DiaTech Oncology
Patient Specific Cancer Testing

SAMPLE REPORT

CLIA ID # 99D1030993

CAP ID # 7186701

Patient : Patient X

Date of birth : 01/01/1930

Specimen ID : HP10-2520

Specimen type : Fluid

Collected : 01/01/2010

Received : 01/02/2010

Physician : Dr. X

Institution : Walter Reed Army

Clinical

Female with a diagnosis of non-small cell lung cancer stage IV since 04/2004, currently in relapse. Prior chemotherapy with carboplatin+paclitaxel, gefitinib, pemetrexed, erlotinib, vinorelbine, AV951. Resulted in partial response with carboplatin+paclitaxel.

Recommendation

Based on the results of the MiCK assay the drug regimen of choice is cisplatin with Taxol in maximum tolerable dose. The response curve (number of KUs obtained) increased with increasing well concentration of drugs. A synergistic relationship was noted with the two drugs in that neither drug alone was particularly effective against the tumor cells but in combination showed to be highly effect.

Should the cisplatin be too toxic for the patient, the single drugs Taxol, doxorubicin and Abraxane as well as the combination of Taxol with Alimta gave slightly lower KU values but would still be expected to give a reasonable clinical response.

MiCK Assay Results

Drug tested	Max. Resp. (KU)	Resp. level
Cisplatin+Taxol	5.16	Sensitive
Taxol+Alimta	4.49	Moderate
Doxorubicin	4.18	
Taxol	4.16	
Abraxane	3.91	
Cisplatin+Vinorelbine	2.83	Low to Moderate
Cisplatin+Gemcitabine	2.83	
Taxotere	2.67	
Epirubicin	2.66	
Tarceva	2.5	
Vinorelbine	2.36	
Cisplatin+Alimta	2.33	
Carboplatin+Taxol	2.16	
Topotecan	2.13	
Cisplatin+Taxotere	2.05	
Vinblastine	1.5	Low
Mitomycin	1.34	

Drug tested	Max. Resp. (KU)	Resp. level
Cisplatin+Etoposide	1.34	Low
Irinotecan	1.33	
Vincristine	1.25	
Cisplatin+Vinblastine	1.17	
Alimta	1.17	
Oxaliplatin	0.88	Nonsensitive
CCNU	0.72	
Velcade	0.69	
Methotrexate	0.53	
5-Fluorouracil	0.53	
Carboplatin	0.33	
Cisplatin	0.03	
4HI(ifosfamide)	0.0	
Gleevec(imatinib)	0.0	
Caelyx(Doxil)	0.0	
Gemcitabine+Alimta	0.0	
Etoposide	0.0	
Gemcitabine	0.0	

Interpretation

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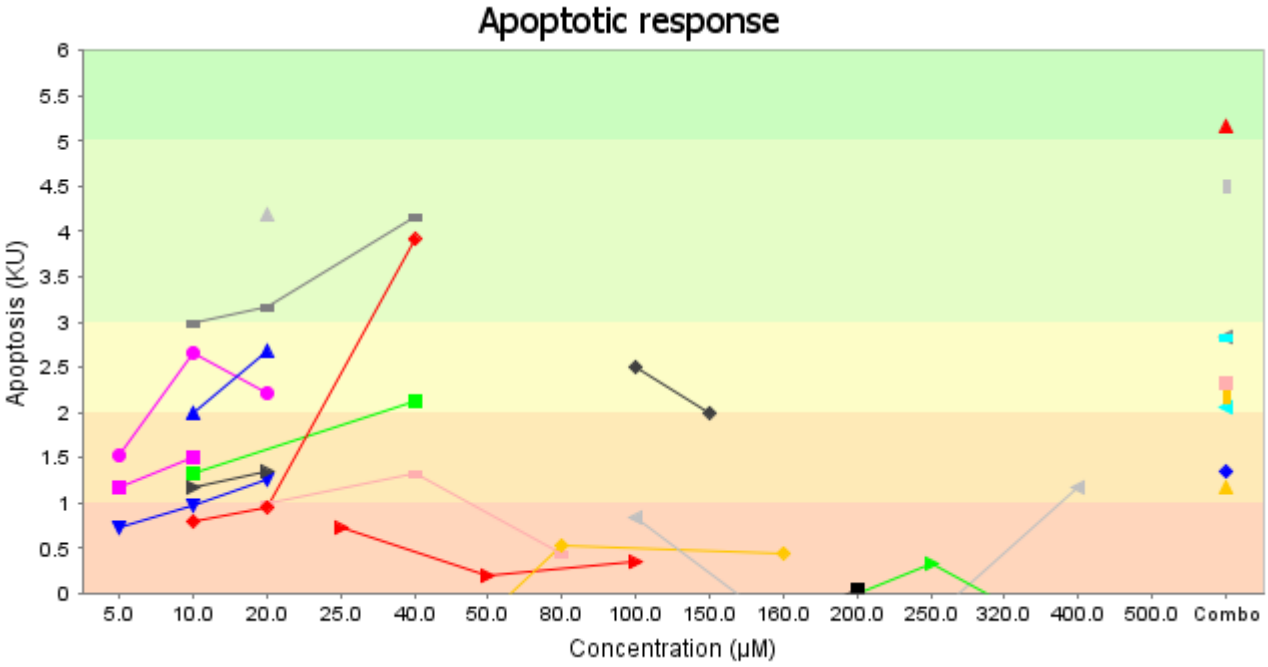
Stage IV Lung Carcinoma, Pleural Effusion:

1. A population of cells with morphological and immunophenotypic features of an epithelial malignancy is present.
2. In the MiCK assay, the patient's tumor cells were most sensitive to the combination of cisplatin with taxol, giving 5.16KU of apoptosis.
3. Based on the MICK assay the extent of the response was consistent with high sensitivity of the tumor to this drug combination.
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.



Legend: NS: data not shown

	Cisplatin+Taxol	5.16		Carboplatin+Taxol	2.16	NS	Velcade	0.69
	Taxol+Alimta	4.49		Topotecan	2.13	NS	Methotrexate	0.53
	Doxorubicin	4.18		Cisplatin+Taxotere	2.05		5-Fluorouracil	0.53
	Taxol	4.16		Vinblastine	1.5		Carboplatin	0.33
	Abraxane	3.91		Mitomycin	1.34		Cisplatin	0.03
	Cisplatin+Vinorelbine	2.83		Cisplatin+Etoposide	1.34	NS	4HI(ifosfamide)	0.0
	Cisplatin+Gemcitabine	2.83		Irinotecan	1.33	NS	Gleevec(imatinib)	0.0
	Taxotere	2.67		Vincristine	1.25	NS	Caelyx(Doxil)	0.0
	Epirubicin	2.66		Cisplatin+Vinblastine	1.17	NS	Gemcitabine+Alimta	0.0
	Tarceva	2.5		Alimta	1.17	NS	Etoposide	0.0
NS	Vinorelbine	2.36	NS	Oxaliplatin	0.88	NS	Gemcitabine	0.0
	Cisplatin+Alimta	2.33		CCNU	0.72			

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Comments

Viable neoplastic cells collected from the specimen were tested for their sensitivity to multiple single drugs and drug combinations at multiple concentrations. Since so many cells were isolated from the effusion we were able to test not only the requested drugs but also NCCN drugs.

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, the combination of cisplatin and taxol was most effective in inducing apoptosis causing 5.16KU maximal response which is consistent with high sensitivity of the tumor cells to this drug combination. Of note, a response of greater than 5.0KU is consistent with a high drug sensitivity and has previously been associated with a good 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 preparation contains a population of malignant cells which are CK, CK7, TTF-1 positive and CK20 negative. The initial viability was 80%.

The report was faxed to Dr. X's office on 01-05-2010.

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

Electronically signed on 01/05/2010