

CLIA ID # 99D1030993

CAP ID # 7186701

Patient : Patient X

Collected : 04/29/2010

Date of birth : 12/19/1949

Received : 04/30/2010

Specimen ID : HP10-2281

Physician : Karl Rogers

Specimen type : Abdominal mass

Institution : Baptist Hospital

### Clinical

60-year-old male with a diagnosis of possible adenocarcinoma. First presentation, no prior chemotherapy.

### Recommendation

Based on the results of the MiCK assay the patient should benefit most from a regimen of Taxol with either cisplatin or carboplatin.

### MiCK Assay Results

Drug tested	Max. Resp. (KU)	Resp. level
Taxol	4.6	Moderate
Cisplatin	2.9	Low to moderate
Carboplatin	2.9	
Doxorubicin	2.9	
Oxaliplatin	2.6	
Taxotere	1.9	Low
Epirubicin	1.9	
Etoposide	1.4	
4HC(cytoxan)	1.4	
Abraxane	1.3	
Gleevec(imatinib)	1.0	
Bleomycin	1.0	
Gemcitabine	1.0	
4HI(ifosfamide)	0.6	Nonsensitive
5-Fluorouracil	0.0	
Methotrexate	0.0	

### Interpretation

Tumor of unknown primary biopsy:

1. A population of cells with morphological features of an epithelial malignancy is present.
2. In the MiCK assay, the patient's tumor cells were most sensitive to the single agent taxol, giving 4.6KU of apoptosis.
3. Based on the MICK assay the extent of the response was consistent with moderate sensitivity of the tumor to this single agent.
4. Responses to carboplatin (2.9KU), cisplatin (2.9KU), and doxorubicin (2.9KU) were slightly lower but still moderately effective. Other reagents were consistent with even lower sensitivity to these reagents.
5. The Table and Graph below show all reagents tested, their concentrations, and the MICK assay results.

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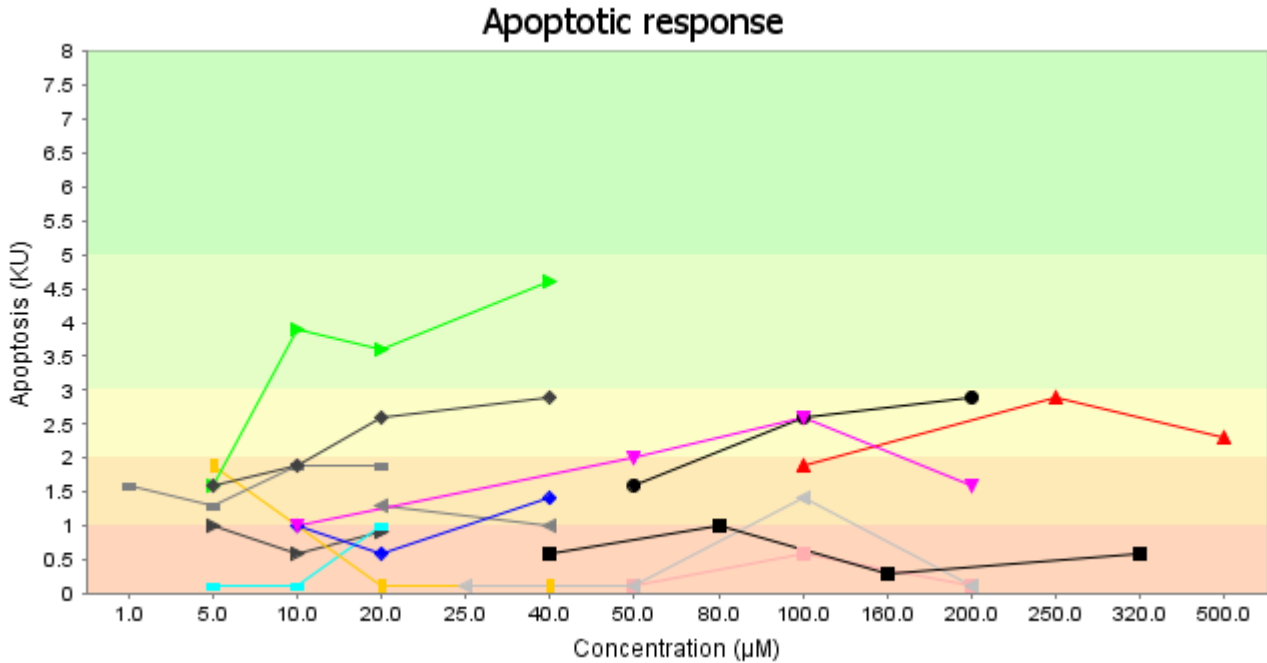
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<b>Legend: ND: data not displayed NS: not sensitive</b>					
▲ Taxol	4.6	■ Epirubicin	1.9	■ Gemcitabine	1.0
● Cisplatin	2.9	● Etoposide	1.4	■ 4HI(ifosfamide)	0.8
▲ Carboplatin	2.9	▲ 4HC(cytosan)	1.4	ND 5-Fluorouracil	0.0
● Doxorubicin	2.9	▲ Abraxane	1.3	ND Methotrexate	0.0
▼ Oxaliplatin	2.6	▲ Gleevec(imatinib)	1.0		
■ Taxotere	1.9	■ Bleomycin	1.0		

## Comments

Viable neoplastic cells collected from the specimen were tested for their sensitivity to requested single agents at three concentrations each.

Of note, the alkylating agent Cytosan requires hepatic metabolic transformation to the active metabolite, 4HC, and therefore cannot be tested directly in vitro. For the MICK assay the active metabolite, 4HC, was used.

The MICK assay identifies chemotherapy reagents that are most effective in killing malignant cells by inducing apoptosis, it specifically identifies and quantitates apoptotic cells. In this study, taxol was most effective in inducing apoptosis causing 4.6KU maximal response. Carboplatin, cisplatin, and doxorubicin also gave results which are consistent with moderate sensitivity of the tumor cells to these reagents. Of note, a response of between 3.0 and

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5.0KU is consistent with a moderate drug sensitivity and has previously been associated with a partial clinical response to chemotherapy. Other tested reagents induced lower levels of apoptosis. All tested chemotherapy reagents induced apoptosis in appropriate control cell lines.

### Microscopic/Immunophenotypic studies

The Wright stained cytospin preparations contain a population of malignant cells which are intermediate to large in size and have abundant cytoplasm. Cytoplasmic secretory material is not visible by H&E stain. Nuclei are generally single, large, and have an irregular outline. Hyperchromasia is only moderate. Nucleoli tend to be prominent.

The report was faxed to Dr.Roger's office on 5-3-2010.

Attending pathologist

Medical Director

DiaTech Oncology, LLC

Electronically signed on 10-11-2011

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The pathologist's signature on this report indicates that the case was personally reviewed and the findings confirmed by the attending pathologist. This test was performed at DiaTech Clinical Pathology Laboratory. This laboratory is certified under CAP and CLIA-88 and is qualified to perform high complexity clinical testings. The MiCK assay measures drug induced apoptosis and its performance characteristics were determined at Vanderbilt University and at DiaTech Oncology. Clinical use of the MiCK assay is based on a statistically significant increase in CR rate and overall survival of AML patients whose treatment protocol included a drug to which the patient's tumor cells were sensitive in the assay. When used with solid tumors, the MiCK assay is expected to identify drugs most effective in killing patient's tumor cells by apoptosis. This test has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such approval was not required.

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