

DNA FISH Assay



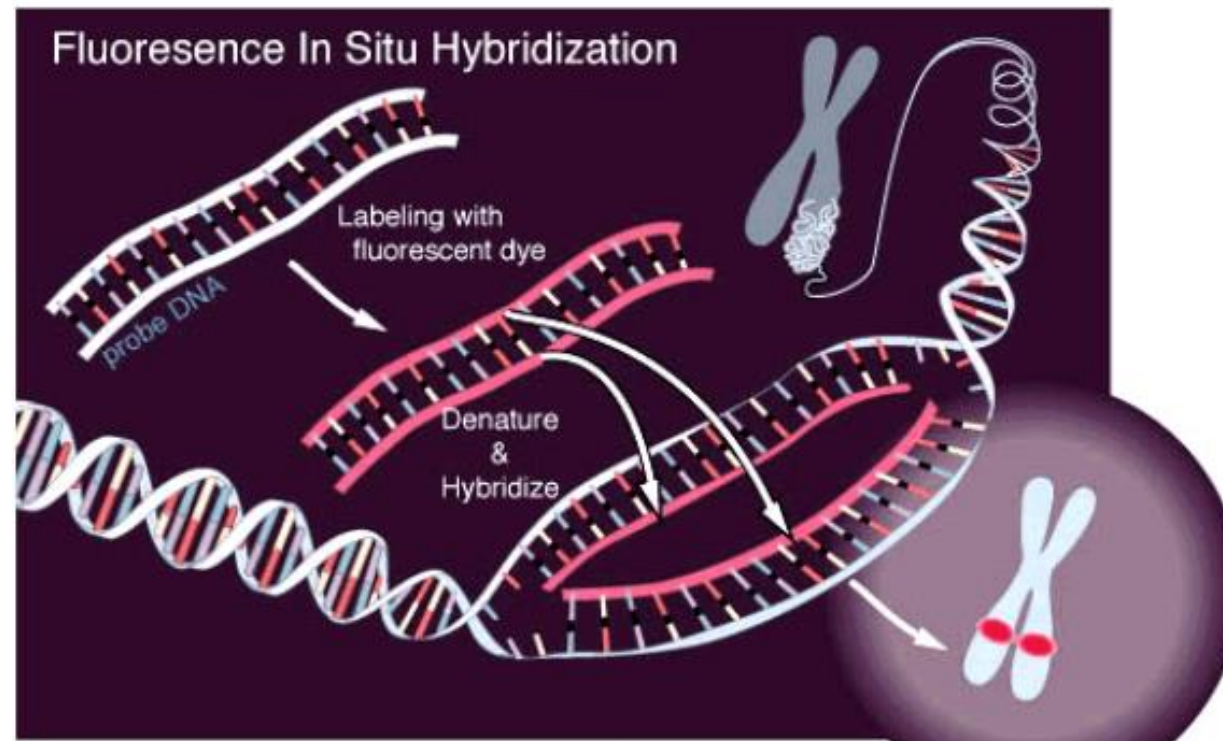
WuXi AppTec Research Service Division
Oncology & Immunology Unit



2018.01

Introduction

- Fluorescence in situ hybridization (FISH) is a technique that makes use of fluorescence dye labeled DNA sequence named probes to detect and localize the presence or absence of specific DNA or RNA sequence based on sequence complementarity.
- DNA FISH can detect genetic abnormalities, such as gene amplification, gene rearrangement, and chromosome abnormalities.



Introduction

- Many diseases, especially tumors, were caused by driver genetic abnormalities. Some important genetic abnormalities were not only proven to be suitable drug targets, but also could predict the response to therapies.
- Many DNA FISH based companion diagnostics have been developed, and approved by FDA to determine the suitability to receive certain therapy for patients.

Disease/Use	Trade Name	Manufacturer
Acute Myeloid Leukemia	Vysis D7S486/CEP 7 FISH Probe Kit	Abbott Molecular Inc.
	Vysis EGR1 FISH Probe Kit	Abbott Molecular Inc.
Acute Myeloid Leukemia or Myelodysplastic Syndrome	VYSIS EGR1 FISH PROBE KIT - SC (SPECIMEN CHARACTERIZATION	ABBOTT MOLECULAR, INC.
B-cell chronic lymphocytic leukemia	VYSIS CLL FISH PROBE KIT	ABBOTT MOLECULAR, INC
	VYSIS CLL FISH PROBE KIT	ABBOTT MOLECULAR, INC
Breast cancer	INFORM HER2 Dual ISH DNA Probe Cocktail	Ventana Medical Systems, Inc.
	HER2 CISH pharmDx™ Kit	Dako Denmark A/S
	Dako TOP2A FISH PharmDx Kit	Dako Denmark A/S
	HER2 IQFISH PHARMDX	DAKO DENMARK A/S
	INSITE HER-2/NEU KIT	BIOGENEX LABORATORIES, INC.
	SPOT-LIGHT HER2 CISH KIT	INVITROGEN CORPORATION
Non-Small Cell Lung Cancer	VYSIS ALK BREAK APART FISH PROBE KIT	ABBOTT MOLECULAR, INC.

Adapted from www.fda.gov.

Introduction

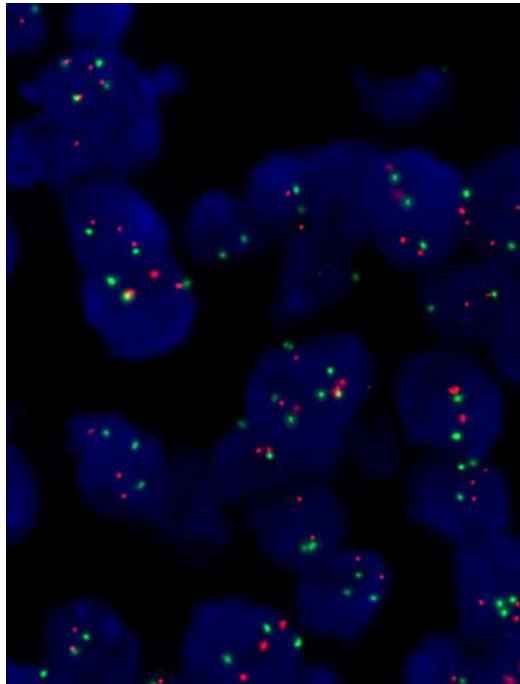
■ DNA FISH Workflow



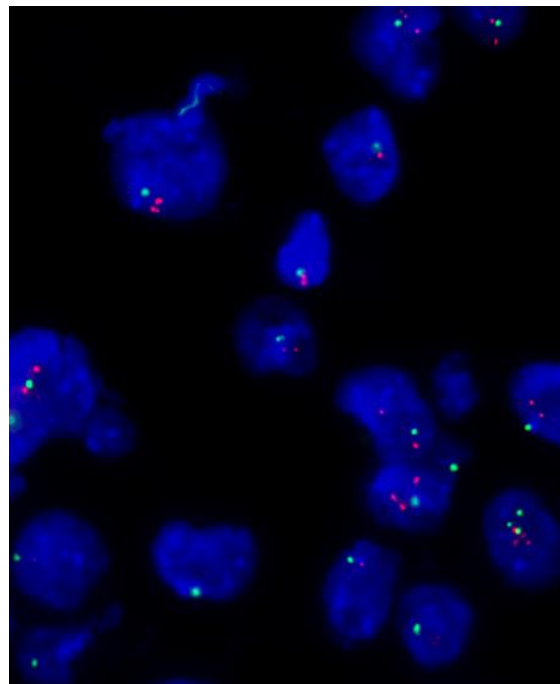
- Counterstain with DAPI, slides reading is performed using fluorescence microscope (oil lens, 1000x).

HER2 FISH on FFPE slides, 1000x

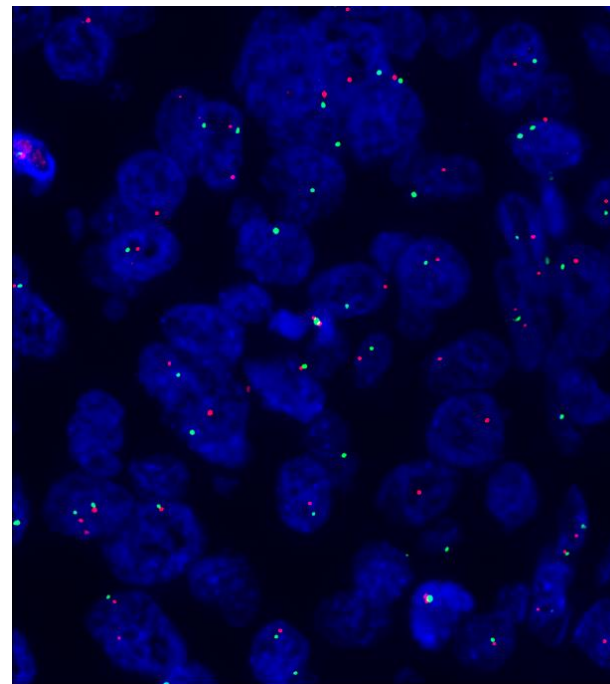
HER2/CEP 17



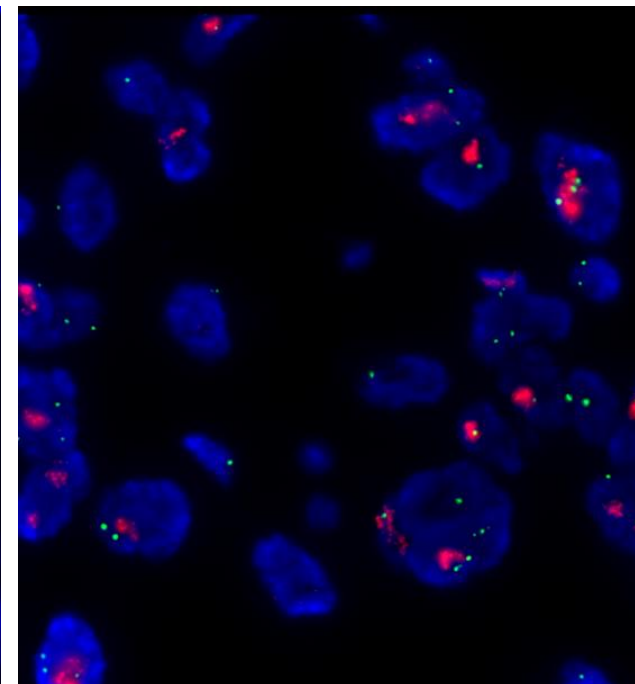
A: HER2 FISH negative control cell



B: HER2 FISH cut-off control cell



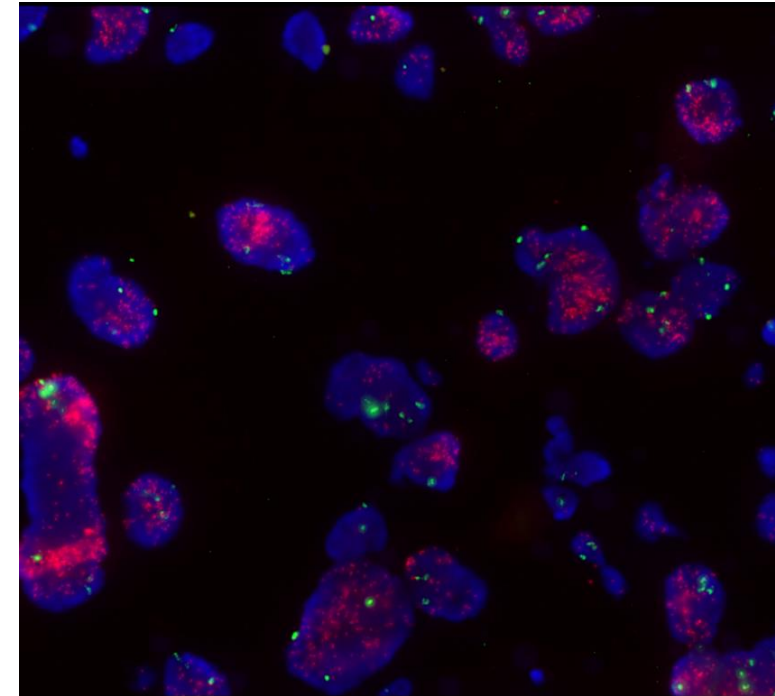
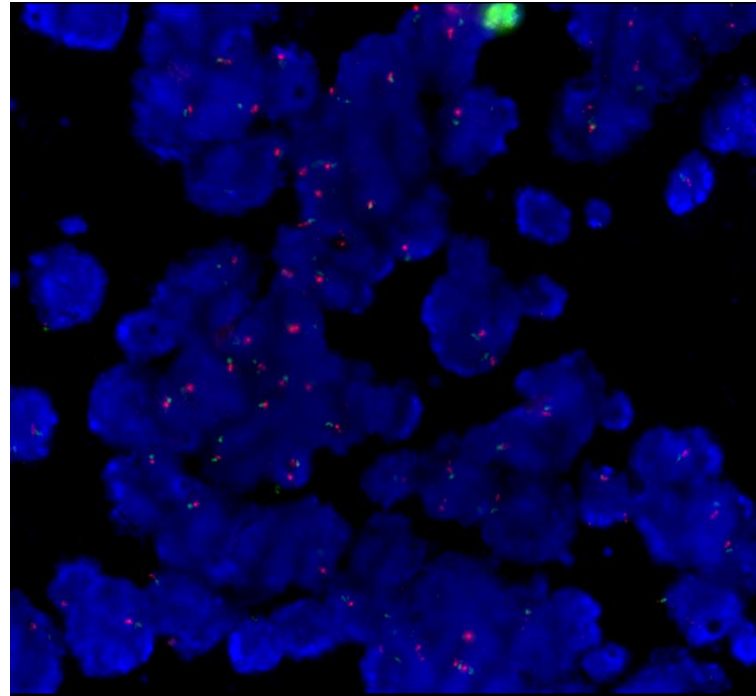
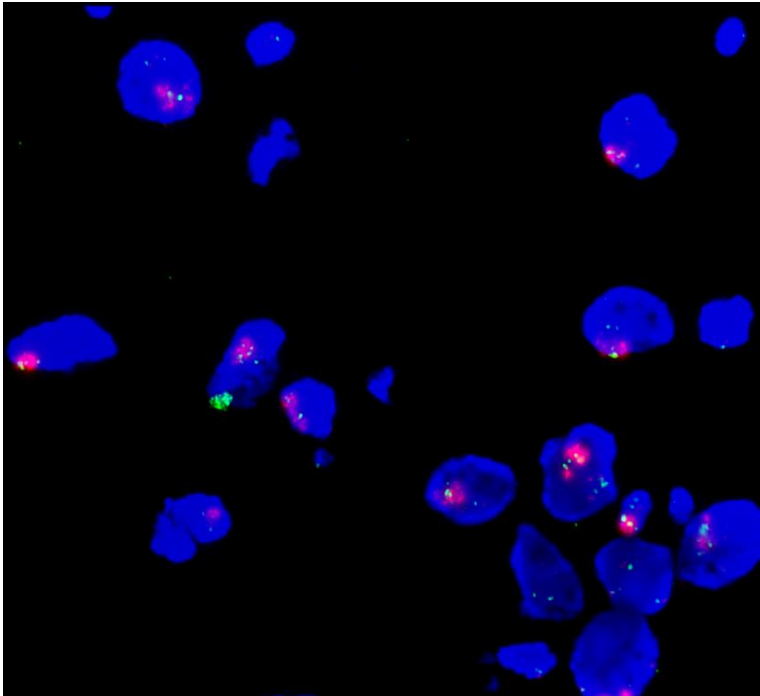
C: HER2 FISH negative case, breast cancer.



D: HER2 FISH positive case, breast cancer.

EGFR FISH on FFPE slides, 1000x

EGFR/CEP 7

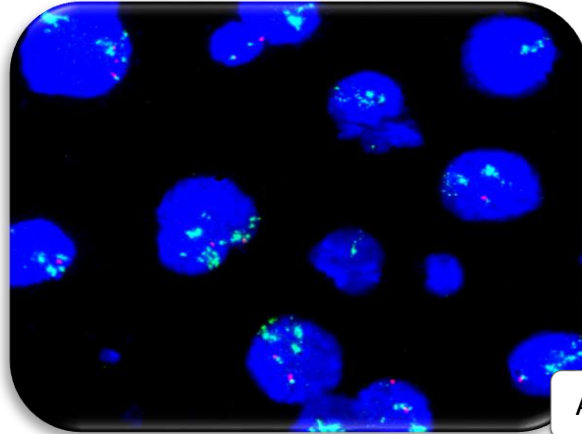


A: EGFR FISH on cells with amplification. B: EGFR FISH negative case, GBM.

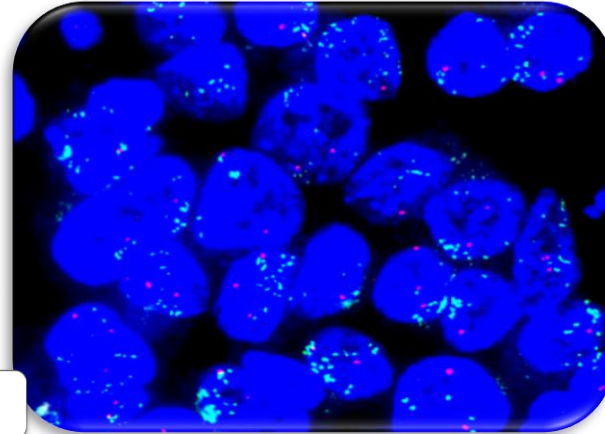
C: EGFR FISH amplified case, GBM.

FISH on FFPE slides, 1000x

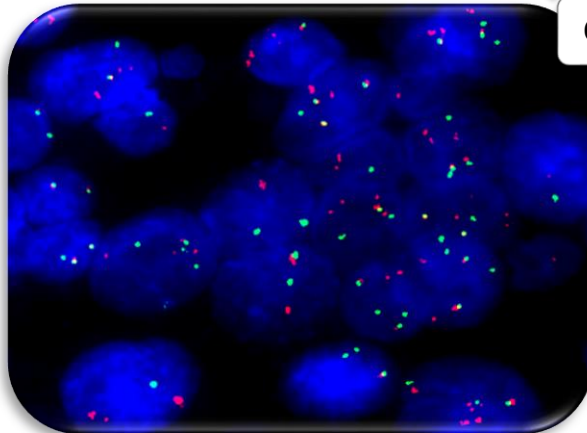
A: FGFR1 amplified,
FGFR1 and CEP 8



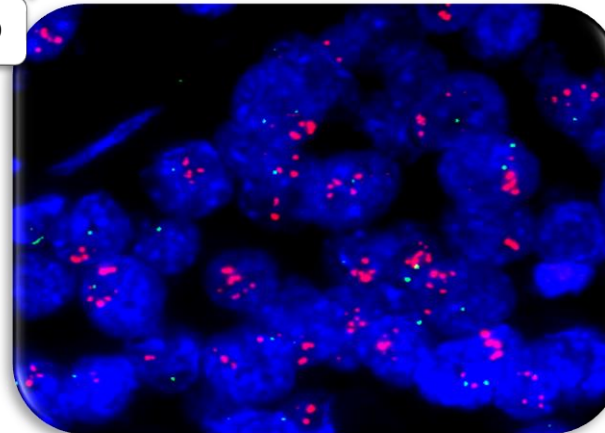
B: MET amplified,
MET and CEP 7



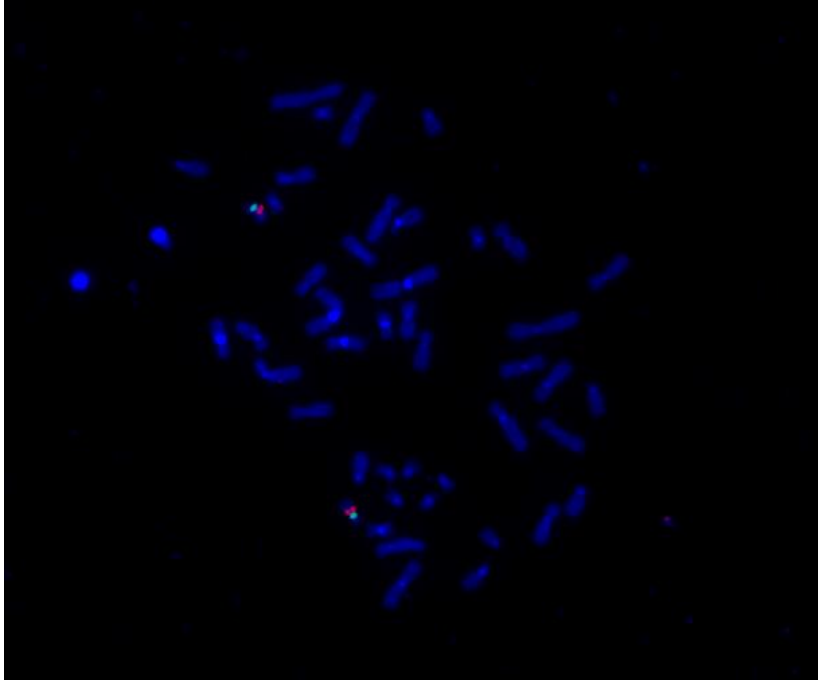
C: ALK rearrangement,
split 3'-ALK and 5'-ALK



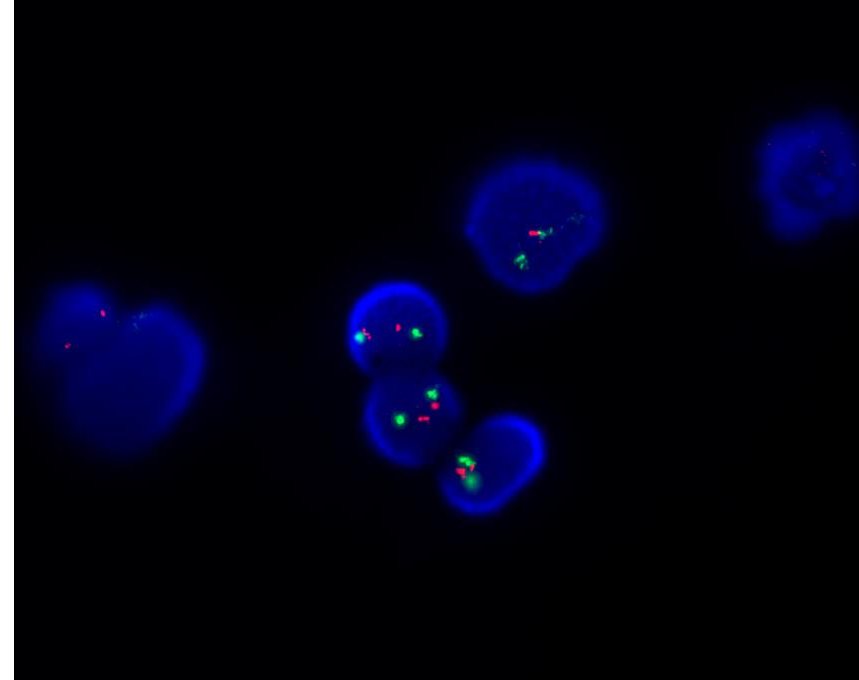
D: HER2 amplified,
HER2 and CEP 17



FISH on blood samples (or bone marrow)



A: **HER2** localization on chromosome 17(**CEP 17**) in metaphase cell.



B: FISH assay performed in interphase cell on blood sample. HER2 negative case, show **HER2** signals and **CEP 17** signals.



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