MOLECULAR DIAGNOSTICS

PATHVYSION

SUPPORTING MILLIONS OF DECISIONS, LIVES AND HER STORIES

ABBOTT DELIVERS TRUSTED HER-2 SOLUTIONS

HER-2 status assessment is the standard of care in the selection of therapy in invasive breast cancer.[1,2] It is a well-established, strong and independent predictor of prognosis and disease-free progression. Accurate evaluation of HER-2 status is important in selecting appropriate therapy, including trastuzumab treatment.[2–4]

The PathVysion HER-2 test enables the assessment of a patient's HER-2 status at the DNA level with a high degree of accuracy and helps guide doctors to make the most appropriate therapy decisions based on a patient's own genetic profile.[5]

THE VALUE OF DNA-BASED TESTING

Tests for HER-2 status usually measure either gene copy number or presence of protein receptors. Immunohistochemistry (IHC) is used to measure the HER-2 protein in the tissue, whereas FISH detects the HER-2 gene copy number in the cell nucleus.[2]

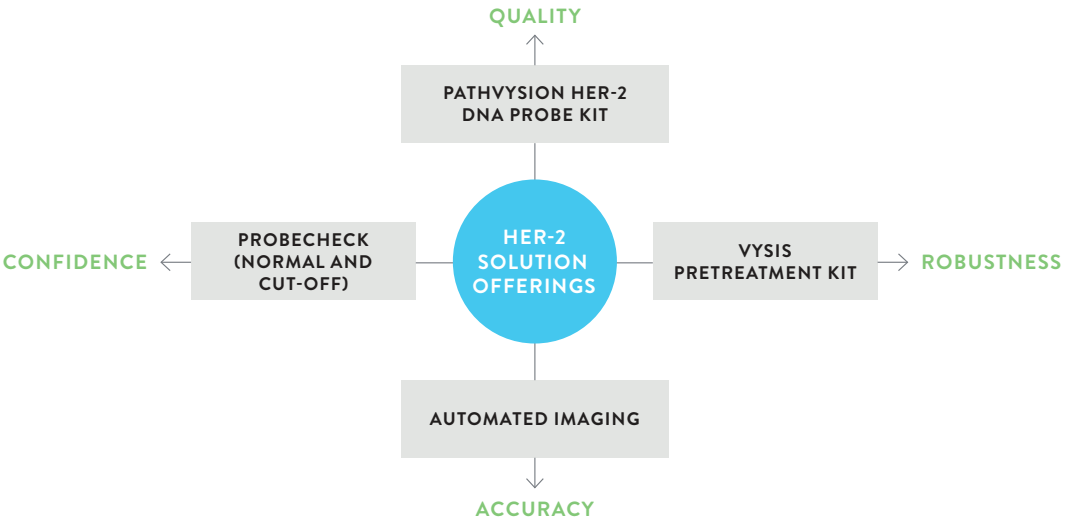
Direct FISH is a very sensitive method that yields highly accurate, reliable and reproducible results simply from counting the number of fluorescent signals. FISH technology targets stable DNA at a molecular level within FFPE specimens, thereby overcoming possible misclassifications associated with IHC, which can still be used in conjunction with FISH.

The PathVysion HER-2 DNA Probe Kit utilizes direct labeled FISH DNA probes to yield definitive results of HER-2 status evaluation, at the molecular level.

Intended Use[6]

The PathVysion HER-2 DNA Probe Kit (PathVysion Kit) is designed to detect amplification of the HER-2/*neu* gene via fluorescence in situ hybridization (FISH) in formalin-fixed, paraffin-embedded human breast cancer tissue specimens. Results from the PathVysion Kit are intended for use as an adjunct to existing clinical and pathologic information currently used as prognostic factors in stage II, node-positive breast cancer patients. The PathVysion Kit is further indicated as an aid to predict disease-free and overall survival in patients with stage II, node-positive breast cancer treated with adjuvant cyclophosphamide, doxorubicin and 5-fluorouracil (CAF) chemotherapy.[3]

HER-2 RELIABLE RESULTS



ORDERING INFORMATION

LIST NUMBER	PRODUCT NAME	QUANTITY
02J01-030	PathVysion HER-2 DNA Probe Kit	20 assays
02J01-035	PathVysion HER-2 DNA Probe Kit	50 assays
02J01-036	PathVysion HER-2 DNA Probe Kit	100 assays
02J05-030	ProbeChek HER-2 Normal Control Slides	5 slides
02J04-030	ProbeChek HER-2 Cutoff Control Slides	5 slides
02J02-032	Vysis Paraffin Pretreatment Reagent Kit	1 kit

Limitations of the Procedure[6]

1. The PathVysion Kit has been optimized only for identifying and quantifying chromosome 17 and the HER-2/*neu* gene in interphase nuclei from formalin-fixed, paraffin-embedded human breast tissue specimens. Other types of specimens or fixatives should not be used.
2. The performance of the PathVysion Kit was validated using the procedures provided in the package insert only. Modifications to these procedures may alter the performance of the assay.
3. Performance characteristics of the PathVysion Kit have been established only for node positive patients receiving the designated regimens of CAF and for metastatic breast cancer patients being considered for HERCEPTIN therapy. Performance with other treatment regimens has not been established.
4. The clinical interpretation of any test results should be evaluated within the context of the patient's medical history and other diagnostic laboratory test results.
5. FISH assay results may not be informative if the specimen quality and/or specimen slide preparation is inadequate.
6. Technologists performing the FISH signal enumeration must be capable of visually distinguishing between the orange and green signals.

JOIN ABBOTT IN RAISING AWARENESS OF BREAST CANCER.
ENCOURAGE HOPE. SCREEN. DIAGNOSE.

FOR MORE INFORMATION ON PATHVYSION, PLEASE VISIT THE SITE OR CONTACT YOUR LOCAL ABBOTT REPRESENTATIVE

REFERENCES

1. Mansfield, Aaron S, "Comparison of Fluorescence In Situ Hybridization (FISH) and Dual-ISH (DISH) in the Determination of HER-2 Status in Breast Cancer," *Anatomic Pathology*, vol. 139, pp. 144–150, 2013.c **2.** American Cancer Society website accessed www.cancer.org/cancer/types/breast-cancer/understanding-a-breast-cancer-diagnosis/breast-cancer-her2-status.html. **3.** Cho, Soo Youn, "Standardized pathology report for breast cancer," *Journal of Pathology and Translational Medicine*, pp. 1–15, 2021. **4.** Nicolini, Andrea, "Prognostic and predictive biomarkers in breast cancer: Past, present and future," *Seminars in Cancer Biology*, pp. 56–73, 2018. **5.** Rimawi, Mothaffar F., "Targeting HER-2 for the Treatment of Breast Cancer," *Annu. Rev. Med.*, vol. 66, pp. 111–128, 2015. **6.** Abbott, PathVysion HER-2 DNA Probe Kit Product Insert,30-608377/R9.

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