



The DirectHit™ Test Panel for Breast Cancer Fact Sheet

CCC Diagnostics, LLC has developed the DirectHit Test Panel for Breast Cancer to assist physicians in designing personalized treatment regimens for breast cancer patients. DirectHit can predict a tumor's response to four distinct, commonly prescribed treatment classes (8 drugs) with a high degree of accuracy. The drugs and their respective Drug Response Indicators (DRI) are: 5-FU, capecitabine/thymidylate synthase, docetaxel, paclitaxel, abraxane /beta-tubulin isoform III, trastuzumab/Her-2, antiestrogens /estrogen receptor. When used in combination with standard measurements, DirectHit allows physicians to avoid ineffective treatments.

Technology

DirectHit is a diagnostic service that quantitatively measures Drug Response Indicator (DRI) expression levels in formalin fixed, paraffin embedded tumor tissue. DRI quantitation in > 500 tumor cells is based on fluorescent dye-labeled monoclonal antibody staining, followed by analysis of digital images using computer-assisted microscopy that is calibrated to an external standard. Standardization to an external reference allows a high degree of inter-observer and inter-instrumentation reproducibility.

DirectHit Advantage

- Has quick turnaround time.
- Helps physician create individualized treatment plan.
- Lessens exposure to ineffective drug treatments.
- Reduces potential for side effects.
- Saves money.
- Improves quality of life.
- Approved by Medicare, Blue Cross, Blue Shield and others.

Clinical Validation

- DirectHit analysis of ER displays higher accuracy (91%) than immunochemistry (67%).
- DirectHit displays exceptional predictive accuracy for chemotherapy response (86%).
- DirectHit predictive accuracy (87%) outperforms SOC treatment success (73%).
- DirectHit displays a high degree of diagnostic performance (sensitivity 0.99, positive predictive value 0.86, and negative predictive value 0.92).
- DirectHit accurately identifies both effective and ineffective treatments.

Clinical Partners: University of Maryland, Harbor Hospital, Walter Reed, Zhangzhou Hospital.

Contact

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