

CLIA ID # 99D1030993

CAP ID # 7186701

Patient : Patient X

Collected : 08/05/2010

Date of birth : 07/09/1933

Received : 08/06/2010

Specimen ID : HP10-2480

Physician : Dr. X

Specimen type : Lymph node

Institution : Hospital X

### Clinical

77 years-old male with a diagnosis of lung cancer since 07/2010. First presentation.

### Recommendation

Based on the results of the MiCK assay Taxotere should be in the chemotherapy regimen for the patient, perhaps in combination with cisplatin which also showed significant activity against the tumor. Unfortunately, the lack of sufficient cells did not allow for the testing of this combination looking for synergy between them.

### MiCK Assay Results

Drug tested	Max. Resp. (KU)	Resp. level
Taxotere	4.63	Moderate
4HC(cytoxan)	3.32	
Cisplatin	2.67	Low to Moderate
Taxol	2.31	
Vinorelbine	1.96	Low
Etoposide	1.66	
Carboplatin	1.66	
Abraxane	1.37	
5-Fluorouracil	1.3	
Alimta	1.3	
Gemcitabine	1.3	
Methotrexate	0.98	Nonsensitive

### Interpretation

Primary lung carcinoma, metastatic to a lymph node:

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 Taxotere, 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. Cytoxa (4HC) also gave a moderate response of 3.3KU.
4. Responses to other reagents were consistent with 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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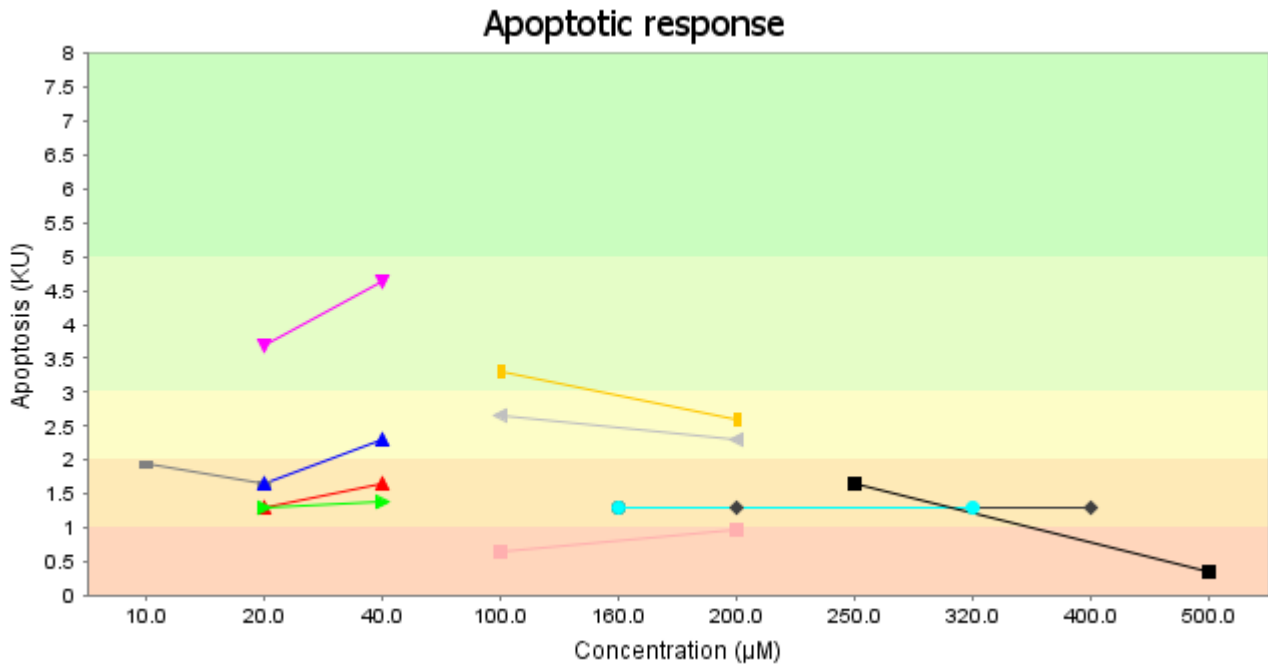
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**Legend: NS: data not shown**

◆ Taxotere	4.63	■ Vinorelbine	1.96	■ 5-Fluorouracil	1.3
■ 4HC(cytoxan)	3.32	▲ Etoposide	1.66	◆ Alimta	1.3
▲ Cisplatin	2.67	■ Carboplatin	1.66	● Gemcitabine	1.3
▲ Taxol	2.31	▶ Abraxane	1.37	■ Methotrexate	0.98

## Comments

A limited number of viable neoplastic cells were collected from the specimen and tested for their sensitivity to most of the requested drugs at two concentrations of each. Of note, the alkylating agent cytoxan requires hepatic metabolic transformation to the active metabolite, 4HC, and therefore cannot be tested directly invitro. 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, Taxotere was most effective in inducing apoptosis causing 4.6KU maximal response, Cytosin (4HC) was slightly lower with 3.3KU. Both of these results are consistent with moderate sensitivity of the tumor cells to these drugs. Of note, a response of between 3.0 and 5.0KU is consistent with a moderate drug sensitivity and has previously been associated with at least 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.

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### Microscopic/Immunophenotypic studies

The H&E stained cytospin preparation contain a near pure population of malignant epithelioid cells with prominent anisocytosis and generally abundant cytoplasm. An occasion cell is noted to have vacuoles suggesting that this is an adenocarcinoma. Nuclei are obviously enlarged and are hyperchromatic with prominent nucleoli. Binucleate cells are readily identified. Immunocytochemistry were not performed in order to conserve cells for the assay. Final viability of the cell solution was 92%.

The report was faxed to Dr.X 's office on 8-9-2010.

Attending pathologist  
DiaTech Oncology, LLC  
514-389-5372 office

Electronically signed on 08/09/2010

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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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