



DirectHit™ Test Panel for Breast Cancer

A Personalized Approach to Anticancer Therapy



cccdiag.com

CCC Diagnostics

- Our mission: To create innovative approaches to cancer disease management by integrating discoveries diagnostic, therapeutic and information technologies.
- CCC Diagnostics was founded in 2004 by a group of former researchers at Johns Hopkins University, including the late Dr. Paul Ts'o, former Director of Biophysics Div. Of JHU School of Public Health.

THE CHALLENGE

- Current treatments... 30-50% effective
- Significant side effects
- Annual costs can exceed \$30,000 per patient
- Effective treatment relies on drug selection
- No way to select personalized chemotherapy

CURRENT TESTING LANDSCAPE

- Routine testing IHC/FISH
 - ER / PR ⇨ Hormonal therapy
 - Her-2 ⇨ Trastuzumab
- Oncotype Dx
 - Recurrence after surgery
- Mammaprint / TargetPrint
 - Recurrence after surgery
 - ER/PR/HER-2 status

No tests available to determine best chemotherapy regimen

THE SOLUTION

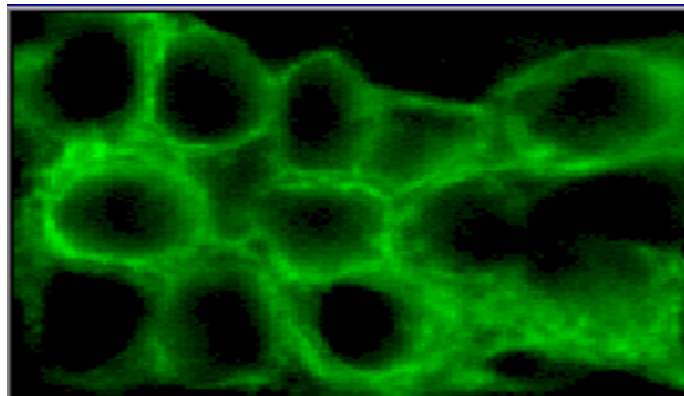
DirectHit™ Test Panel for Breast Cancer

- Diagnostic service for individual patients
- Predicts response to chemotherapy/hormonal drugs
- Excludes ineffective drug treatments
- Enables personalized treatment selection



DirectHit™ Technology

- Microscopy based computerized fluorescence
- Simultaneous analysis of 4 biomarker classes
- Correlates biomarker expression with clinical response

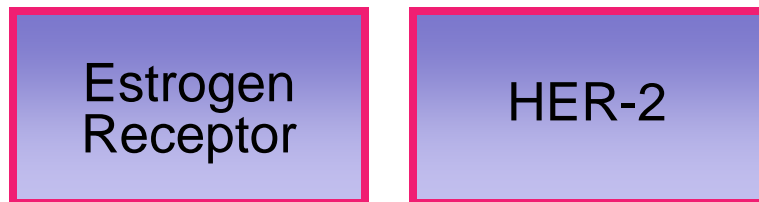


Cytokeratin stain

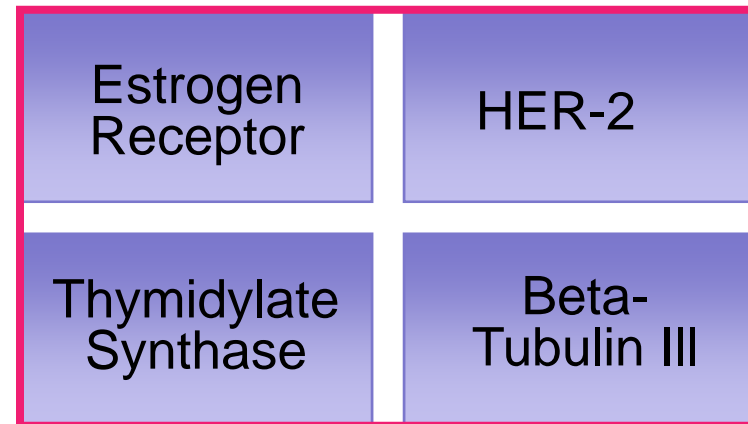
DirectHit™ Test Panel for Breast Cancer

- DirectHit™ is a Test Panel - includes in one test:
 - ER, HER-2
 - Biomarkers for commonly used chemotherapy drugs

IHC/FISH



DirectHit™ Test Panel





DirectHit™ Biomarkers

- Drugs - FDA approved, NCCN recommended
- Clinical literature support links drug and biomarkers

| DRUG | BIOMARKERS |
|--------------------------|--------------------------|
| Antiestrogens | Estrogen Receptor |
| Taxanes/ Vinca Alkaloids | Beta-Tubulin III |
| 5 FU/ Capecitabine | Thymidylate Synthase |
| Trastuzumab | HER-2/neu |
| Gemcitabine* | Ribonucleotide Reductase |
| Anthracyclines * | Topoisomerase IIa |
| Platinum Drugs* | ERCC-1 |

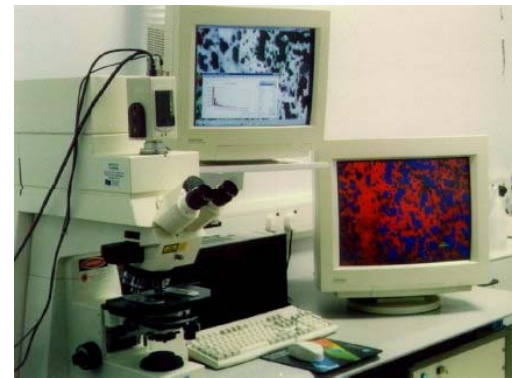
* DirectHit™ assays in development

DirectHit™ Methods

1. Slide Processing



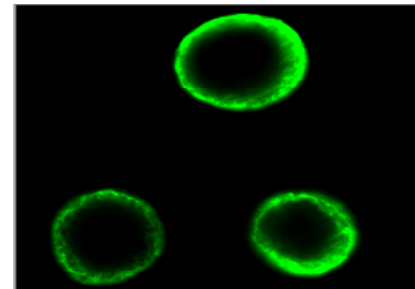
2. Imaging



4. DRI Expression



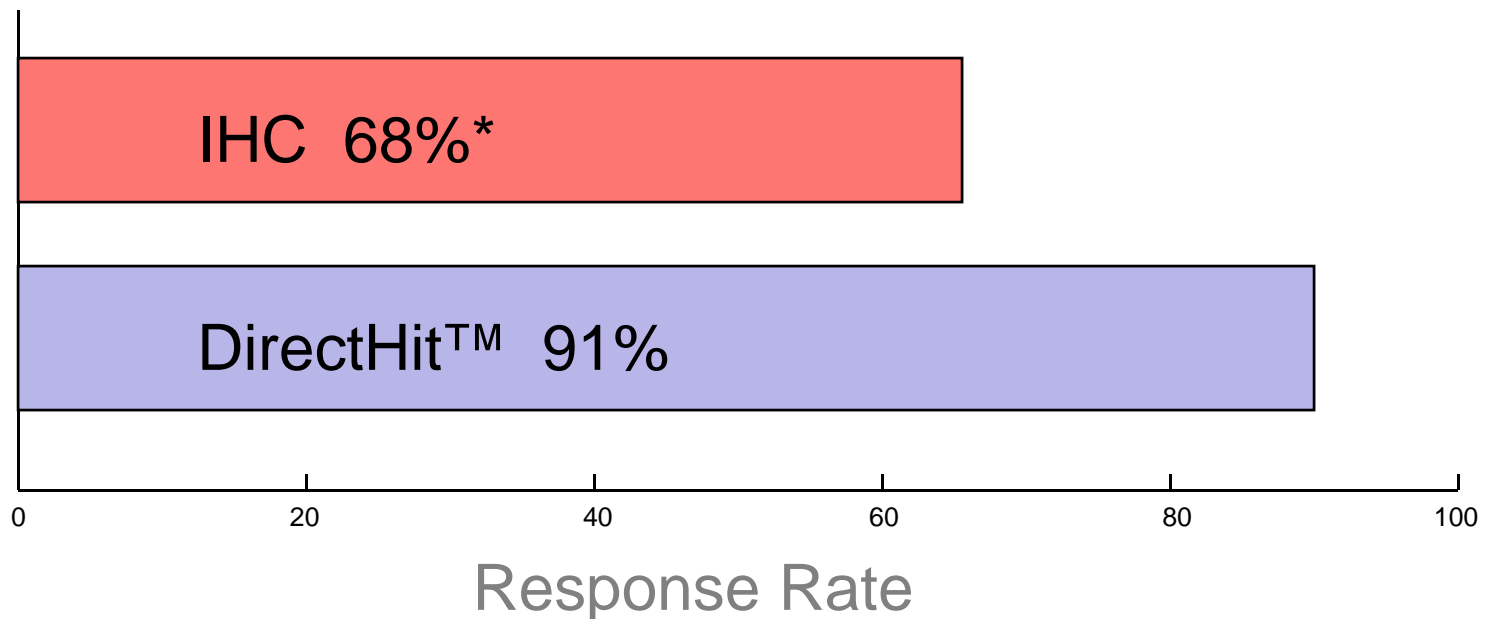
3. Cancer Cell ID



DirectHit™ Prediction Accuracy

Hormonal Treatment

DirectHit™ is more accurate than standard methods

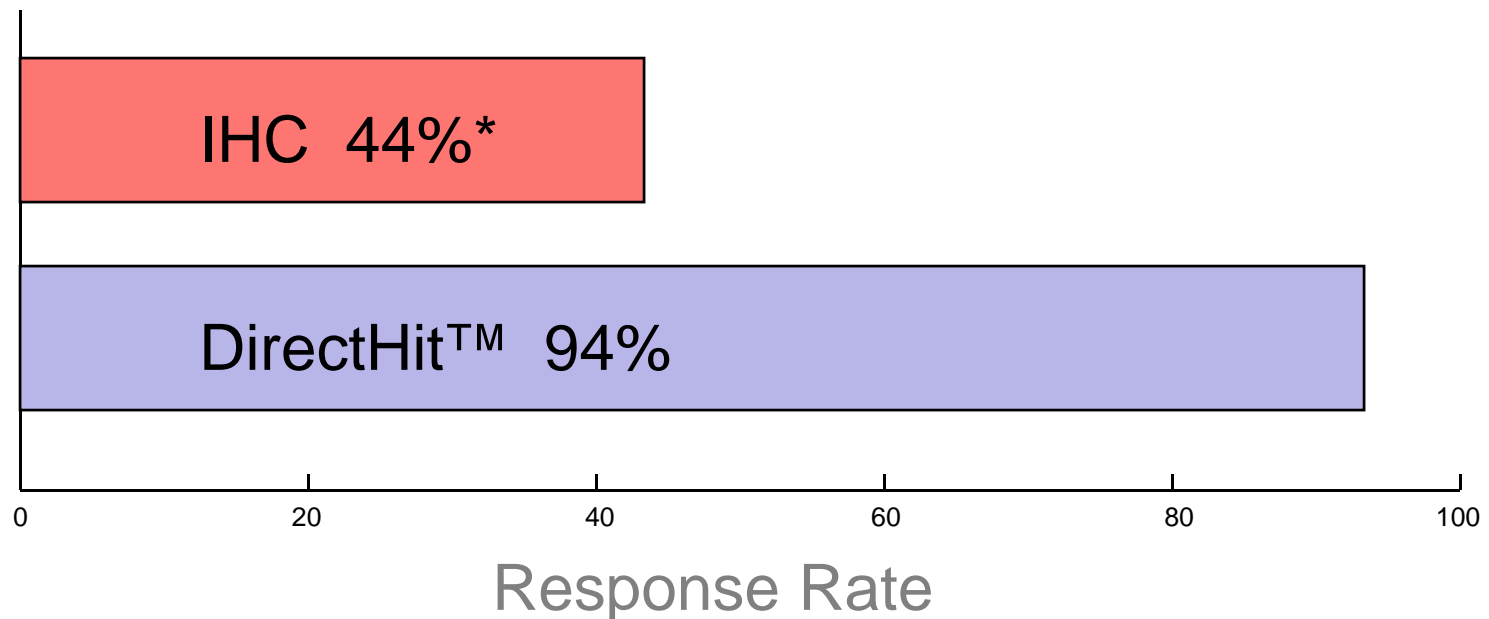


* Based on ongoing retrospective clinical trials

DirectHit™ Prediction Accuracy

Trastuzumab Treatment

DirectHit™ is more accurate than standard methods



* Based on ongoing retrospective clinical trials

DirectHit™ Prediction Accuracy

Chemotherapy

DirectHit™ accurately predicts response to chemotherapy



DirectHit™ Results Summary

- High degree ER measurement accuracy
- Accurate chemotherapy response
- Able to identify ineffective treatments

| Drug Class | Biomarker | Other Tests Response Rate | DirectHit Response Rate |
|-----------------------------|-------------------------|---------------------------|-------------------------|
| Anti-estrogens | Estrogen Receptor | 60-70% * | 91% |
| Trastuzumab | HER-2/neu | 35% * | 94% |
| Taxanes/ Vinca Alkaloids | beta-tubulin III | Not available | 86% |
| 5FU/Xeloda | Thymidylate Synthase | Not available | 78% |

* Based on ongoing retrospective clinical trials

DirectHit™ Test Panel for Breast Cancer

Cost Savings

- Single drug treatment - Taxotere
- Assumption = 50% efficacy
- Drug Cost / 100 patients = \$ 1.75 M
- Drug Savings / 50 resistant patients = \$878,850


 DirectHit™ Test Panel for Breast Cancer

Benefits for Patients

DirectHit™ as a Diagnostic Service will:

- Individualize anticancer therapy selection
- Lessen exposure to ineffective therapies
- Reduce potential side effects
- Save significant treatment costs
- Improve quality of life

THE FUTURE

- Expanded breast cancer biomarker selection
- Expanded health insurance coverage
- Extension of DirectHit™ platform to GI cancer
 - Retrospective Trials in progress
 - Commonly used chemotherapy drugs
 - Preliminary Results = 85% predictive accuracy