cell astrocytoma is a cystic astrocytoma with a clear border and slow growth that often occurs in children and young adults. It has been found that 60%-80% of hair cell astrocytoma patients have a KIAA1549/BRAF gene fusion, and the detection of this gene fusion by FISH has a differential significance in low-grade glioma.



KIAA1549/BRAF fusion [-] KIAA1549/BRAF fusion [+]

Product name	Cat. No.	Probe name	Specification
BRAF gene break apart probe reagent	FP-016	BRAF	100μL/Kit

References

- Dougherty MJ, et al. (2010) Neuro Oncol 12: 621-30.
- Hutchinson KE, et al. (2013) Clin Cancer Res 19: 6696-702.

CERVICAL CANCER

Cat.# FP-013: TERC gene amplification probe CE-IVD

Background

Cervical cancer is a major malignant tumor that seriously threatens women's health, and its incidence rate ranks second among female reproductive system malignancies. At present, the widespread application of cervical cytology screening and HPV testing have significantly reduced the incidence and mortality of cervical cancer, but the current screening procedures still have certain limitations. For young women, mild cytologic abnormalities are common, and most will naturally return; HPV infection may be short-lived and may naturally turn negative. More importantly, cervical cytology screening does not distinguish well between cervical intraepithelial neoplasia (CIN) and predict whether it progresses. The development of CIN for cervical cancer is a long-term process, and early diagnosis and appropriate treatment may completely block it in the CIN or early stage of cancer and cure it completely. However, not all CIN lesions progress to high lesions, and the currently used morphological diagnosis-based methods sometimes make it difficult to accurately identify CIN and non-tumor lesions, different levels of CIN, resulting in over-treatment or under-treatment. Therefore, other means are needed to assist in the diagnosis of CIN.

Recent studies have shown that cervical cell carcinogenesis is almost accompanied by the amplification of the long arm of chromosome 3, and the most important gene involved may be the telomerase RNA gene (TERC), which can prevent cell apoptosis. Death leads to the development of tumors. Sufficient data suggest that as the level of cervical lesions increases, the positive rate of TERC gene amplification increases. For example, the proportion of TERC gene amplification in CIN I samples is about 10%, while the proportion of TERC gene amplification in CIN II samples is as high as 60%. When the patient's pathological examination cannot determine whether the condition is CIN I or CIN II, if the TERC gene is amplified, the probability of the patient being CIN II and above is 90%, and there is a possibility of canceration. Therefore, the detection of TERC gene amplification by FISH can contribute to the screening and early diagnosis of cervical cancer, and can help to define the pathological grade of precancerous lesions, thus suggesting that the clinical selection of reasonable treatment methods, to avoid over-treatment or inadequate treatment.

Probe description

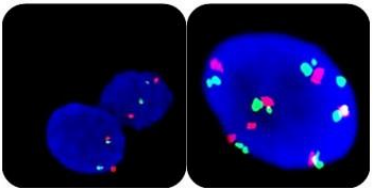
TERC gene amplification probe uses an orange-red dye to mark the TERC gene region, and a green dye to label chromosome 3 centromere region (CEP3). TERC gene marker region is located at 3q26.2, and the CEP3 probe is labeled with a specific alpha satellite sequence.

Clinical significance

Detection of TERC gene status in patients can help to differentiate high and low cervical precancerous lesions, and improve the sensitivity and specificity of cytology and HPV detection in screening cervical lesions.

We can distinguish Aus-US/CIN1 and CIN2/CIN3 by defining pathological grade, adopting reasonable treatment plan and detecting TERC gene status.

Predicting disease progression and early intervention, patients with TERC gene amplification are more than 50% likely to develop to high-level lesions.



TERC amplification [-] TERC amplification [+]

Product name	Cat. No.	Probe name	Specification
TERC gene amplification probe detection kit	FP-013	TERC/CEP3	100μL/Kit

References

- Dougherty MJ, et al. (2010) Neuro Oncol 12: 621-30.
- Hutchinson KE, et al. (2013) Clin Cancer Res 19: 6696-702.

NEUROBLASTOMA

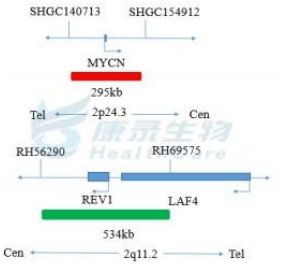
Cat.# FP-048: N-MYC gene amplification probe IVD/RUO

Background

MYCN gene is located in the p24.3 region of chromosome 2 and encodes a 62-64 kDa transcription factor. MYCN is mainly expressed in the nervous system.

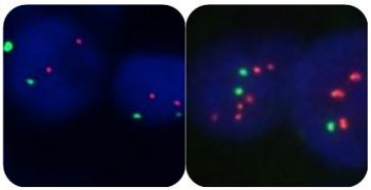
Probe description

MYCN gene amplification probe uses an orange-red dye to mark the MYCN gene region, and a green dye to label the chromosome 2 centromere region (CEP2). The MYCN gene marker region is located at 2p24.3, and the CEP2 probe is labeled with a specific alpha satellite sequence.



Clinical significance

MYCN gene amplification occurs in approximately 25% of patients with neuroblastoma. MYCN gene amplification is associated with infiltration, metastasis and poor prognosis of neuroblastoma. When the MYCN gene amplification factor is less than 10, the clinical treatment plan may not be treated after the complete removal of the primary tumor; when the MYCN gene amplification factor is >10, the conventional chemotherapy should be performed for 12 months after the surgical resection, and local radiotherapy is needed if necessary.



MYC amplification [-]

MYC amplification [+]

Product name	Cat. No.	Probe name	Specification
MYCN gene amplification probe reagent	FP-048	N-MYC/LAF4	100μL/Kit

References

- Gessi M, et al. (2014) Neuro Oncol 16: 924-32.
- Suita S, et al. (2007) J Pediatr Surg 42: 489-93.

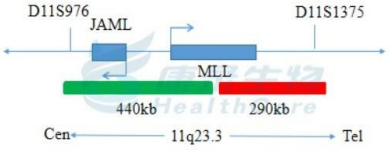
Cat.# FP-026: MLL gene deletion probe CE-IVD

Background

The MLL (KMT2A) gene is located in the q23.3 region of chromosome 11, which encodes a transcriptional coactivator that plays an important role in the regulation of gene expression during early development and hematopoiesis.

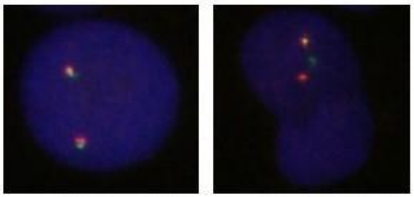
Probe description

The MLL (KMT2A) gene detection probe uses an orange-red dye to label the MLL gene, and a green dye to label chromosome 11 centromere region (CEP11). The MLL (KMT2A) gene marker region is located at 11q23.3, and the CEP11 probe is labeled with a specific alpha satellite sequence.



Clinical significance

MLL (KMT2A) gene deletion is seen in primary neuroblastoma, and MLL (KMT2A) inactivation is associated with malignant progression of neuroblastoma in malignant progression of neuroblastoma without MYCN gene amplification.



MLL break apart [-] MLL break apart [+]

Product name	Cat. No.	Probe name	Specification
KMT2A (MLL) gene break apart probe reagent	FP-026	MLL	100μL/Kit

References

1. Ford DJ & Dingwall AK (2015) Cancer Genet 208: 178-91.
2. Gindin T, et al. (2015) Hematol Oncol 33: 239-46.
3. Keefe JG, et al. (2010) J Mol Diagn 12: 441-52.

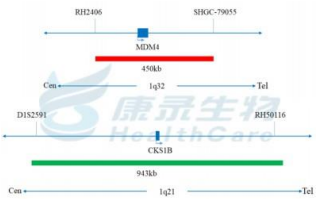
Cat.# FP-049: MDM4 gene amplification probe IVD/RUO

Background

MDM4 (HDMX, MDMX) gene is located in the q32.1 region of chromosome 1, encoding a protein containing 490 amino acid residues. MDM4 is an important regulator of p53 upstream and plays a major role in apoptosis.

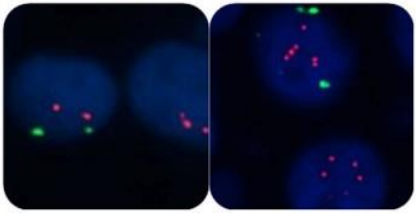
Probe description

MDM4 (HDMX, MDMX) gene amplification probe uses an orange-red dye to label MDM4 gene region, and a green dye to label the chromosome 1 centromere region (CEP1). MDM4 (HDMX, MDMX) gene marker region is located at 1q32.1, and the CEP1 probe is labeled with a specific alpha satellite sequence.



Clinical significance

MDM4 amplification is seen in 65% of primary neuroblastomas, MDM4 is a primary neuroblastoma-specific chemotherapy target, and MDM4 gene amplification patients are not sensitive to chemotherapy.



MDM4 amplification [-] MDM4 amplification [+]

Product name	Cat. No.	Probe name	Specification
MDM4 gene amplification probe reagent	FP-049	MDM4/1q21	100μL/Kit

References

- Duhamel LA, et al. (2012) Histopathology 60: 357-9.
- Laurie NA, et al. (2006) Nature 444: 61-6.

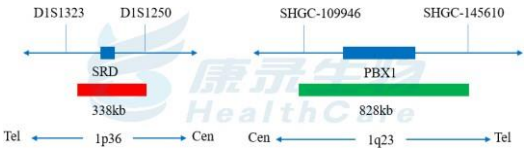
Cat.# FP-050: 1p36(SRD) gene deletion probe IVD/RUO

Background

Deletion of the 1p36 region (SRD gene) can occur in a variety of tumors, such as neuroblastoma, glioma, leukemia, lymphoma, and the like.

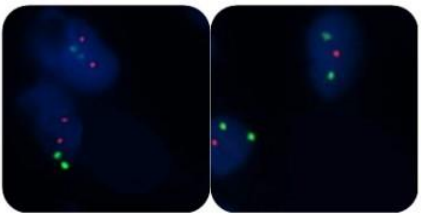
Probe description

1p36 (SRD) gene deletion probe uses an orange-red dye to label the SRD gene region, and a green dye to label chromosome 1 centromere region (CEP1). SRD gene marker region is located at 1p36, and the CEP1 probe is labeled with a specific alpha satellite sequence.



Clinical significance

The deletion of 1p36 (SRD gene) in neuroblastoma is the most typical genetic alteration. The detection of 1p36 heterozygous deletion has a major significance in the clinical guidance and prognosis of neuroblastoma. 1p36 patients with neuroblastoma are prone to recurrence, have a poor prognosis, and are sensitive to chemotherapy.



SRD gene deletion [-] SRD gene deletion [+]

Product name	Cat. No.	Probe name	Specification
SRD(1p36) gene deletion probe reagent	FP-050	SRD(1p36)	100μL/Kit

References

- Elsir T, et al. (2011) Br J Cancer 11: 1747-54.
- Hoeller S, et al. (2012) Hum Pathol 43: 405-12.

SOFT TISSUE CANCER

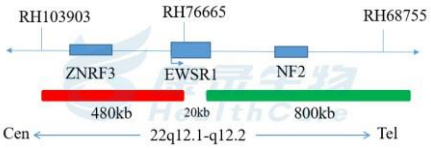
Cat.# FP-051: EWSR1 gene break apart probe IVD/RUO

Background

The full name of the EWSR1 gene is Ewing sarcoma breakpoint region 1 gene. First discovered in Ewing's sarcoma, located at 22q12, consisting of 17 exons, encoding a nuclear protein of 656 amino acids. It is an RNA binding protein. It plays an important role in mitotic cell separation, spindle formation, microtubule stability, DNA repair and cell senescence. It belongs to the cytokine TET family members, which controls cell growth.

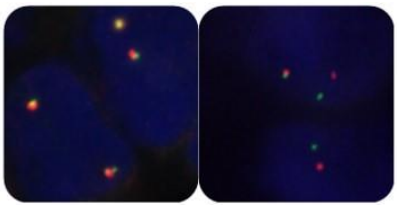
Probe description

EWSR1 gene break apart probe uses orange dye label the 5'end region of EWSR1 gene and green d to label the 3'end region of EWSR1 gene. EWSR1 ge break apart probe can detect all EWSR1 ge rearrangements.



Clinical significance

EWSR1 gene family members have TLS/FUS and TAFl5 genes, all of which are involved in gene translocation of various soft tissue sarcomas, and are fused with transcription factor genes containing the DNA binding domain to form new fusion transcription factors with obvious Tumorigenic effect. Detecting whether EWSR1 gene is broken or not, can be used as auxiliary diagnosis basis for Ewing's sarcoma family tumor.



EWSR1 break apart [-] EWSR1 break apart [+]

Product name	Cat. No.	Probe name	Specification
EWSR1 gene break apart probe reagent	FP-051	EWSR1	100μL/Kit

References

- Rekhi B, et al. (2012) Virchows Arch 461: 687-97.
- Romeo S & Dei Tos AP (2010) Virchows Arch 456: 219-34.

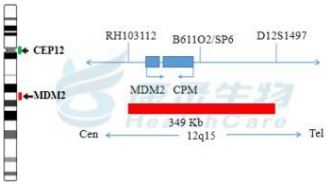
Cat.# FP-054: MDM2 gene amplification probe CE-IVD

Background

MDM2 gene is located in the q15 region of chromosome 12, and the encoded P90 protein can bind to P53 gene, causing P53 gene to lose its normal function, leading to tumorigenesis.

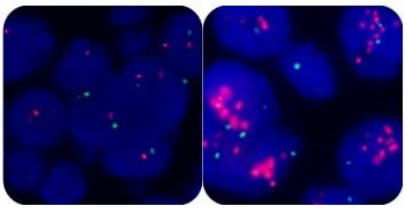
Probe description

MDM2 gene amplification probe uses an orange-red dye to label the MDM2 gene region, and a green chromosome to label chromosome 12 centromere region (CEP12). MDM2 gene marker region is located at 12q15, and the CEP12 probe adopts an alpha satellite sequence, which has extremely high specificity and does not hybridize with other chromosome centromeres to produce noisy spots.



Clinical significance

MDM2 gene amplification is the most common abnormality in fibrosarcoma and can assist in the diagnosis of fibrosarcoma; this gene amplification also occurs in osteosarcoma (16 %) and esophageal cancer (13%). Used to guide the treatment of MDM2 inhibitors.



MDM2 amplification [-] MDM2 amplification [+]

Product name	Cat. No.	Probe name	Specification
MDM2 gene amplification probe reagent	FP-054	MDM2/CEP12	100μL/Kit

References

- Larousserie F, et al. (2013) Eur J Radiol 82: 2149-53.
- Lokka S, et al. (2014) BMC Clin Pathol 14: 36.

Cat.# FP-055: SS18 gene break apart probe IVD/RUO

Background

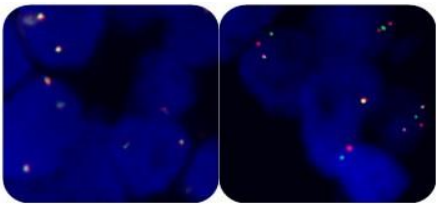
SYT (SS18) gene is located in the q11.2 region of chromosome 18 and encodes a transcriptional co-activator. Specific SYT (SS18) gene translocation exists in 90% of synovial sarcomas.

Probe description

SYT (SS18) gene break apart probe uses an orange dye to label the 5'end region of SYT (SS18) gene and a green dye to label the 3'end region of SYT (SS18) gene. SYT (SS18) gene break apart probe can detect all SYT (SS18) gene rearrangements.

Clinical significance

Specific chromosomal translocation t (X:18) was found in 90% of patients with synovial sarcoma (p11.2: q11.2). This translocation results in the fusion of the SYT (SS18) gene on chromosome 18 with the SSX1 or SSXE gene on the X chromosome. This is used to assist in the diagnosis of synovial sarcoma.

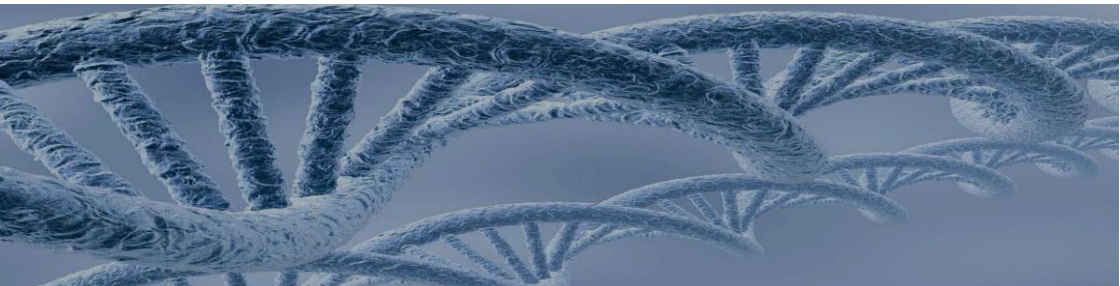


SS18 break apart [-] SS18 break apart [+]

Product name	Cat. No.	Probe name	Specification
SS18 gene break apart probe reagent	FP-055	SS18	100μL/Kit

References

- Surace C, et al. (2004) Lab Invest 84: 1185-92.
- Torres L, et al. (2008) Cancer Genet Cytogenet 187: 45-9.



THYROID CANCER

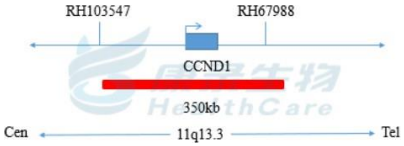
Cat.# FP-041: CCND1 gene amplification probe IVD/RUO

Background

Human CCND1 gene is located in the q13 region of chromosome 11 and encodes cyclin D1. Its main function is to regulate the transition of the cell cycle from the early stage of DNA synthesis (G1 phase) to the DNA synthesis phase (S phase). Overexpression of CCND1 gene will affect the normal cell cycle, leading to a variety of tumor diseases. CCND1 gene amplification is present in thyroid cancer, non-small cell lung cancer, breast cancer, bladder cancer and other tumors.

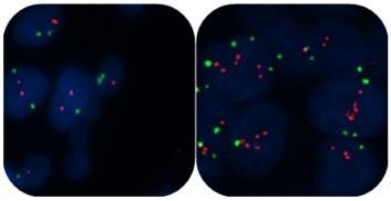
Probe description

CCND1 gene amplification probe uses an orange-red dye to mark CCND1 gene region, and a green dye to label chromosome 11-centromere region (CEP11). CCND1 gene marker region is located at 11q13.3, and the CEP11 probe is labeled with a specific alpha satellite sequence.



Clinical significance

CCND1 gene amplification predicts an important role in tumor development. Patients with CCND1 gene amplification have a poor prognosis and are closely related to chemotherapy resistance.

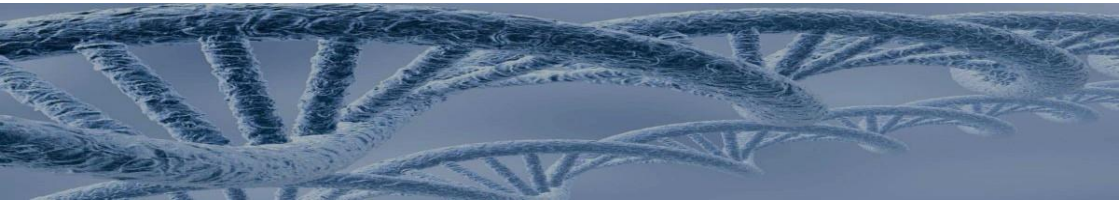


CCND1 amplification [-] CCND1 amplification [+]

Product name	Cat. No.	Probe name	Specification
CCND1 (BCL1) gene amplification probe reagent	FP-041	CCND1/CEP11	100μL/Kit

References

- Motokura T, et al. (1991) Nature 350: 512-5.
- Ormandy CJ, et al. (2003) Breast Cancer Res Treat 78: 323-35.



ACUTE LYMPHOCYTIC LEUKEMIA

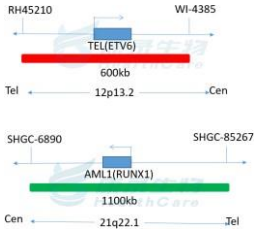
Cat.# FP-029: TEL/AML1 gene fusion probe IVD/RUO

Background

TEL/AML1 dual-color double fusion probe aims to detect the translocation of the ETV6 (TEL) gene in chromosome 12p13.2 region and the RUNX1 (AML1) gene in the region of chromosome 21q22.12. The t(12;21)(p13.2;q22.1) translocation leads to the fusion of ETV6/RUNX1, the most common genetic recombination in patients with acute lymphoblastic leukemia (ALL) and is associated with a good prognosis. It is the highest incidence of childhood leukemia. In pediatric leukemia, acute lymphoblastic leukemia accounts for about 75%. In children with acute lymphoblastic leukemia aged 2-10, the positive rate of ETV6/RUNX1 (TEL/AML1) gene fusion accounts for about 20-25%, among which female is higher than male.

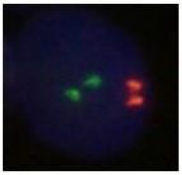
Probe description

TEL probe uses an orange-red fluorescein label, and AML1 probe uses a green fluorescein label. The two probes combine to the target detection site by in situ hybridization. Under normal conditions (TEL/AML1 gene is not fused), it shows two orange-red signals and two green signals under a fluorescence microscope. When there is fusion, the green and orange-red signals form a yellow fusion signal due to recombination.

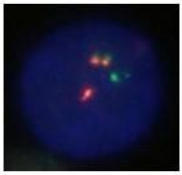


Clinical significance

TEL/AML1 gene fusion has a 20-25% incidence in children with B-ALL. It has a good prognosis, but is prone to recurrence.



TEL/AML1 fusion [-]



TEL/AML1 fusion [+]

Product name	Cat. No.	Probe name	Specification
ETV6(TEL)/RUNX1(AML1) gene translocation probe reagent	FP-029	TEL/AML1	100μL/Kit

References

- Morrow M, et al. (2007) Oncogene 26: 4404-14.
- Peter A, et al. (2009) Eur J Haematol 83: 420-32.

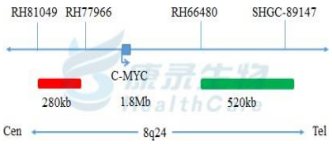
Cat.# FP-243-1: MYC gene break apart probe CE-IVD

Background

MYC proto-oncogene is located on chromosome 8q24 and encodes a transcription factor that regulates cell growth. It is mainly activated by amplification and chromosomal translocation, and its downstream target genes affect cell proliferation, DNA and protein synthesis and metabolism.

Probe description

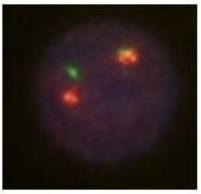
MYC dual-color break apart probe is a two directly labeled hybrid probe that hybridizes at the 8q24.21 region. The probe is directly labeled with an orange-red fluorescent dye that hybridizes with the proximal end of the MYC gene, and with a green fluorescent dye that hybridizes with the distal end of the MYC gene.



Clinical significance

Abnormal MYC gene break apart occurs in 5% of B-ALL patients and can fuse with multiple genes. Approximately 75% of mature B-cell acute lymphocytic patients are morphologically characterized by ALL-L3, often accompanied by a typical t(8;14) (q24; q32). Abnormal MYC gene break apart means that the prognosis is extremely poor and clear in clinical practice.

MYC break apart [-]



MYC break apart [+]

Product name	Cat. No.	Probe name	Specification
MYC(8q24)/BCL6(3q27)/BCL2 (18q21) gene break apart probe reagent	FP-243-1	MYC	100μL/Kit

References

- Boerma EG, et al. (2009) Leukemia 23: 225-34.
- Haralambieva E, et al. (2004) Genes Chromosomes Cancer 40: 10-8.

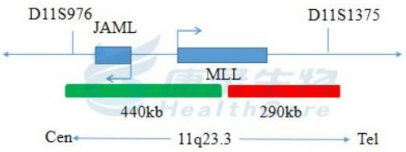
Cat.# FP-026: MLL gene deletion probe CE-IVD

Background

MLL (Mixed-linage leukemia or Myeloid-lymphoid leukemia) gene located at 11q23 was successfully cloned as early as 1991. The MLL gene is a key gene in the regulation of hematopoietic processes, and its abnormality is closely related to the pathogenesis of leukemia.

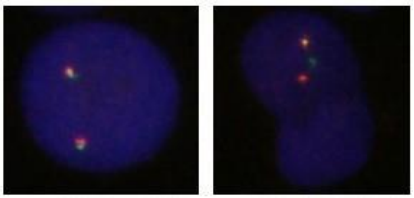
Probe description

MLL gene 5'end region is labeled with an orange-red fluorescein and the 3'end labeled with a green fluorescein. The translocation of 11q23 region is detected with MLL gene break probe. All MLL gene rearrangements can be detected and avoiding separate detection due to missed diagnosis caused by gene fusion.



Clinical significance

MLL gene can fuse with 51 genes after chromosomal translocation. The incidence of MLL gene changes in acute leukemia is about 5%-10%, but in infant ALL it is up to 79%, which is a sign of poor prognosis. EFS in 5 years is only 26.7%.



MLL break apart [-] MLL break apart [+]

Product name	Cat. No.	Probe name	Specification
KMT2A (MLL) gene break apart probe reagent	FP-026	MLL	100μL/Kit

References

- Ford DJ & Dingwall AK (2015) Cancer Genet 208: 178-91.
- Gindin T, et al. (2015) Hematol Oncol 33: 239-46.
- Keefe JG, et al. (2010) J Mol Diagn 12: 441-52.

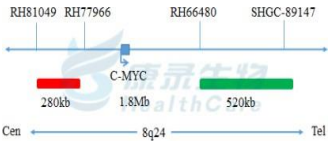
Cat.# FP-242-3: IGH gene break apart probe CE-IVD

Background

IGH separated dual-color probe aims to detect the translocation of 14q32.33 chromosome region (i.e., the IGH gene). IGH gene rearrangement is found in about 50% of NHLs (non-Hodgkin's lymphoma), and also in T-ALL, CLL and ALL. Studies have shown that IGH gene translocation also occurs in children's T-ALL.

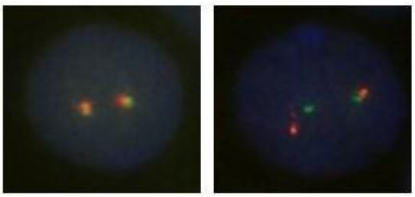
Probe description

5'end of IGH gene region is labeled with an orange-red fluorescein, and the 3'end labeled with a green fluorescein. The translocation of 14q32 region is detected with IGH gene break probe. All IGH gene rearrangements can be detected and avoiding separate detection due to missed diagnosis caused by gene fusion.



Clinical significance

In ALL, the ratio of IGH to C-MYC translocation is the highest. In B-ALL and T-ALL, translocation of IGH with other genes is also more common.

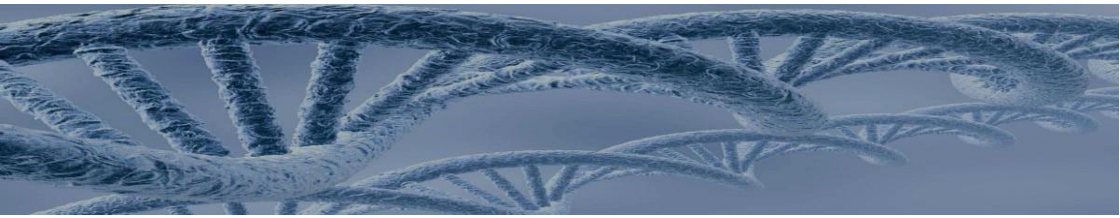


IGH break apart [-] IGH break apart [+]

Product name	Cat. No.	Probe name	Specification
BCL6/MYC/IGH/[BCL2/IGH] gene probe reagent	FP-242-3	IGH	100μL/Kit

References

- Bernicot I, et al. (2007) Cytogenet Genome Res 118: 345-52.
- Hehne S, et al. (2012) Pathol Res Pract 208: 510-7.
- Quintero-Rivera F, et al. (2009) Cancer Genet and Cytogenet 190: 33-9.



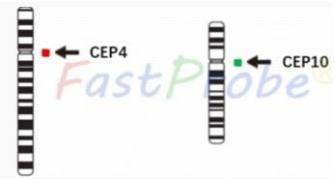
Cat.# FP-030: Chromosomes 4 and 10 probe IVD/RUO

Background

About 25% of children with ALL have an increase in the number of chromosomes, and chromosomes 4, 5, 6, 10, 17 and 21 are more common, among which trisomy 10 is the most common.

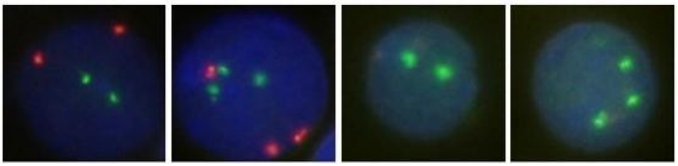
Probe description

Chromosome 4-centromere region is labeled with an orange-red fluorescein, and the centromere region of chromosomes 10 and 17 is labeled with a green fluorescein. In normal cells, two orange-red signals and two green signals are observed under fluorescence microscopy. When chromosome number abnormality exists, three orange-red signals or three green signals are observed.



Clinical significance

The 4, 10, and 17 trisomy are independent prognostic indicators, and these patients have a 7-years EFS greater than 90%. The method of detecting the number of CEP4/CEP10/CEP17 chromosomes provides a reference for the clinical identification, prognosis and medication of leukemia patients.



CEP4/CEP10(-) CEP4/CEP10(+) CEP17(-) CEP17(+)

Product name	Cat. No.	Probe name	Specification
Chromosome 4, 10 centromere probe reagent	FP-030	4q12/CEP10	100μL/Kit

References

- Felice et al., Leuk Lymphoma. 2011 Jul;52(7):1215-21
- Savage et al., Blood. 2009 Oct 22;114(17):3533-7

Cat.# FP-031: Chromosome 17 probe IVD/RUO

Background

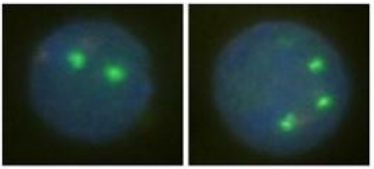
About 25% of children with ALL have an increase in the number of chromosomes, and chromosomes 4, 5, 6, 10, 17 and 21 are more common, among which trisomy 10 is the most common.

Probe description

Chromosome is labeled with a green fluorescein. In normal cells, two green signals are observed under fluorescence microscopy. When chromosome number abnormality exists, three green signals are observed.

Clinical significance

The 17 trisomy is an independent prognostic indicator, and these patients have a 7-years EFS greater than 90%. The method of detecting the number of CEP17 chromosome provides a reference for the clinical [illegible] ation of leukemia patients.



CEP17(-) CEP17(+)

Product name	Cat. No.	Probe name	Specification
Chromosome 17 centromere probe reagent	FP-031	CEP17	100μL/Kit

References

- Felice et al., Leuk Lymphoma. 2011 Jul;52(7):1215-21
- Savage et al., Blood. 2009 Oct 22;114(17):3533-7

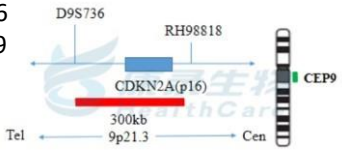
Cat.# FP-032: P16 gene deletion probe CE-IVD

Background

P16 gene is located on the 9p21 chromosome and is a tumor suppressor gene. P16 gene deletion is present in 10% of ALL patients and has a higher proportion in T-ALL. Currently, FISH technology is widely used in the diagnosis of P6 gene deletion in ALL.

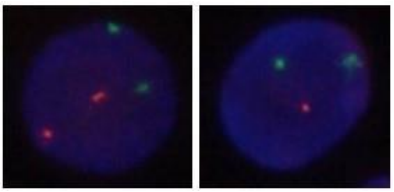
Probe description

P16 gene deletion probe uses an orange-red dye to label P16 gene region, and a green dye is to label chromosome 9 centromere region (CEP9).



Clinical significance

One of the most common abnormalities in ALL is that homozygous deletions are mostly in T-ALL, and the proportion of homozygotes and heterozygotes in B-ALL is comparable; the prognosis is poor.



P16 deletion [-] P16 deletion [+]

Product name	Cat. No.	Probe name	Specification
P16 gene deletion probe reagent	FP-032	P16/CEP9	100μL/Kit

References

- Fry et al., Mol Cancer Ther. 2004 Nov;3(11):1427-38
- Fry et al., Mol Cancer Ther. 2004 Nov;3(11):1427-38

ACUTE MYELOID LEUKEMIA

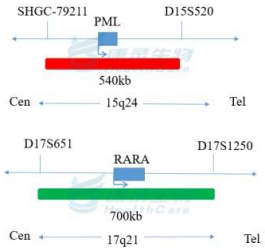
Cat.# FP-005: PML/RARA gene fusion probe CE-IVD

Background

Acute promyelocytic leukemia (APL) is a specific subtype of acute myeloid leukemia. In cytogenetics and molecular biology, APL has a characteristic t(15;17)(q22;21) translocation, forming a PML-RARA fusion gene. A large number of data indicate that patients carrying the PML-RARA fusion gene are predictive of sensitivity to ATRA therapy and good clinical efficacy.

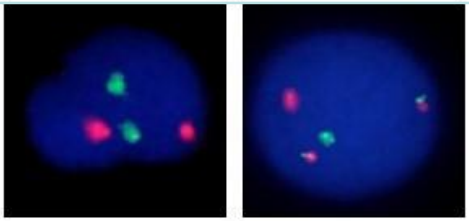
Probe description

The two probes bind to the target detection site by in situ hybridization using an orange-red fluorescein-labeled PML probe and a green fluorescein-labeled RARA probe. Under normal conditions (the PML/RARA gene is not fused), it shows two orange-red signals and two green signals under a fluorescence microscope. When a fusion gene is present, the green and orange-red signals form a yellow fusion signal due to recombination.



Clinical significance

PML/RARA gene fusion is a hallmark of acute promyelocytic leukemia (APL). PML/RARA protein fusion inhibits the differentiation and maturation of promyelocytic cells by dominant negative inhibition, thereby blocking cell differentiation leading to sustained proliferation. All-trans retinoic acid (ATRA) and arsenic trioxide can target the degradation of PML/RARA fusion protein, restore the function of wild-type PML and RARA genes, relieve their inhibition of gene transcription, induce cell differentiation and apoptosis, and effectively treat APL. The combination of ATRA and chemotherapy can achieve a complete response rate of 90% to 95% of APL, and can achieve long-term survival of more than 70% of patients.



PML/RARA fusion [-] PML/RARA fusion[+]

Product name	Cat. No.	Probe name	Specification
RARA (17q21) probe reagent	FP-005	PML/RARA	100μL/Kit

References

- Abe S, et al. (2008) Cancer Genet and Cytogenet 184: 44-7.
- Sanz MA, et al. (2009) Blood 113: 1875-91

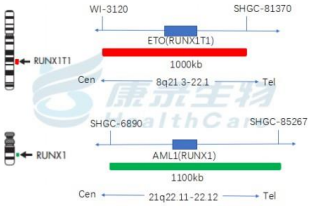
Cat.# FP-004: AML1/ETO gene fusion probe CE-IVD

Background

AML1/ETO gene fusion formed by chromosome 8 and chromosome 21 translocation is a common cytogenetic abnormality in patients with acute myeloid leukemia (AML), and about 12% to 20% of patients with acute myeloid leukemia have AML1/ETO gene fusion. While the positive rate of AML-M2 leukemia is 20% to 40%, and the positive rate of M2b subtype is as high as 90%, which is rare in other types of leukemia. The AML1/ETO protein fusion is a transcriptional repressor that inhibits normal AML1 protein-mediated function, alters the process of self-renewal and maturation of hematopoietic progenitor cells, and also signals the initiation of abnormal hematopoietic cell proliferation, causing the proliferation of leukemia cells.

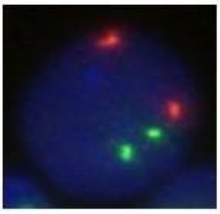
Probe description

ETO probe is labeled with an orange-red fluorescein, and AML1 probe with a green fluorescein. The two probes combine to the target detection site by in situ hybridization. Under normal conditions (AML1/ETO gene is not fused), it shows two orange-red signals and two green signals under a fluorescence microscope. When a fusion gene is present, the green and orange-red signals form a yellow fusion signal due to recombination.

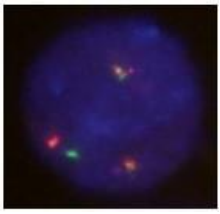


Clinical significance

AML1/ETO gene fusion can be used as AML diagnostic assistant and prognosis assessment means. Clinically, t(8;21) leukemia represents a type of acute leukemia with good prognosis. Adult patients have good response to treatment, high complete remission rate, long median survival time, but prone to recurrence. Children's treatment and prognosis are not as good as adult patients.



AML1/ETO fusion [-]



AML1/ETO fusion [+]

Product name	Cat. No.	Probe name	Specification
AML1/ETO gene fusion detection kit	FP-004	AML1/ETO	100μL/Kit

References

- Dayyani F, et al. (2008) Blood 111: 4338-47.
- Estey E & Döhner H (2006) Lancet 368: 1894-907.
- Gmidène A, et al. (2010) Med Oncol: 28 Suppl 1: 509-12.

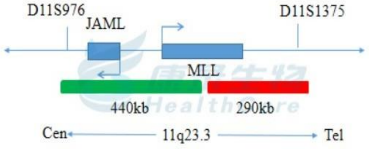
Cat.# FP-026: MLL gene deletion probe CE-IVD

Background

The MLL (Mixed-linage leukemia or Myeloid-lymphoid leukemia) gene is located in the No. 11 staining map, Zone 2, Zone 3 (11q23), and was successfully cloned as early as 1991. The MLL gene is a key gene in the regulation of hematopoietic processes, and its abnormality is closely related to the pathogenesis of leukemia. According to statistics, there are at least 104 MLL gene rearrangements, and up to 64 MLL genes fusion have been identified. Most of the leukemia's with MLL gene fusion are highly malignant, not sensitive to chemotherapy, and have low remission rate. Therefore, the detection of MLL gene fusion in acute leukemia is of great significance for the choice of treatment options for leukemia, residual lesion detection and prognosis.

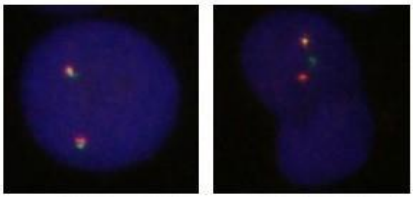
Probe description

MLL gene region 5' end is labeled with an orange-red fluorescein, and the 3' end of MLL gene labeled with a green fluorescein. MLL gene break apart probe is used to detect 11q23 segment translocation, and all MLL gene rearrangements could be detected, avoiding separate detection or missed diagnosis caused by gene fusion.



Clinical significance

Common translocation forms of the MLL gene are t(4;11), t(9;11), t(11;19) and other recombination's. 8-10% of acute myeloid leukemia (AML) has this abnormality. MLL recombination exists in 80% of infants with AML, suggesting a moderate risk type; other MLL genes are recombined into high-risk types.



MLL break apart [-] MLL break apart [+]

Product name	Cat. No.	Probe name	Specification
KMT2A (MLL) gene break apart probe reagent	FP-026	MLL	100μL/Kit

References

- Ford DJ & Dingwall AK (2015) Cancer Genet 208: 178-91.
- Gindin T, et al. (2015) Hematol Oncol 33: 239-46.
- Keefe JG, et al. (2010) J Mol Diagn 12: 441-52.

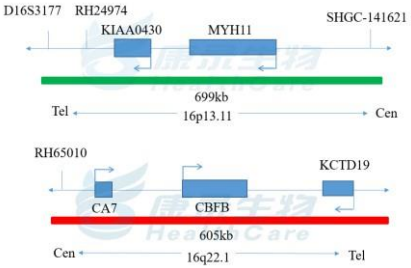
Cat.# FP-028: CBFB/MYH11 gene fusion probe CE-IVD

Background

Acute myeloid leukemia (AML) is a group of highly heterogeneous hematopoietic malignancies, often associated with acquired chromosomal abnormalities, the most common of which is chromosomal translocation. Chromosomal inversion of inv16 (p13q22) or translocation t(16;16) (p13; q22) found in myeloid leukemia (AML-M4) cells with eosinophilia, resulting in the MYH11 gene located at 16p13. The CBFB gene located at 16q22 is recombined to form a CBFB/MYH11 gene fusion. The detection rate of CBFB/MYH11 gene fusion in myeloid leukemia is about 7%. Since the CBFB/MYH11 gene fusion is only found in AML, according to the WHO leukemia diagnostic criteria, AML can be diagnosed by detecting the CBFB/MYH11 gene fusion.

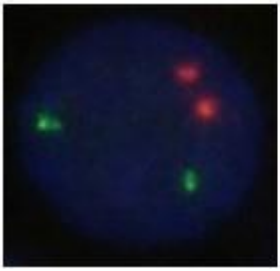
Probe description

CBFB probe is labeled with an orange-red fluorescein, and MYH11 probe is labeled with a green fluorescein. The two probes combine to the target detection site by in situ hybridization. Under normal conditions (CBFB/MYH11 gene did not fuse), it shows two orange-red signals and two green signals under a fluorescence microscope. When a fusion gene is present, the green and orange-red signals form a yellow fusion signal due to recombination. The method was used to detect the status of CBFB/MYH11 gene fusion providing a reference for the identification, prognosis and drug administration guidance for clinical AML leukemia patients.

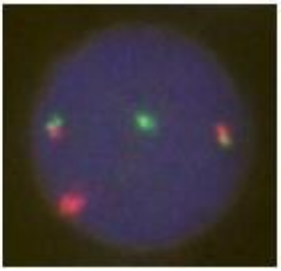


Clinical significance

CBFB/MYH11 gene fusion can be used for the diagnosis of AML. In addition, in the case of positive CBFB/MYH11 gene fusion, the detection of CBFB/MYH11 gene fusion has become the most valuable indicator for the determination of therapeutic options and therapeutic efficacy evaluation. For example, quantitative analysis of CBFB/MYH11 gene fusion can also be used to judge the level of leukemia cells in patients, the detection of minimal residual disease and the prediction of recurrence risk. AML patients with CBFB/MYH11 gene fusion have a better prognosis, and high DFS and low recurrence rates can be achieved by HDAC regimen.



CBFB/MYH11 fusion [-]



CBFB/MYH11 fusion [+]

Product name	Cat. No.	Probe name	Specification
CBFB/MYH11 gene fusion probe reagent	FP-028	CBFB/MYH11	100μL/Kit

References

- Aventín A, et al. (2002) Cancer Genet Cytogenet 134: 142-4.
- Li MM, et al. (2013) Curr Genet Med Rep 1: 99-112.

Cat.# FP-027: CBFB gene break apart probe IVD/RUO

Background

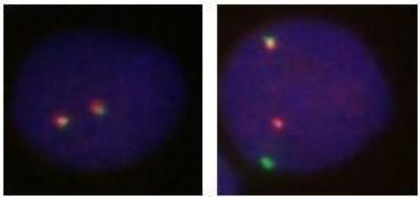
CBFB gene break apart is a characteristic chromosomal abnormality of AML, accounting for 5%-10% of total AML patients and 23% of M4 patients It is usually found in the AML-M4E0 subtype, but less in M2, M5 and M4 (no eosinophilic granulocytosis). It is now considered that CBFB gene break apart is a characteristic genetic alteration of M4E0.

Probe description

CBFB gene 5'end region uses an orange-red fluorescein, the CBFB gene 3'end uses a green fluorescein, and the translocation of 16q22 region is detected with MLL gene break probe. All CBFB gene rearrangements can be detected and avoiding separate detection due to missed diagnosis caused by gene fusion.

Clinical significance

Most AML patients with CBFB gene break apart are sensitive to chemotherapy and have a good prognosis.



CBFB break apart [-] CBFB break apart [+]

Product name	Cat. No.	Probe name	Specification
CBFB gene break apart probe reagent	FP-027	CBFB	100μL/Kit

References

- Krauter J, et al. (2001) Genes Chromosomes and Cancer 30: 342-8.
- Li MM, et al. (2013) Curr Genet Med Rep 1: 99-112.

CHRONIC LYMPHOCYTIC LEUKEMIA

Cat.# FP-014: CLL gene and chromosome detection probe

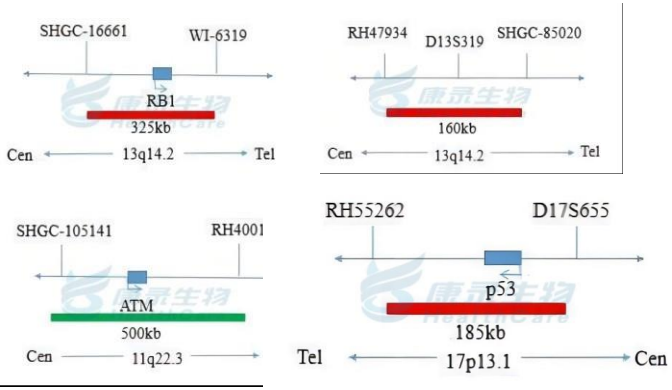
CE-IVD

Background

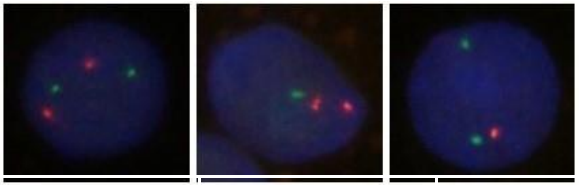
Chronic lymphocytic leukemia (CLL) is a mature B lymphocyte clonal proliferative tumor characterized by the accumulation of lymphocytes in peripheral blood, bone marrow, spleen and lymph nodes. Chronic lymphoblastic leukemia is also diagnosed in patients with persistent (3 months) peripheral blood B lymphocyte (≥5x109/L), such as peripheral blood B lymphocyte (< ≥5x109/L) accompanied by hematocytopenia or disease-related symptoms caused by bone marrow infiltration. About 80% of patients with chronic lymphocytic leukemia have chromosomal abnormalities detected by fluorescence in situ hybridization. The most common deletions are on chromosome 13 long arm del (13q14.1); chromosome 12 deletion or trisomy, chromosome 17 short am deletion del(17p).

Probe description

This kit consists of three sets of probes: RB1/ATM, P53/CEP17, and D13S319/CEP12. The probes of RB1, P53 and D13S319 use an orange-red fluorescent label, and ATM, CEP17 and CEP12 probes are labeled with a green fluorescence. The probes are combined with the target sites by in situ hybridization. Under normal conditions (no gene deletion and chromosome abnormalities), two orange-red signals and two green signals are shown under a fluorescence microscope. When there is gene deletion, there will be a lack of green or orange-red signal, and when there is a chromosomal polysomy, the centromere gene probe signal will increase. This method is used to detect gene deletion and chromosome abnormalities, and provide reference for clinical differentiation, prognosis and medication for leukemia patients.



Chromosome abnormalities are found in 80% of patients with chronic lymphocytic leukemia. The most common deletion is in the long arm del 13 (13q14.1) of chromosome 13; the chromosome 12 deletion or trisomy; the short arm of chromosome 17 deletion del(17p). These abnormalities are important for the diagnosis, differential diagnosis, treatment options, and prognosis of chronic lymphocytic leukemia.



RB1/ATM deletion [-] RB1/ATM deletion [+] RB1/ATM deletion [+]

D13S319/CEP12 deletion [-] D13S319/CEP12 deletion [+] P53 deletion [-] P53 deletion [+]

Product name	Cat. No.	probe name	Specification
CLL chromosome and gene anomaly probe detection kit	FP-014-1	RB1/ATM	100μL/Kit
	FP-014-2	P53/CEP17	100μL/Kit
	FP-014-3	D13S319/CEP12	100μL/Kit

References

- Schnaiter A et al. (2013) Hematol Oncol Clin North Am. 27(2):289-301.
- Dal Bo M, , et al. (2011) Genes Chromosomes Cancer. 50(8):633-43.
- Novak U, , et al. (2004) Leuk Lymphoma.45(5):887-96.

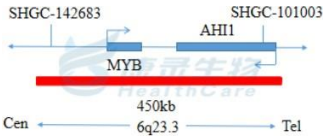
Cat.# FP-036: MYB gene deletion probe CE-IVD

Background

MYB/CEP6 dual-color probe aims to detect the deletion of the MYB gene at chromosome 6q23.3. The MYB gene encodes a transcript that is expressed primarily in early lymphocytes and bone marrow cells. In different types of lymphoid tumors, 6q aberration is the most common chromosomal variation, and several major deletion regions are on the long arm of chromosome 6. One is 6q23. 3-10% of CLL (chronic lymphocytic leukemia) have chromosome structural aberrations at 6q. The absence of MYB is often accompanied by a secondary change. Because traditional cytogenetic methods are not effective in detecting changes in CLL, the use of fluorescence in situ hybridization (FISH) molecular cytogenetic research method can diagnose and prognose CLL.

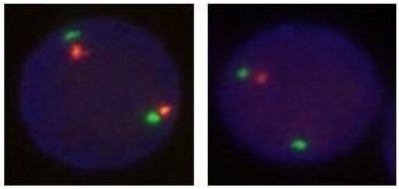
Probe description

MYB/CEP6 is a dual-color hybrid probe in which a green fluorescent dye directly labels the CEP6 probe, which specifically acts on chromosome 6 (D6Z1), while an orange- red fluorescent dye directly labels the MYB probe, which specifically acts on the MYB gene at the chromosomal region 6q23.2-23.3.



Clinical significance

Abnormal 6q deletion is the fourth most common abnormality in B-CLL, about 10%. The prognosis of 6q deletion is poor in many tumors including CLL. This probe can detect 2Mb microdeletion regions that cannot be distinguished by karyotyping analysis.



MYB deletion [-] MYB deletion [+]

Product name	Cat. No.	Probe name	Specification
MYB (6q23) gene probe reagent	FP-036	MYB/CEP6	100μL/Kit

References

- Urbankova H, et al. (2014) Biomed Pap Med Fac Univ Palacky Olomouc Czech Repub 158: 56-64.
- Wang DM, et al. (2011) Leuk Lymphoma 52: 230-7.

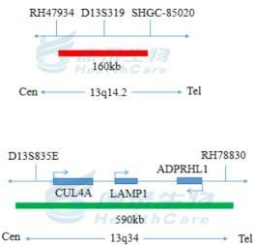
Cat.# FP-025: D13S319/LAMP1 gene probe IVD/RUO

Background

13q14/13q34 dual-color probe is designed to detect the deletion of the long arm end of chromosome 13. The most common aberration in chronic lymphocytic leukemia (CLL) is the deletion of 13q14.2, which contains the D13S319 gene and has a good prognosis for single genetic variant. Combined with further biomarkers, morphological and clinical applications, fluorescence in situ hybridization (FISH) can be an important tool for predicting disease progression and overall survival in CLL patients.

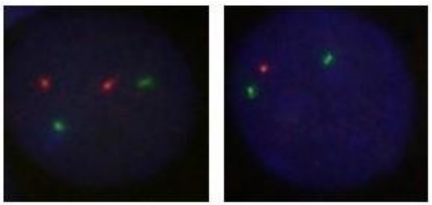
Probe description

13q14/13q34 is a dual-color hybrid probe. The orange-red fluorescent dye directly labels the D13S319 probe and the probe specifically detects the D13S319 gene at 13q14.2. The green fluorescent dye directly labels the 13q34 probe, which specifically detects LAMP1 gene in the 13q34 region.



Clinical significance

Studies have shown that the deletion of 13q has a negative impact on the survival of patients in event-free survival and overall survival. The most common aberration in CLL is the deletion of 13q14.2, which contains D13S319 gene and has a good prognosis for individual genetic variants. These abnormalities are important for the diagnosis, differential diagnosis, treatment options and prognosis in chronic lymphocytic leukemia.



D13S319/LAMP1 deletion [-] | D13S319/LAMP1 deletion [+]

Product name	Cat. No.	Probe name	Specification
13 (13q14) probe reagent	FP-025	D13S319/13q34	100μL/Kit

References

- Chang H, et al. (1999) Leukemia 13: 105-9.
- Dal Bo M, et al. (2011) Genes Chromosomes Cancer 50: 633-43.
- Liu Y, et al. (1998) Blood 86: 1911-15.

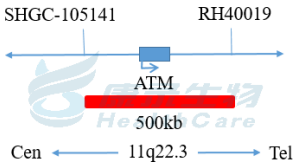
Cat.# FP-245-3: ATM gene deletion probe IVD/RUO

Background

ATM gene (ataxia telangiectasia mutated gene) is located at 11q22.3 and encodes a protein kinase involved in cell cycle regulation and activation of TP53 activity.

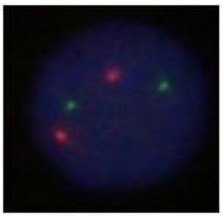
Probe description

ATM gene deletion kit is a dual-color hybrid probe that directly labels ATM probe with an orange-red fluorescent dye. The probe specifically acts on the ATM gene at the chromosome 11q22.3 region, and the chromosome 11 centromere is directly labeled with a green fluorescent dye.

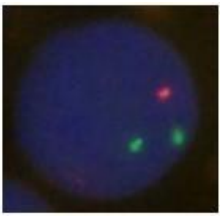


Clinical significance

ATM gene deletion has a 15-20% incidence in B cell CLL, which is associated with disease invasiveness and poor prognosis. ATM gene deletion is the most common deletion abnormality in CLL, which can guide the selection of treatment options and prognosis evaluation.



ATM deletion [-]



ATM deletion [+]

Product name	Cat. No.	Probe name	Specification
p53/[CCND1/IGH]/ATM/CSP 12/D13S25 gene probe reagent	FP-245-3	ATM/CEP11	100μL/Kit

References

- Ripollés L, et al. (2006) Cancer Genet Cytogenet 171: 57-64.
- Shanafelt TD, et al. (2006) Ann Intern Med 145: 435-47.
- Stilgenbauer S, et al. (2002) Leukemia 16: 993-1007.

Cat.# FP-034: Chromosome 12 probe CE-IVD

Background

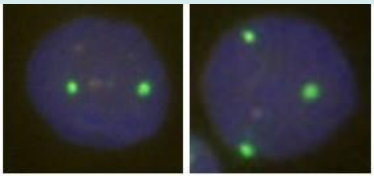
Trisomy 13 is the most common chromosome number abnormality in chronic lymphocytic leukemia (CLL), with an incidence of 40%-60%. It is often characterized by unique cytogenetic abnormalities. Among other genetic disorders, patients with trisomy 12 are considered to be at low risk.

Probe description

The centromere region of chromosome 12 is directly labeled with a green fluorescent dye.

Clinical significance

Chromosome 12 trisomy is the most common chromosome number abnormality in B-CLL, with an abnormal proportion of more than 55%. The total survival time of trisomy 12 decreases and needs early treatment.



CEP12 [-] CEP12 [+]

Product name	Cat. No.	Probe name	Specification
Chromosome 12 centromere probe reagent	FP-034	CEP12	100μL/Kit

References

- Swerdlow et al., editors, WHO Classification of Tumours of Haematopoietic and
- Lymphoid Tissues, Lyon, France, IARC:2008
- Puiggros et al., Biomed Res Int 2014;1-13
- Rossi et al., Blood 2013;121(8):1403-1412

CHRONIC MYELOID LEUKEMIA

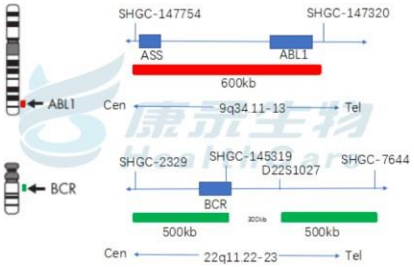
Cat.# FP-003: BCR/ABL gene fusion probe CE-IVD

Background

BCR/ABL is a dual-color double fusion probe designed to detect specific translocations of the ABL1 gene of chromosomal region 9q34.12 and the BCR gene of 22q11.23. Random rearrangements of t(9,22) (q34.1, q11) were found in approximately 90% of patients with chronic myelogenous leukemia (CML) and approximately 25% of acute lymphoblastic leukemia (ALL). Frequent translocations result in the production of the BCR/ABL gene fusion on chromosome 22. The gene product is a BCR/ABL protein with an abnormal tyrosine kinase activity. In normal cells, ABL kinase activity is well regulated by growth factors and other factors, while BCR/ABL proteins fusion result in sustained activation of downstream signaling pathways (Ras, Jak/Stat, and PI-3K). Fluorescence in situ hybridization (FISH) allows the identification of rearrangements that could not be detected by conventional nuclear types.

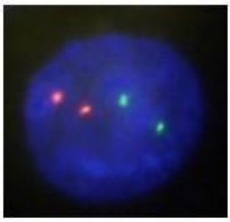
Probe description

ABL probe uses an orange-red fluorescein label, and BCR probe uses a green fluorescein label. The two probes combine to the target detection site by in situ hybridization. Under normal conditions (BCR/ABL gene is not fused), it shows two orange-red signals and two green signals under a fluorescence microscope. When there is fusion, the green and orange-red signals form a yellow fusion signal due to recombination.

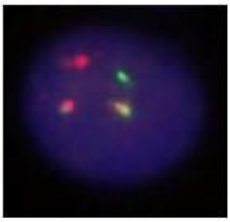


Clinical significance

BCR/ABL gene fusion is a common cytogenetic abnormality in patients with chronic myeloid leukemia (CML). BCR/ABL gene fusion can be found in 90% of CML patients. Patients with BCR/ABL gene fusion have poor prognosis. It is clinically possible to selectively use molecular targeted therapeutic drugs depending on whether a patient has a BCR/ABL gene fusion. In addition, the clinician can combine the patient's other signs to make more effective differential diagnosis.



BCR/ABL fusion [-]



BCR/ABL fusion [+]

Product name	Cat. No.	Probe name	Specification
BCR/ABL gene fusion detection kit	FP-003	BCR/ABL	100μL/Kit

E-mail: cs@healthcare-biotech.com

References

- Hehne S, et al. (2012) Pathol Res Pract 208: 510-7.
- Lim TH, et al. (2005) Ann Acad Med Singapore 34: 533-8.
- Zheng X, et al. (2009) PLoS One 4: e7661.

LYMPHOMA

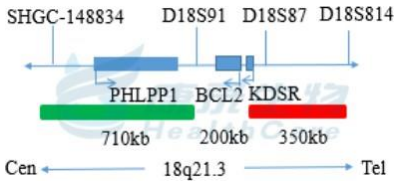
Cat.# FP-243-3: BCL2 gene break apart probe CE-IVD

Background

BCL2 is a tumor suppressor gene located in the 18q21 region. BCL2 gene encodes a mitochondrial membrane protein that regulates apoptosis and is expressed in B cells. Translocation of the BCL2 gene is usually recognized in B cell lymphoma. In particular, translocation of t(14;18)(q32.3;q21.3) is present in approximately 80% of follicular lymphoma (FM), 20%-30% of diffuse large B-cell lymphoma In (DLBCL), it rarely occurs in B-cell chronic lymphocytic leukemia (B-CLL). Therefore, the detection of BCL2 translocation by fluorescence in situ hybridization (FISH) may have diagnostic and prognostic significance.

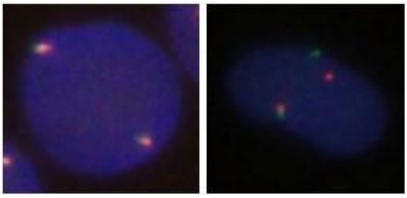
Probe description

BCL2 is a dual-color break apart probe composed of two probes directly labeled at 18q21.33-q22.1. The green fluorescent dye labeled probe hybridizes to the proximal end of the BCL2 gene, while the orange-red fluorescent dye labeled probe hybridizes to the distal end of the BCL2 gene.



Clinical significance

Follicular lymphoma (FL) is a less malignant B cell tumor derived from the center of follicle development. FL is a common type of non-Hodgkin's lymphoma (NHL), accounting for about 10% of NHL in China and 25%-45% of NHL in Europe and America. BCL2 gene break apart and MTC gene break apart can be used both in the lymphoma diagnosis.



Product name	Cat. No.	Probe name	Specification
MYC(8q24)/BCL6(3q27)/**BCL2 (18q21)** gene break apart probe reagent	FP-243-3	BCL2	100μL/Kit

References

- Da Cunha Santos G, et al. (2011) Cancer Cytopathol 119: 254-62.
- Gu K, et al. (2008) Arch Pathol Lab Med 132: 1355-61.
- Impera L, et al. (2008) Oncogene 27: 6187-90.
- Tibiletti MG, et al. (2009) Hum Pathol 40: 645-52.
- Tomita N, et al. (2009) Haematologica 94: 935-43.

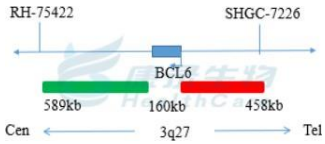
Cat.# FP-243-2: BCL6 gene break apart probe CE-IVD

Background

BCL6 gene is located at the 3q27 region, and the protein encoded by the BCL6 gene is a transcriptional repressor involved in the development and function of the lymphatic system. Chromosome recombination of the BCL6 gene region is present in different types of non-Hodgkin's lymphoma (NHL), including diffuse large B-cell lymphoma (DLBCL) and follicular lymphoma (FL). The most common translocation t(3;14)(q27;q 32.3) of BCL6 led to fusion of the IGH-BCL6 gene. Therefore, detection of BCL6 rearrangement by fluorescence in situ hybridization may be helpful in predicting clinical outcomes in patients with NHL (non-Hodgkin's lymphoma).

Probe description

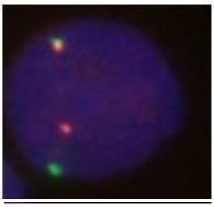
BCL6 is a dual-color break apart probe composed of two probes directly labeled to 3q27.3-q28. The green-labeled fluorescent probe directly hybridizes with the 3q27.3 proximal BCL6 gene, while the orange-red labeled fluorescently probe directly hybridizes with the distal end of the BCL6 gene at the 3q27.3-q28 distal group.



Clinical significance

In diffuse large B-cell lymphoma, BCL6 gene can translocate with multiple genes, the incidence rate is 20%-40%; in follicular lymphoma, the incidence rate is 5-15%. Burkitt's lymphoma is morphologically suggestive of typical age, morphology, and immune characterization. If any of these three features is not typical or has a history of follicular lymphoma, and is accompanied by MYC gene breaks and BCL6 gene breaks, it should be diagnosed as a grey-area lymphoma between Burkitt and DLBCL. This probe aims to detect whether the BCL6 gene is broken and translocated. The BCL6 gene break is an independent indicator for evaluating survival rate and recovery rate.

BCL6 break apart [-]



BCL6 break apart [+]

Product name	Cat. No.	Probe name	Specification
MYC(8q24)/**BCL6(3q27)** /BCL2(18q21) gene break apart probe	FP-243-2	BCL6	100μL/Kit

References

- Akyurek N, et al. (2012) Cancer 118: 4173-83.
- Cady FM, et al. (2008) J Clin Oncol 26: 4814-9.
- Ohno H (2004) Histol Histopathol 19: 637-50.
- Ohno H (2006) J Clin Exp Hematop 46: 43-53.

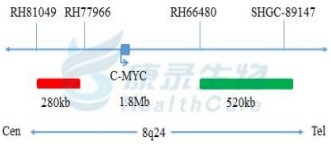
Cat.# FP-243-1: MYC gene break apart probe CE-IVD

Background

MYC proto-oncogene is located on chromosome 8q24 and encodes a transcription factor that regulates cell growth. It is mainly activated by amplification and chromosome translocation rearrangement, and its downstream target genes affect cell proliferation, DNA and protein synthesis and metabolism. In recent years, MYC gene abnormalities have become an important indicator of poor prognosis in patients with DLBCL.

Probe description

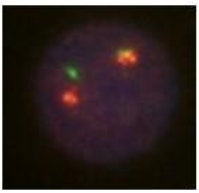
MYC dual color break apart probe is a two directly labeled hybrid probes that hybridize at the 8q24.21 region. The probe directly labeled with the orange-red fluorescent dye hybridizes with the proximal end of the MYC gene, and the green fluorescent-labeled probe hybridizes with the distal end of the MYC gene.



Clinical significance

MYC gene breaks in 5%-10% of patients with diffuse large B-cell lymphoma, and the survival time is significantly shorter than that of normal patients is. MYC gene break, BCL2 gene break or BCL6 gene break can be used for the diagnosis of double-hit lymphoma (DHL).

MYC break apart [-]



MYC break apart [+]

Product name	Cat. No.	Probe name	Specification
MYC(8q24)/BCL6(3q27)/BCL2 (18q21) gene break apart probe	FP-243-1	MYC	100μL/Kit

References

- Savage et al., Blood. 2009 Oct 22;114(17):3533-7
- Seo et al., Ann Lab Med. 2012 Jul;32(4):289-93

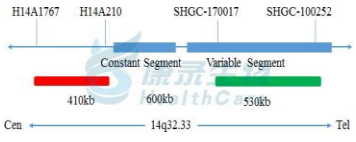
Cat.# FP-242-3: IGH gene break apart probe CE-IVD

Background

IGH separated dual-color probe is designed to detect translocation of the IGH gene at chromosome 14q32.33. IGH gene rearrangement can be used as a specific molecular marker for detecting minimal residual disease of DLBCL. IGH gene breaks and translocations occur in 50% of B cell NHL and various other lymphomas, and can translocate with more than 50 genes.

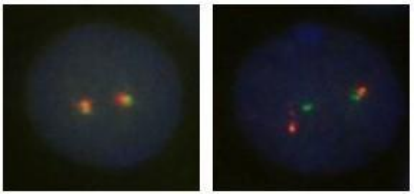
Probe description

IGH is a dual-color break apart probe, consisting of two probes directly labeled at 14q32.33. The probe labeled with orange-red fluorescence hybridizes at the IGH gene proximal end, while the probe labeled with green fluorescence hybridizes with the distal end of the IGH gene.



Clinical significance

The fusion of the IGH gene with a variety of genes can be used for diagnosis, especially for B-cell and T-cell NHL, non-classical HL, and reactive hyperplasia that are not characterized by histopathology and immunohistochemistry. These tests are helpful for the diseases diagnosis.



IGH break apart [-] IGH break apart [+]

Product name	Cat. No.	Probe name	Specification
BCL6/MYC/**IGH**/[BCL2/IGH] gene probe reagent	FP-242-3	IGH	100μL/Kit

E-mail: cs@healthcare-biotech.com

References

- Bernicot I, et al. (2007) Cytogenet Genome Res 118: 345-52.
- Hehne S, et al. (2012) Pathol Res Pract 208: 510-7.
- Quintero-Rivera F, et al. (2009) Cancer Genet and Cytogenet 190: 33-9.

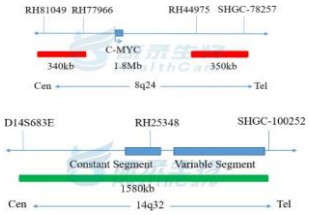
Cat.# FP-234-3: MYC/IGH gene fusion probe CE-IVD

Background

MYC proto-oncogene is located on chromosome 8q24, and its encoded transcription factors are closely related to cell growth and proliferation, as well as tumorigenesis. Translocation of the MYC gene is considered to be a cytogenetic marker of Burkitt's lymphoma (BL), but is also present in other types of lymphoma. About 80% of BL cases have a translocation between the c-MYC gene locus and the Ig gene locus (t(8;14) (q24;q32)), ie, the high activity of the c-MYC translocation to the Ig locus, thus constituting a highly active genes rearrangement, initiating c-MYC transcription, enhancing c-MYC expression, promoting malignant transformation, and ultimately leading to tumorigenesis. The t(8;14) (q24;q32) test helps to diagnose Burkitt's lymphoma and can guide the treatment of high-grade B-cell lymphoma.

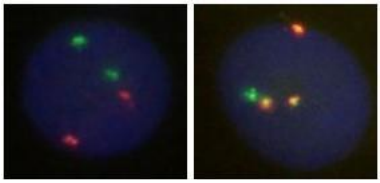
Probe description

MYC /IGH is a dual-color, double-fusion probe consisting of a green fluorescent directly labeling IGH probe across known IGH breakpoint, and an orange-red fluorescence directly labeling MYC probe across known MYC breakpoint.



Clinical significance

T(8;14) can be used to assist in the diagnosis of Burkitt's lymphoma - BL- (75% incidence) and guide the treatment of high-grade B lymphoma the prognosis is poor.



MYC/IGH fusion [-]

MYC/IGH fusion [+]

Product name	Cat. No.	Probe name	Specification
[MAFB/IGH][CCND3/IGH] [**MYC/IGH**] gene fusion probe reagent	FP-234-3	C-MYC/IGH	100μL/Kit

E-mail: cs@healthcare-biotech.com

References

- May P, et al. (2010) Cancer Genet Cytogenet 198: 71-5.
- Perkins A, et al. (2008) Hematology Am Soc Hematol Educ Program 2008: 341-8.
- Veronese ML, et al. (1995) Blood 85: 2132-8.

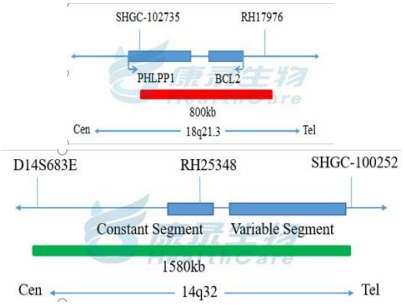
Cat.# FP-242-4: BCL2/IGH gene fusion probe CE-IVD

Background

BCL2/IGH dual-color double fusion probe is designed to detect the translocation of t(14;18)(q32.3;q21.3), that is, the IGH gene at chromosome 14q32.33 and the BCL2 gene at 18q21.33 region. The translocation of the IGH (immune sphere gene) and BCL2 (B cell lymphoma) gene involved is a cytogenetic marker of FL (follicular lymphoma). FL is one of the most common NHL (non-Hodgkin's lymphoma). The t(14;18)(q32.3;q21.3) translocation is present in approximately 80% of patients with follicular lymphoma, but it is also found in 20% to 30% of diffuse large B-cell lymphoma (DLBCL) patients. If histology is uncertain, fluorescence in situ hybridization (FISH) can be used to detect t(14;18).

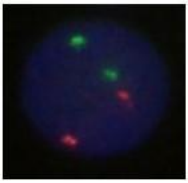
Probe description

BCL2 orange probe labeled with an orange-red fluorescent dye and IGH green probe labeled with a green fluorescent dye bound to the target detection site by in situ hybridization. Under normal conditions (BCL2/IGH gene is not fused), it shows two orange-red signals and two green signals under a fluorescence microscope. When there is gene fusion, the green and orange-red signals form a yellow fusion signal due to recombination.



Clinical significance

The t(14;18) translocation occurs in 85% of follicular lymphoma (FL) and 1/3 of diffuse lymphoma (DL) with a poor prognosis. Studies have shown that BCL2/IGH translocation rearrangement plays a role in stimulating B lymphocyte hyper proliferation. The incidence of most translocations in patients with non-Hodgkin's lymphoma is significantly higher than that in healthy controls.



BCL2/IGH fusion [-]

BCL2/IGH fusion [+]

Product name	Cat. No.	Probe name	Specification
BCL6/MYC/IGH/[BCL2/IGH] gene probe reagent	FP-242-4	BCL2/IGH	100μL/Kit

References

- Baró C, et al. (2011) Leuk Res 35: 256-9.
- Da Cunha Santos G, et al. (2011) Cancer Cytopathol 119: 254-62.
- Einerson RR, et al. (2005) Am J Clin Pathol 124: 421-9.
- Gu K, et al. (2008) Arch Pathol Lab Med 132: 1355-61.
- Nguyen-Khac F, et al. (2011) Am J Blood Res 1: 13-21.
- Weinberg OK, et al. (2007) J Mol Diagn 9: 530-7.

Cat.# FP-233-1: CCND1 (BCL1)/IGH gene fusion probe

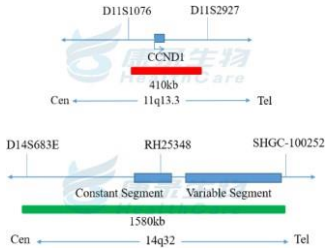
CE-IVD

Background

CCND1/IGH dual-color fusion probe is used to detect t(11;14) (q13.3; q32.3) translocations in up to 95% of mantle cell lymphomas (MCLs). At the same time, t(11;14) is also present in other lymphoproliferative diseases, such as juvenile lymphoblastic leukemia (PLL) and plasma cell myeloma.

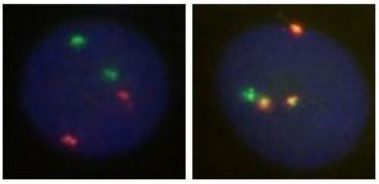
Probe description

CCND1 probe labeled with an orange-red fluorescent dye and IGH green probe labeled with a green fluorescent dye bound to the target detection site by in situ hybridization. Under normal conditions (CCND1/IGH gene is not fused), it shows two orange-red signals and two green signals under a fluorescence microscope. When there is a gene fusion, the green and orange signals recombine to form yellow fusion signal.



Clinical significance

Mantle cell lymphoma is a subtype of NHL with poor prognosis; t(11;14)(q13.3;q32.3) can be used for the auxiliary diagnosis of mantle cell lymphoma (MCL). It can also be used for the MCL and CLL differentiation.



CCND1/IGH fusion [-] CCND1/IGH fusion [+]

Product name	Cat. No.	Probe name	Specification
[IGH/CCND1]/[IGH/MAF]/ [IGH/MAFB]/[IGH/FGFR3] gene fusion probe reagent	FP-233-1	IGH/CCND1	100μL/Kit

References

- Bentz JS, et al. (2004) Cancer 102: 124-31.
- Li JY, et al. (1999) Am J Pathol 154: 1449-52.

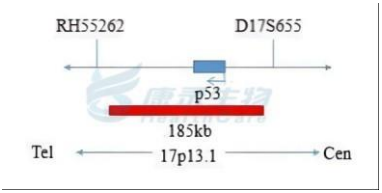
Cat.# FP-014-2: P53 gene probe gene probe CE-IVD

Background

P53 gene is highly correlated with human tumors and is an important gene tumor suppressor. The 53kD protein encoded by the P53 gene plays an important regulatory role in the cell cycle, has a growth inhibitory effect under normal conditions, and plays an important role in DNA cell damage response, cell death and differentiation in the cell cycle.

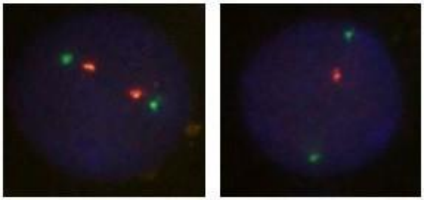
Probe description

P53 gene probe uses an orange-red dye to label P53 gene region, and a green dye to label chromosome 17-centromere region (CEP17). P53 gene marker region is located at 17q13.1, and CEP17 probe is labeled with a specific alpha satellite sequence.



Clinical significance

P53 gene deletion indicates patient's poor response to chemo-radiotherapy and are prone to metastasis, which can be used as an indicator for therapeutic efficacy and prognosis. If p53 gene mutation occurs in the early stage of tumorigenesis, it will be helpful for the tumor early diagnosis.



P53 deletion [-] P53 deletion [+]

Product name	Cat. No.	Probe name	Specification
CLL chromosome and gene anomaly probe detection kit	FP-014-2	P53/CEP17	100μL/Kit

References

- Chang H, et al. (2010) Am J Clin Pathol 133: 70-4.
- Herrera JC, et al. (2010) Biomedica 30: 390-400.

MULTIPLE MYELOMA (MM)

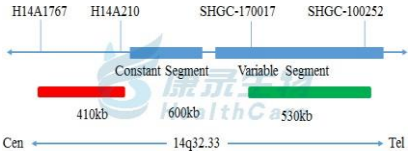
Cat.# FP-242-3: IGH gene break apart probe CE-IVD

Background

IGH gene (encoding the immunoglobulin heavy chain) rearrangement has been proved to be an early event in the MM ladder molecular pathogenesis, usually occurring at the 14q32 region. The breakpoints are mainly in the D and J regions, occurring in about 50% to 60% of MM patients. Partner chromosomes of the IGH gene translocation mainly include 11q13 (BCL1/CCND1), 4p16.3 (FGFR3), 16q23 (MAF), 20q11 (MAFB) and 6p21 (CCND3).

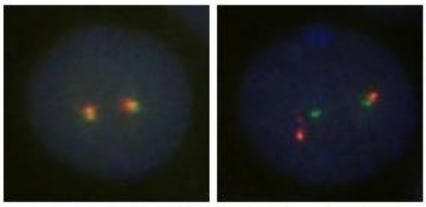
Probe description

IGH is a dual-color break apart probe consisting of two probes directly labeled at 14q32.33, in which the orange-red fluorescent-labeled probe hybridizes to the proximal end of the IGH gene, while the green fluorescent-labeled probe hybridizes to the IGH gene distal end.



Clinical significance

IGH gene break and translocation types are complex and involve multiple genes, commonly found in ALL/MM/lymphoma; can be used to detect abnormalities and minimal residual lesions of IGH gene; IGH gene break apart can be used as a marker for malignant cloning of myeloma cells, not affected by clinical stages and immune types, it can be used as a strong basis for MM diagnosis.



IGH break apart [-] IGH break apart [+]

Product name	Cat. No.	Probe name	Specification
BCL6/MYC/IGH/[BCL2/IGH] gene probe reagent	FP-242-3	IGH	100μL/Kit

References

- Bernicot I, et al. (2007) Cytogenet Genome Res 118: 345-52.
- Hehne S, et al. (2012) Pathol Res Pract 208: 510-7.

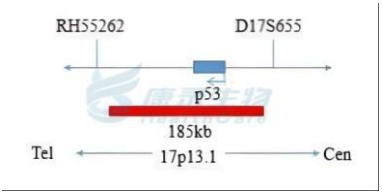
Cat.# FP-014-2: P53 gene probe gene probe CE-IVD

Background

P53 gene is highly correlated with human tumors and is an important gene tumor suppressor. The 53kD protein encoded by the P53 gene plays an important regulatory role in the cell cycle, and has a growth inhibitory effect under normal conditions, and plays an important role in DNA cell damage response, cell death and differentiation in the cell cycle.

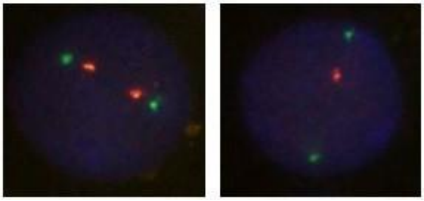
Probe description

P53 gene probe uses an orange-red dye to label P53 gene region, and a green dye to label chromosome 17-centromere region (CEP17). P53 gene marker region is located at 17q13.1, and CEP17 probe is labeled with a specific alpha satellite sequence.



Clinical significance

P53 deletion occurs in 1/3 of newly diagnosed MM (Multiple myeloma), which means short survival and poor prognosis for patients receiving conventional chemotherapy dose.



P53 deletion [-] P53 deletion [+]

Product name	Cat. No.	Probe name	Specification
CLL chromosome and gene anomaly probe detection kit	FP-014-2	P53/CEP17	100μL/Kit

References

- Chang H, et al. (2005) Blood 105: 358-60.
- Chang H, et al. (2010) Am J Clin Pathol 133: 70-4.
- Herrera JC, et al. (2010) Biomedica 30: 390-400.
- Lozanski G, et al. (2004) Blood 103: 3278-81.
- Tavor S, et al. (2011) Leuk Lymphoma 52: 642-7.

Cat.# FP-025: D13S319/LAMP1 gene probe gene probe

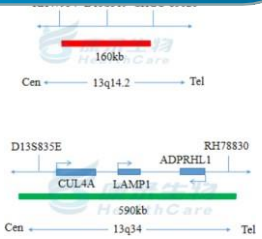
IVD/RUO

Background

Multiple myeloma (MM) is one of the most common malignant plasma cell diseases, accounting for 10% of hematopoietic malignancies. It is characterized by malignant proliferation of monoclonal plasma cells and secretion of a large number of monoclonal immunoglobulins, causing a series of clinical changes such as bone pain, pathological fracture, hematopoietic abnormalities, monoclonal globulinemia and impaired renal function. The current general MM diagnostic criteria are mainly standard WHO (2001) and International MM Working Group (2003). This disease is easily misdiagnosed and the rate of misdiagnosis is as high as 60%. Clinical studies have found that the development of MM is accompanied by changes in the number or structure of related genes at various specific cytogenetic levels. For example, chromosome 13 occurs in 85% of MM patients.

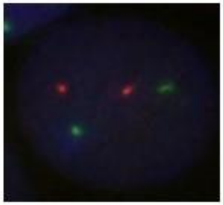
Probe description

13q14/13q34 is a dual-color hybrid probe. The orange-red fluorescent dye directly labels the D13S319 probe and specifically detects the D13S319 gene at 13q14.2. The green fluorescent dye directly labels the 13q34 probe, which specifically detects LAMP1 gene at the 13q34 region.

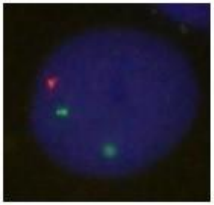


Clinical significance

Clinical studies have found that the occurrence and development of MM is accompanied by a variety of specific changes in the number or structure of related genes at the cytogenetic level. Chromosome 13 haplotypes occur in 85% of patients with MM, and adverse prognostic factor found.



D13S319/LAMP1 [-]



D13S319/LAMP1 [+]

Product name	Cat. No.	Probe name	Specification
13 (13q14) probe reagent	FP-025	D13S319/13q34	100μL/Kit

References

- Dal Bo M, et al. (2011) Genes Chromosomes Cancer 50: 633-43.
- La Starza R, et al. (2018) Molecular Cytogenetics 11: 6.
- Ouillette P, et al. (2011) Clin Cancer Res 21: 6778-90.

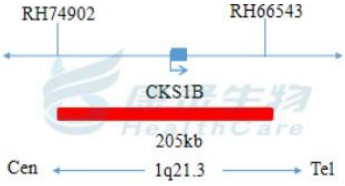
Cat.# FP-022: 1q21 gene amplification probe CE-IVD

Background

Chromosome 1 abnormality is one of the most common cytogenetic findings in MM (Multiple myeloma). A major feature of B cell malignancies is the slow increase in malignant plasma cells grown in the bone marrow. The CKS1B gene is located at 1q21 of chromosome 1 long arm end. In the progression of myeloma disease, tandem repetition and skip translocations of the 1q21 band occur, whereas in patients with multiple myeloma, 1q amplification is associated with poor prognosis.

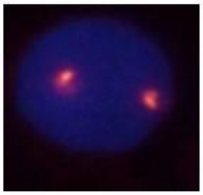
Probe description

1q21 gene amplification detection probe uses an orange-red fluorescent label 1q21 region, and the 1q21 probe binds to the target detection site by in situ hybridization. This method is used to detect abnormalities of multiple myeloma genes, and provide clinical reference for the differentiation, prognosis and medication for leukemia patients.

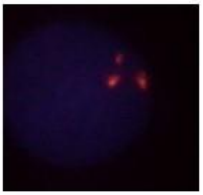


Clinical significance

1q21 (CKS1B) is the most common genetic abnormality in MM. The expansion of CKS1B gene leads to the up-regulation of cell cycle, which causes many proliferative diseases. 1q21 amplification is often associated with MM phenotype infiltration, poor prognosis and rapid disease progress.



1q21 amplification [-]



1q21 amplification [+]

Product name	Cat. No.	Probe name	Specification
1q21 gene amplification probe reagent	FP-022	1q21	100μL/Kit

References

- Chang H, et al. (2010) Bone Marrow Transplant 45: 117-21.
- Kulkarni MS, et al. (2202) Leukemia 16:127-34.
- Walker BA, et al. (2010) Blood 116: 56-65.
- Shaughnessy J, et al. (2005) Hematology 10: 117-26.
- Zhan F, et al. (2007) Blood 109: 4995-5001.

Cat.# FP-021: RB1 gene deletion probe IVD/RUO

Background

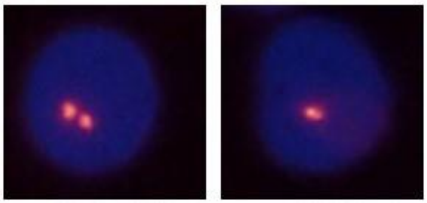
RB1 gene is located in the 13q14.2 region, its encoded protein acts as a tumor suppressor and plays a very important role in cell cycle and genomic DNA stability.

Probe description

RB1 gene deletion detection probe uses an orange-red fluorescent label RB1 gene, and the RB1 probe bind to the target detection site by in situ hybridization. This method is used to detect the abnormalities in multiple myeloma genes, and provide clinical reference for the differentiation, prognosis and medication for leukemia patients.

Clinical significance

Some reseachers recommend MM differential diagnosis at the cytogenetic level. These changes are closely related to the prognosis of patients. Patients with RB1 gene deletion have a moderate prognosis with a median survival of 40 months.



RB1 deletion [-] RB1 deletion [+]

Product name	Cat. No.	Probe name	Specification
RB1 gene deletion probe reagent	FP-021	RB1	100μL/Kit

References

- Chang H, et al. (2010) Bone Marrow Transplant 45: 117-21.
- Kulkarni MS, et al. (2202) Leukemia 16:127-34.
- Walker BA, et al. (2010) Blood 116: 56-65.
- Shaughnessy J, et al. (2005) Hematology 10: 117-26.
- Zhan F, et al. (2007) Blood 109: 4995-5001.

Cat.# FP-233-1: CCND1 (BCL1)/IGH gene fusion probe

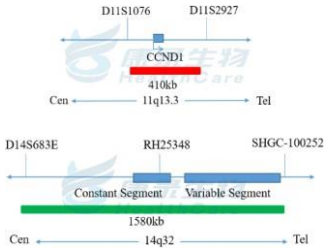
CE-IVD

Background

CCND1/IGH dual-color double fusion probe is used to detect the translocation of t(11;14)(q13.3;q32.3) which often occurs in MM. This translocation exists in the CCND1 gene near the IGH (immunoglobulin heavy chain) gene, which leads to overexpression of the CCDN1 gene. Detection of t (11; 14) translocation has important clinical significance.

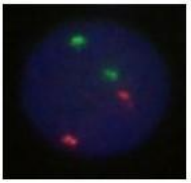
Probe description

CCND1/IGH is a dual-color, double-fusion probe with an orange-red fluorescent dye directly labeled with the CCND1 probe and a green fluorescent directly labeled IGH probe. Under normal conditions (CCND1/IGH gene did not fuse), it shows two orange-red signals and two green signals under a fluorescence microscope. When there is gene fusion, the green and orange-red signals form a yellow fusion signal as recombination result.



Clinical significance

t(11;14) is one of the most common abnormal translocations in MM. MM patients with t(11;14) translocation or no other genetic changes have a good prognosis, with a median survival of 50 months.



CCND1/IGH fusion [-]

CCND1/IGH fusion [+]

Product name	Cat. No.	Probe name	Specification
[IGH/CCND1]/[IGH/MAF]/[IGH/MAFB]/[IGH/FGFR3] gene fusion probe reagent	FP-233-1	IGH/CCND1	100μL/Kit

References

- Bentz JS, et al. (2004) Cancer 102: 124-31.
- Li JY, et al. (1999) Am J Pathol 154: 1449-52.
- Siebert R, et al. (1998) Ann of Oncol 9: 519-26.
- Vaandrager JW, et al. (1996) Blood 88: 1177-82.

MYELODYSPLASTIC SYNDROME

Cat.# FP-011: MDS gene and chromosome detection probe

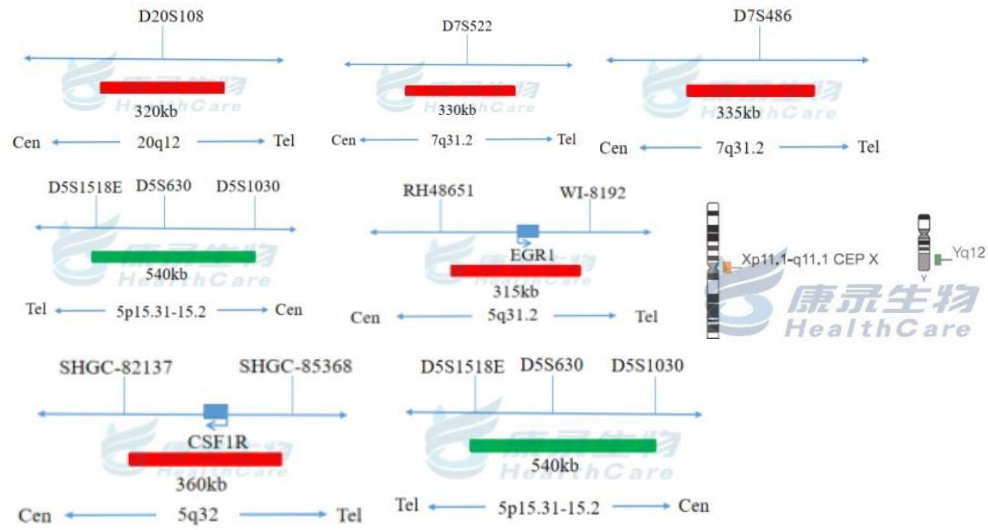
CE-IVD

Background

Myelodysplastic syndrome (MDS) is a group of heterogeneous diseases that are thought to originate from hematopoietic stem cells and are malignant clonal diseases characterized by bone marrow failure, blood cell dysplasia, and high conversion to acute myeloid leukemia. Studies have shown that 40% to 60% of patients with MDS have non-random chromosomal abnormalities, of which -5/5q-, -7/7q-, +8, 20q- and -Y are the most common.

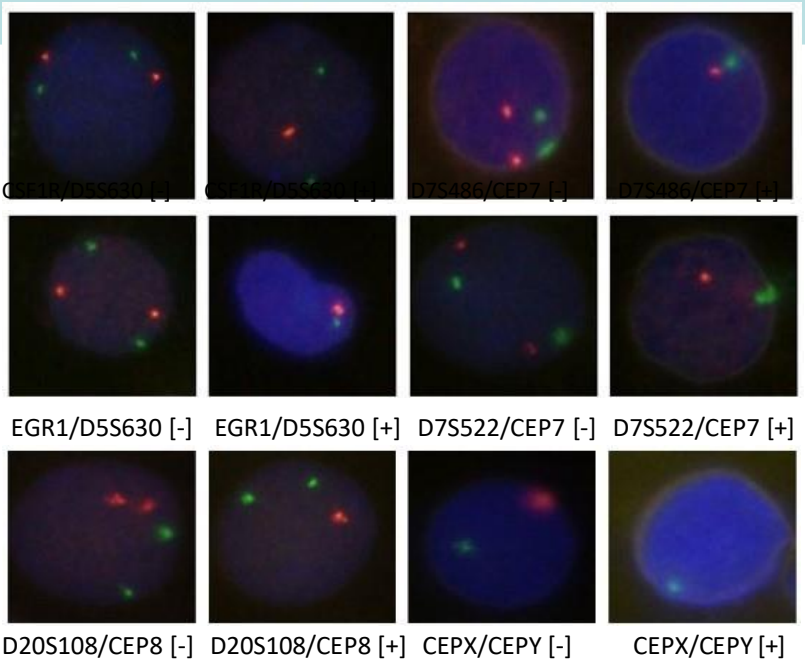
Probe description

This kit uses an orange-red fluorescent dye to label CSF1R, EGR1, D7S486, D7S522, D20S108, CEPY probes, and a green fluorescent dye to label D5S630, CEP7, CEP8 and CEPX probes. The probes bind to the target detection site by in situ hybridization. Under normal conditions (no gene deletion and chromosome abnormality), two orange-red signals and two green signals are shown under a fluorescence microscope. When there is a gene deletion, there will be a lack of green or orange-red signal, and when there is a chromosomal polysomy, the centromere gene probe signal will increase. The detection of gene deletion and chromosome abnormality by FISH method is of great clinical significance for the diagnosis, treatment and prognosis of MDS.



Clinical significance

Some chromosomal abnormalities have specific diagnostic value among the common chromosome abnormalities in MDS patients. Immunosuppressive therapy is effective in some patients with simple +8, 20q- or Y- chromosomes. Karyotyping is also of great value in the classification, treatment and prognosis of MDS. For example, patients with single Y-, 5q- or 20q- chromosomes have better prognosis, while those with complex chromosome abnormalities (≥3 abnormalities) or chromosome 7 abnormalities have worse prognosis, while those with other abnormalities have moderate prognosis. The National Comprehensive Cancer Network – NCCN – guidelines and the Chinese Expert Consensus for the Diagnosis and Treatment of Myelodysplastic Syndrome (2014 Edition) recommend that all patients suspected of having MDS should undergo chromosomes detection, and fluorescence in situ hybridization probes (commonly abnormal sets of probes) are recommended. Abnormalities are important for the diagnosis, treatment, and prognosis of MDS.



Product name	Cat. No.	probe name	Specification
MDS chromosome and gene anomaly probe detection kit	FP-011-1	D7S486/CEP7	100μL/Kit
	FP-011-2	D7S522/CEP7	100μL/Kit
	FP-011-3	CSF1R/D5S630	100μL/Kit
	FP-011-4	EGR1/D5S630	100μL/Kit
	FP-011-5	D20S108/CEP8	100μL/Kit
	FP-011-6	CEPY/CEPX	100μL/Kit
	FP-011-7	Yq12/CEPX	100μL/Kit

References

- Boultwood J, et al. (2010) Blood 116: 5803-11.
- Coleman JF, et al. (2011) Am J Clin Pathol 135: 915-20.
- Tefferi A, et al. (2009) N Engl J Med 361: 1872-85.

Cat.# FP-018: Chromosome 8 probe CE-IVD

Background

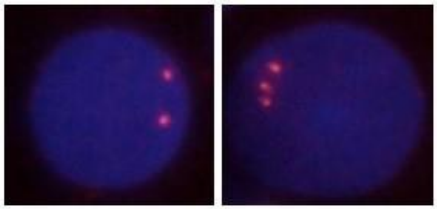
Trisomy 8 is the most common cytogenetic abnormality detected in MDS patients in China and Southeast Asia occurring between 25-31% of MDS patients.

Probe description

The centromere region of chromosome 8 is directly labeled with an orange-red fluorescent dye.

Clinical significance

Immunosuppressive therapy is effective in MDS patients with simple +8, with poor prognosis.



CEP8 [-] CEP8 [+]

Product name	Cat. No.	Probe name	Specification
Chromosome 8 centromere probe reagent	FP-018	CEP8	100μL/Kit

References

- Kawankar N, et al. (2010) Hematology, 16:131-8.
- Coleman JF, et al. (2011) Am J Clin Pathol 135: 915-20.

Diagnosis	Description	Name	Format	Volume
	ALK gene fusion detection probe	ALK	CE-IVD/RUO	100μL
	6q(ROS1) gene detection probe	ROS1	CE-IVD/RUO	100μL
	MET gene detection probe	C-MET/CEP7	CE-IVD/RUO	100μL
	MAML2(11q21) gene break apart detection probe	MAML2	IVD/RUO	100μL
	NTRK1 gene break apart detection probe	NTRK1	CE-IVD/RUO	100μL
	NTRK2(9q21) gene break apart detection probe	NTRK2	CE-IVD/RUO	100μL
	NTRK3(15q25) gene break apart detection probe	NTRK3	CE-IVD/RUO	100μL
Non-Small Cell Lung Cancer	PDL1(9p24)/CSP9 gene amplification detection probe	PD-L1/CEP9	IVD/RUO	100μL
	ALK gene fusion detection probe	ALK	CE-IVD/RUO	100μL
	6q(ROS1) gene detection probe	ROS1	CE-IVD/RUO	100μL
	MET gene detection probe	C-MET/CEP7	CE-IVD/RUO	100μL
	MAML2(11q21) gene break apart detection probe	MAML2	IVD/RUO	100μL
	NTRK1 gene break apart detection probe	NTRK1	CE-IVD/RUO	100μL
	NTRK2(9q21) gene break apart detection probe	NTRK2	CE-IVD/RUO	100μL
	NTRK3(15q25) gene break apart detection probe	NTRK3	CE-IVD/RUO	100μL
	PDL1(9p24)/CSP9 gene amplification detection probe	PD-L1/CEP9	IVD/RUO	100μL
	HER2 gene amplification detection probe	HER2/CEP17	CE-IVD/RUO	100μL
	TOP2A gene amplification detection probe	TOP2A	IVD/RUO	100μL
Breast Cancer	ETV6/NTRK3 gene fusion t(12;15) detection probe	ETV6/NTRK3	IVD/RUO	100μL
	CCND1(BCL1) gene amplification detection probe	CCND1/CEP11	IVD/RUO	100μL
	EPOR(19p13) gene break apart detection probe	EPOR	IVD/RUO	100μL
Stomach Cancer	HER2 gene amplification detection probe	HER2	CE-IVD/RUO	100μL
Bladder Cancer	Bladder Cancer Cells chromosome and gene anomaly detection probe	CEP3/CEP7 ; P16/CEP17	CE-IVD/RUO	200μL
	CLL chromosome and gene anomaly detection probe	P53/CEP17	CE-IVD/RUO	100μL
Cervical Cancer	TERC gene amplification detection probe	TERC	CE-IVD/RUO	100μL
Brain Cancer	1p/19q deletion detection probe	1p/19q	CE-IVD/RUO	200μL
	BRAF gene break apart detection probe	BRAF	CE-IVD/RUO	100μL
	MYC(8q24) ; BCL6(3q27) ; BCL2(18q21) gene break apart detection probe	BCL6	CE-IVD/RUO	100μL
	MYC(8q24) ; BCL6(3q27) ; BCL2(18q21) gene break apart detection probe	BCL2	CE-IVD/RUO	100μL
	BCL6 ; MYC ; IGH ; BCL2/IGH gene detection probe	IGH	CE-IVD/RUO	100μL
	MAFB/IGH ; CCND3/IGH ; MYC/IGH gene fusion detection probe	IGH/C-MYC	CE-IVD/RUO	100μL
	BCL6 ; MYC ; IGH ; BCL2/IGH gene detection probe	IGH/BCL2	CE-IVD/RUO	100μL
	CLL chromosome and gene anomaly detection probe	P53/CEP17	CE-IVD/RUO	100μL
Lymphoma	MYC(8q24) ; BCL6(3q27) ; BCL2(18q21) gene break apart detection probe	MYC	CE-IVD/RUO	100μL
	IGH/CCND1; IGH/MAF ; IGH/MAFB ; IGH/FGFR3 gene fusion detection probe	CCND1/IGH	CE-IVD/RUO	100μL
	MALT1 gene break apart detection probe	MALT1	IVD/RUO	100μL
	MALT1/IGH gene fusion t(14; 18) detection probe	MALT1/IGH	IVD/RUO	100μL
	IRF4(6p25) gene break apart detection probe	IRF4	IVD/RUO	100μL
	API2/MALT1 t(11;18) gene detection probe	API2/MALT1	IVD/RUO	100μL
	11q23.3/11q24.3 gene deletion detection probe	11q23.3/CEP11 11q24.3/CEP11	IVD/RUO	200μL
	PDL1(9p24)/CSP9 gene amplification detection probe	PDL1/CEP9	IVD/RUO	100μL
		RB1/ATM	CE-IVD/RUO	100μL
	CLL chromosome and gene anomaly detection probe	P53/CEP17	CE-IVD/RUO	100μL
		D13S319/CEP12	CE-IVD/RUO	100μL
Chronic Lymphocytic Leukemia (CLL)	Chromosome 12 centromere detection probe	CEP12	CE-IVD/RUO	100μL
	P53; CCND1/IGH ; CEP11/ATM ; CEP12/D13S25 gene detection probe	CEP11/ATM	CE-IVD/RUO	100μL
	13(13q14) gene detection probe	D13S319/LAMP1	CE-IVD/RUO	100μL
	MYB(6q23) gene detection probe	MYB/CEP6	CE-IVD/RUO	100μL
	D13S25(13q14) gene deletion detection probe	D13S25	IVD/RUO	100μL
	D13S319 gene deletion detection probe	D13S319	IVD/RUO	100μL
	AML1/ETO gene fusion detection probe	AML1/ETO	CE-IVD/RUO	100μL
	RARA(17q21) detection probe	PML/RARA	CE-IVD/RUO	100μL
Acute Myeloid Leukemia/AML (Non APL)	CBFB gene break apart detection probe	CBFB	IVD/RUO	100μL
	KMT2A(MLL) gene break apart detection probe	MLL	CE-IVD/RUO	100μL
	CBFBMYH11gene fusion detection probe	CBFB/MYH11	CE-IVD/RUO	100μL
	RARA gene break apart detection probe	RARA	IVD/RUO	100μL
	EVI gene break apart detection probe	EVI1	CE-IVD/RUO	100μL

Diagnosis	Description	Name	Format	Volume
Chronic Myeloid Leukemia (CML)	BCRABL gene fusion detection probe	BCR/ABL	CE-IVD/RUO	100μL
	CHIC2 gene deletion (PDGFRA break) detection probe	CHIC2(PDGFRA)	IVD/RUO	100μL
	NUP98 gene break apart detection probe	NUP98	IVD/RUO	100μL
	FGFR1 gene break apart detection probe	FGFR1	CE-IVD/RUO	100μL
	PDGFRA ; PDGFRB gene break apart detection probe	PDGFRA	CE-IVD/RUO	100μL
	ABL1 ; ABL2 ; PDGFRB ; CRLF2 ; JAK2 gene break apart detection probe	JAK2	IVD/RUO	100μL
Acute Lymphoblastic Leukemia (ALL)	ETV6(TEL)/RUNX1(AML1) gene translocation detection probe	TEL/AML1	CE-IVD/RUO	100μL
	BCRABL gene fusion detection probe	BCR/ABL	CE-IVD/RUO	100μL
	BCL6 ; MYC ; IGH ; BCL2IGH gene detection probe	IGH	CE-IVD/RUO	100μL
	P16 gene deletion detection probe	P16	CE-IVD/RUO	100μL
	KMT2A(MLL) gene break apart detection probe	MLL	CE-IVD/RUO	100μL
	Chromosomes 4, 10 detection probe	CEP4/CEP10	IVD/RUO	100μL
	Chromosome 17 centromeric detection probe	CEP17	IVD/RUO	100μL
	MYC(8q24)/BCL6(3q27)/BCL2(18q21) gene break apart detection probe	MYC	CE-IVD/RUO	100μL
	TCF3/PBX1 gene fusion detection probe	TCF3/PBX1	CE-IVD/RUO	100μL
	ABL1 ; ABL2 ; PDGFRB ; CRLF2 ; JAK2 gene break apart detection probe	CRLF2	IVD/RUO	100μL
	E2A gene break apart detection probe	E2A	CE-IVD/RUO	100μL
	MLL gene deletion detection probe	MLL/CEP11	IVD/RUO	100μL
	ETV6 gene break apart detection probe	ETV6	IVD/RUO	100μL
	DEK/NUP214 gene fusion detection probe	DEK/NUP214	IVD/RUO	100μL
	TCRB (7q34) gene break apart detection probe	TCRB (7q34)	IVD/RUO	100μL
Multiple Myeloma (MM)	RB1 gene deletion detection probe	RB1	IVD/RUO	100μL
	CLL chromosome and gene anomaly detection probe	P53/CEP17	CE-IVD/RUO	100μL
	BCL6 ; MYC ; IGH ; BCL2IGH gene detection probe	IGH	CE-IVD/RUO	100μL
	IGH/CCND1 ; IGH/MAF ; IGH/MAFB ; IGH/FGFR3 gene fusion detection probe	CCND1/IGH	CE-IVD/RUO	100μL
	13 (13q14) gene detection probe	D13S319/LAMP1	CE-IVD/RUO	100μL
	1q21 and 1p32 anomaly detection probe	1q21 and 1p32	CE-IVD/RUO	100μL
	IGH/CCND1 ; IGH/MAF ; IGH/MAFB ; IGH/FGFR3 gene fusion detection probe	MAF/IGH	CE-IVD/RUO	100μL
	MAFB/IGH ; CCND3/IGH ; MYC/IGH gene fusion detection probe	CCND3/IGH	CE-IVD/RUO	100μL
	IGH/CCND1 ; IGH/MAF ; IGH/MAFB ; IGH/FGFR3] gene fusion detection probe	FGFR3/IGH	CE-IVD/RUO	100μL
	IGH/CCND1 ; IGH/MAF ; IGH/MAFB ; IGH/FGFR3 gene fusion detection probe	MAFB/IGH	CE-IVD/RUO	100μL
	15q22 and 6q21 anomaly detection probe	15q22/6q21	IVD/RUO	100μL
	D13S319 gene deletion detection probe	D13S319	IVD/RUO	100μL
Myelodysplastic Syndrome (MDS)	MDS chromosome and gene anomaly detection probe	D7S486/CEP7	CE-IVD/RUO	100μL
		D7S522/CEP7	CE-IVD/RUO	100μL
		CSF1R/D5S630	CE-IVD/RUO	100μL
		EGR1/D5S630	CE-IVD/RUO	100μL
		D20S108/CEP8	CE-IVD/RUO	100μL
		CEPX/CEPY	CE-IVD/RUO	100μL
		Yq12/CEPX	CE-IVD/RUO	100μL
	Chromosome 8 centromere detection probe	CEP8	CE-IVD/RUO	100μL
	PDGFRB gene break apart detection probe	PDGFRB	IVD/RUO	100μL
	D13S319 gene deletion detection probe	D13S319	IVD/RUO	100μL
	13q gene detection probe	RB1/13q34	CE-IVD/RUO	100μL
Aplastic Anemia	Chromosome 8 centromeric detection probe	CEP8	CE-IVD/RUO	100μL
	MDS chromosome and gene anomaly detection probe	D7S486/CEP7	CE-IVD/RUO	100μL
	MDS chromosome and gene anomaly detection probe	EGR1/D5S630	CE-IVD/RUO	100μL
	20q gene deletion detection probe	20q12/20q13.12	CE-IVD/RUO	100μL
Acute Lymphoblastic Leukemia (ALL)	ETV6(TEL)/RUNX1(AML1) gene translocation detection probe	TEL/AML1	CE-IVD/RUO	100μL
	BCRABL gene fusion detection probe	BCR/ABL	CE-IVD/RUO	100μL
	BCL6 ; MYC ; IGH ; BCL2IGH gene detection probe	IGH	CE-IVD/RUO	100μL
	P16 gene deletion detection probe	P16	CE-IVD/RUO	100μL
	KMT2A(MLL) gene break apart detection probe	MLL	CE-IVD/RUO	100μL
	Chromosomes 4, 10 detection probe	CEP4/CEP10	IVD/RUO	100μL
	Chromosome 17 centromeric detection probe	CEP17	IVD/RUO	100μL
	MYC(8q24)/BCL6(3q27)/BCL2(18q21) gene break apart detection probe	MYC	CE-IVD/RUO	100μL
Soft Tissue Cancer	SS18(SYT) gene break apart detection probe	SS18(SYT)	IVD/RUO	100μL
	MDM2 gene amplification detection probe	MDM2	CE-IVD/RUO	100μL
	CDK4 (12q13)/SE12 detection probe	CDK4/CEP12	IVD/RUO	100μL
Ph. Like ALL	NR4A3(9q22) gene break apart detection probe	NR4A3	IVD/RUO	100μL
	CSF1R(5q32) gene break apart detection probe	CSF1R	IVD/RUO	100μL
	ABL1(9q34) gene break apart detection probe	ABL1	IVD/RUO	100μL
	ABL2(1q25) gene break apart detection probe	ABL2	IVD/RUO	100μL
	ABL1 ; ABL2 ; PDGFRB ; CRLF2 ; JAK2 gene break apart detection probe	JAK2	IVD/RUO	100μL
Soft Tissue Cancer	SS18(SYT) gene break apart detection probe	SS18(SYT)	IVD/RUO	100μL
	MDM2 gene amplification detection probe	MDM2	CE-IVD/RUO	100μL
	CDK4 (12q13)/SE12 detection probe	CDK4/CEP12	IVD/RUO	100μL
	NR4A3(9q22) gene break apart detection probe	NR4A3	IVD/RUO	100μL

Diagnosis	Description	Name	Format	Volume
Central Nervous System Tumor	MYCN gene amplification detection probe	N-MYC/LAF4	IVD/RUO	100μL
	Chromosome 7 centromeric detection probe	CEP7 (Green)	IVD/RUO	100μL
Peripheral Nerve Tissue Tumor	SRD(1p36) gene deletion detection probe	SRD/PBX1	IVD/RUO	100μL
Prenatal Diagnosis and Postnatal Examination	Prenatal chromosomes detection probe	13/21 ; 18/X/Y	CE-IVD/RUO	200μL/10 Tests
Non-Hodgkin Lymphoma	BCL6/IGH gene fusion t(3;14) detection probe	BCL6/IGH	IVD/RUO	100μL
Acute Myeloid Leukemia /AML	D13S319 gene deletion detection probe	D13S319	IVD/RUO	100μL
	ABL1 ; ABL2 ; PDGFRB ; CRLF2 ; JAK2 gene break apart detection probe	PDGFRB	IVD/RUO	100μL
	13q gene detection probe	RB1/13q34	CE-IVD/RUO	100μL
Prostate Cancer	TMPRSS2 gene break apart detection probe	TMPRSS2	IVD/RUO	100μL
Kidney & Vascular Tumor	TFE3 gene break apart detection probe	TFE3	IVD/RUO	100μL
Cartilage Tumor	CDK4(12q13)/SE12 detection probe	CDK4/CEP12	IVD/RUO	100μL
Myeloproliferative Disease	13q gene detection probe	RB1/13q34	CE-IVD/RUO	100μL
Extraskeletal Myxoid Chondrosarcoma (EMC)	NR4A3(9q22) gene break apart detection probe	NR4A3	IVD/RUO	100μL
Fibroblast/Myofibroblastic Tumor	ETV6 gene break apart detection probe	ETV6	IVD/RUO	100μL
	USP6(17p13) gene break apart detection probe	USP6	IVD/RUO	100μL
	FUS gene break apart detection probe	FUS	IVD/RUO	100μL
	EWSR1 gene break apart detection probe	EWSR1	IVD/RUO	100μL
Striated muscle tumor(Rhabdomyoma)	FKHR gene break apart detection probe	FKHR	IVD/RUO	100μL
	PAX3(2q36) gene break apart detection probe	PAX3	IVD/RUO	100μL
Thyroid	RET gene break apart detection probe	RET	IVD/RUO	100μL
Fibrohistiocytoma	DDIT3(12q13) gene break apart detection probe	DDIT3	IVD/RUO	100μL
Renal Cell Carcinoma (RCC)	3p gene detection probe	3p25/CEP3	IVD/RUO	100μL
Plasma Cell Myeloma (PCM)	20q gene detection probe	D20S108	IVD/RUO	100μL
Angiosarcoma	MYC(8q24) gene amplification detection probe	MYC	CE-IVD/RUO	100μL
Endometrial Stromal Tumor (EST)/Endometrial Cancer	JAZF1(7p15) gene break apart detection probe	JAZF1	IVD/RUO	100μL

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