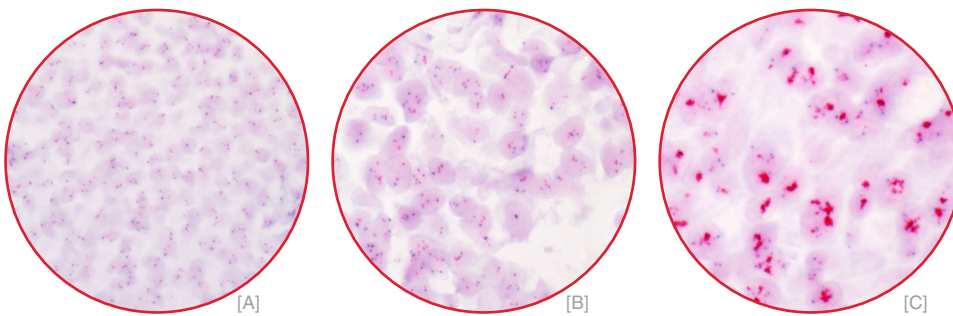


**PHARMACODIAGNOSTIC®**
**HER2 CISH pharmDx™ Kit**

Combining convenience of bright field microscopy with accuracy of FISH


 Examples of *HER2* CISH pharmDx™ Kit stained breast cancer tissue specimens with A) non-amplified, B) polyploid, C) amplified *HER2* gene status.

**HER2 CISH pharmDx™ Kit provides all you need to perform 20 CISH assays**
**Chromogenic dual color visualization on one slide**

- Distinguishes true gene amplifications from aneuploidy or polyploidy
- Eases scoring by having CEN-17 and *HER2* gene stained on the same slide
- Reduces scoring time by approximately 25% compared to FISH

**Preservation of morphology**

- Enables fast and easy identification of invasive tissue as well as surrounding non-tumor tissue

**Archivable stains**

- Provides the opportunity to archive and re-evaluate

**Interpretation by bright field microscopy**

- Eliminates the need for fluorescence microscopy equipment and training

With a **97.7% FISH concordance**  
 Dako lets you put patient safety first

 Overall agreement:  $(342/350 \times 100) = 97.7\%$  (CI95: 95.7%; 98.9%)

		HER2 PathVysion FISH status		Total
		non-amplified	amplified	
HER2 CISH pharmDx™ status	non-amplified	302	4	306
	amplified	4	40	44
Total		306	44	350

**Table summarizes findings from the concordance study**

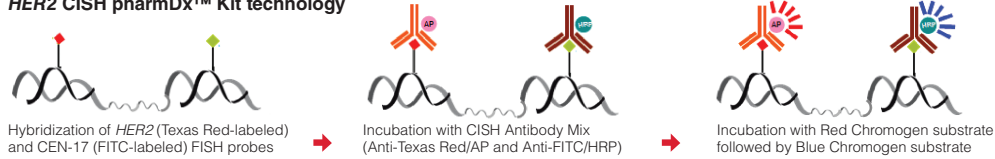
The clinical utility of *HER2* CISH pharmDx™ Kit was investigated in a clinical study comprising 365 (350 eligible for statistical analysis) invasive breast cancer specimens analyzed by *HER2* CISH pharmDx™ Kit and PathVysion *HER-2* DNA Probe Kit (FISH). The overall agreement between *HER2* status obtained was 97.7%. The same study showed 97.9% concordance between Dako *HER2* FISH pharmDx™ Kit and Dako *HER2* CISH pharmDx™ Kit, on 200 specimens (189 eligible for statistical analysis). Results not shown.

*"It is recommended to perform HER2 testing, laboratories show 95% concordance with another validated test for positive and negative assay values."*

J Clin Oncol 2007; 25:118-45.

**FROM CERTAINTY COMES TRUST**

**HER2 CISH pharmDx™ Kit technology**



*HER2* CISH pharmDx™ Kit is a direct dual-color chromogenic in situ hybridization (CISH) assay designed to quantitatively determine *HER2* gene amplification in formalin-fixed, paraffin-embedded (FFPE)

breast cancer tissue specimens. *HER2* CISH pharmDx™ Kit generates red (*HER2*) and blue (CEN-17) chromogenic signals on the same tissue section for evaluation by bright field microscopy.

**HER2 CISH pharmDx™ Kit includes**

- \_\_\_\_\_ Pretreatment Solution
- \_\_\_\_\_ Pepsin (Ready-to-Use)
- \_\_\_\_\_ *HER2*/CEN-17 Probe Mix (Ready-to-Use)
- \_\_\_\_\_ Stringent Wash Buffer
- \_\_\_\_\_ Wash Buffer I & II
- \_\_\_\_\_ Peroxidase Block (Ready-to-Use)
- \_\_\_\_\_ CISH Antibody Mix (Ready-to-Use)
- \_\_\_\_\_ Red & Blue Substrate Buffer
- \_\_\_\_\_ Red & Blue Chromogen
- \_\_\_\_\_ Mounting Medium (Ready-to-Use)
- \_\_\_\_\_ Coverslip Sealant (Ready-to-Use)
- \_\_\_\_\_ User-fillable Bottles



**Specifications**

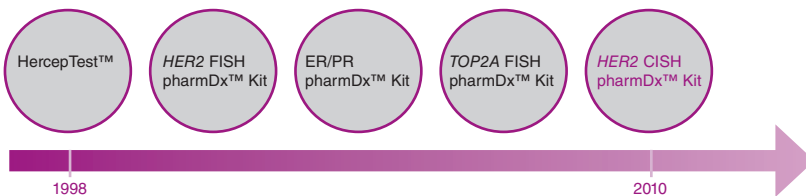
Product Code	SK109
Package Size	20 tests
Expiry	10 months

**Dako's pharmDx™ is all about personalized medicine**

The advantages of using the Dako pharmDx™ *HER2* product range for treatment selection include:

- Validated assay
- Reliable assay performance
- Optimal diagnostic result
- Proven outcome

**Dako's expanding pharmDx™ breast cancer diagnostic portfolio**



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