

## DirectHit™ Test Panel for Breast Cancer Test Results Report

### Drug Response Indicator Test

#### Patient Information

Patient First Name + Middle initial:	Patient Last Name:	
Patient ID #: (From submission site):	CCCD Accession No:	
Date of birth:	CCCD Confirmation No:	
Gender:	Test Schedule Date:	
Ordering Physician:	Sample Receipt Date/Time:	
Submitting Pathologist:	Report Date:	
CCCD Account No.	Report Recipient Name:	
QC Certification - Initials/Date:	Report Delivery Address:	
	Second recipient: Name/address:	

#### Patient Results

No.	Drug	Drug Response Indicator (DRI)	DRI Expression Level in Tumor Sections Drug Response Indicator Units (DRIU)			
			Mean	Std Dev	Low	High
1	Antiestrogens	Estrogen Receptor				
2	Taxanes/Vinca Alkaloids	Beta Tubulin III				
3	5-FU/Xeloda	Thymidylate Synthase				
4	Trastuzumab	HER-2/neu				
5	Anthracyclines	Topoisomerase II $\alpha$				
6	Gemcitabine	Ribonucleotide Reductase				

No.	DRUG	DRUG RESPONSE INDICATOR (DRI)	RECOMMENDATION FOR PRESCRIPTION		CLINICAL POPULATION STUDY DISTRIBUTION	
			Anticancer Drug Regimen		Responsive	Nonresponsive
			Recommended	Not Recommended		
1	Antiestrogens	Estrogen Receptor			22.9 $\pm$ 11.8	In Progress
2	Taxanes/Vinca Alkaloids	Beta Tubulin III			24.9 $\pm$ 18.2	In Progress
3	5-FU/Xeloda	Thymidylate Synthase			12.5 $\pm$ 5.0	In Progress
4	Trastuzumab	HER-2/neu			39.1 $\pm$ 8.0	3.4 $\pm$ 1.7
5	Anthracyclines	Topoisomerase II $\alpha$	Correlation Study in Progress			
6	Gemcitabine	Ribonucleotide Reductase				

#### Result Definition

Recommended—The DRI values strongly suggest sensitivity to the specified drug. Treatment using the drug regimen is recommended.

Not Recommended—The DRI values strongly suggest a lack of sensitivity to the specified drug. Treatment using the drug regimen is not recommended.

#### Assay Description

The DirectHit™ Panel for Breast Cancer is a diagnostic service that quantitatively measures Drug Response Indicator (DRI) expression levels in formalin fixed, paraffin embedded tumor tissue. DRI quantitation is based on fluorescent dye-labeled monoclonal antibody staining, followed by quantitative analysis of digital images using computer-assisted microscopy. Results are expressed in Drug Response Indicator Units (DRIU's), which correlate to the number of fluorescent units/pixel. The predictive accuracy of DirectHit was determined to be 87% in retrospective clinical trials. The tumor sections used by DirectHit are obtained from surgical samples. The DRI expression level in a tumor may be affected if there was drug treatment prior to removal of the tumor.

David A. Van Echo, M.D. \_\_\_\_\_ Date: \_\_\_\_\_

Laboratory Director

This test was developed and its performance characteristics determined by CCC Diagnostics, LLC. It has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance is not necessary. Test results should be interpreted in the context of additional clinical and/or histopathological findings. This test is used for clinical purposes and should not be regarded as investigational or for research. How this information is used to guide patient care is the responsibility of the physician.