DiaTech Oncology
Patient Specific Cancer Testing

CLIA ID # 99D1030993 CAP ID # #7186701

Patient: [redacted]
Date of Birth: [redacted]
Specimen ID: [redacted]
Specimen Type: [redacted]

Collected: [redacted]
Received: [redacted]
Physician: [redacted]
Institution: [redacted]

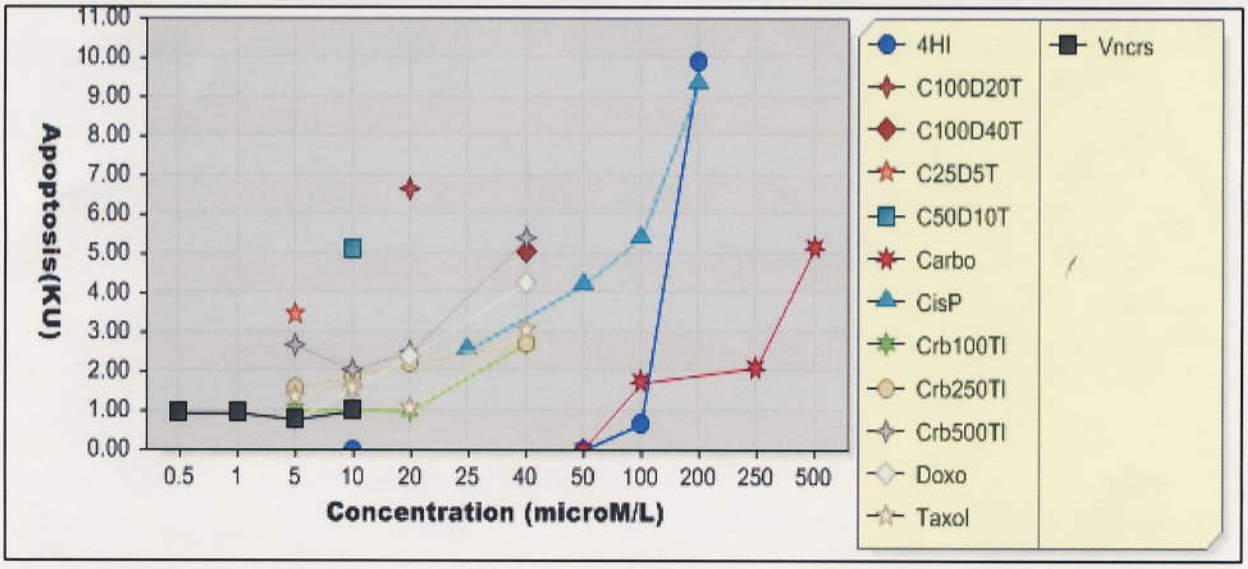
Clinical
46-year-old female with a recent diagnosis of endometrial cancer, first presentation, no prior chemotherapy.

INTERPRETATION:

Endometrial tissue biopsy:
1. A population of cells with morphological and immunocytochemical features consistent with an epithelial neoplasm is present(see comment).
2. In the MiCK assay, the patient's tumor cells were highly sensitive to multiple drug combinations as well as single agents. The tumor cells were most sensitive to cytoxan (4HI) and cisplatin(see comment).
3. Extent of the response to cytoxan and cisplatin, as single agents, was consistent with a high sensitivity of the tumor cells to these compounds (see comment).
4. Responses to other tested, tested as the three drug combinations requested, were consistent with lower sensitivity of the patient's tumor cells to these compounds(see comment).

Maximum Apoptotic Response (Kinetic Units):

4HI	CisP	C100D20T	Crb500TI	Carbo	C50D10T	C100D40T	Doxo	C25D5T	Taxol	Crb100TI	Crb250TI
9.89	9.34	6.63	5.36	5.14	5.08	5.03	4.25	3.43	3.04	2.71	2.71



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Patient Specific Cancer Testing

CLIA ID # 99D1030993 CAP ID # #7186701

Patient: [redacted] Collected: 09/09/2008
Date of Birth: [redacted] Received: 09/10/2008
Specimen ID: [redacted] Physician [redacted]
Specimen Type: [redacted] Institution [redacted]

COMMENT:

Viable neoplastic cells collected from the specimen were tested for their sensitivity to multiple doses of single agents and drug combinations as requested per schedule.

The MiCK assay identifies drugs most effective in killing patient's tumor cells by apoptosis. Extent of drug-induced apoptosis is measured in Kinetic Units (KU). In this study, single agents cytoxan(as the active metabolite 4HI) and cisplatin were the most effective inducers of apoptosis causing 9.89 and 9.34KU maximal response respectively, consistent with a high degree of sensitivity of the tumor cells to these single compounds. Of note, responses greater than 5KU are consistent with a high drug sensitivity of tumor cells and have been previously seen in patients with a good clinical response to chemotherapy.

Responses to combinations of cisplatin, doxil, and taxol also gave readings consistent with a response rate but not as high as the single agent cytoxan and cisplatin.

Single agents doxorubicin and taxol and the combination of carboplatin&taxol gave a moderate(3-5KU)degreee of apoptosis.

A table in the "Interpretation" section shows maximal apoptotic responses achieved with each of the tested agents and combinations of agents.

In conclusion, results of this study would support including cisplatin and cytoxan, as single agents, in the treatment protocol if clinically indicated. Triple drug combinations of cisplatin, doxil, and taxol also gave high readings of induced apoptosis.

All tested chemotherapeutic agents induced apoptosis in a control cell line.

MICROSCOPIC/IMMUNOPHENOTYPIC STUDIES:

Wright stained cytospin preparations of the disaggregated tissue showed relatively uniform cells and clusters of cells. Individual cells had a very high N/C ratio with only a modest amount of cytoplasm. Nuclei were single, had coarse chromatin, and frquently had multiple small nucleoli. Tumor cells were panCK and Ca125 positive. Approxamamtely 20% of the cells were Ki67 positive.

The report was faxed to Dr. Holmesley 9/16/08.

AE Hallquist MD
Medical Director
514-398-5372 office
Electronically signed on 09/17/2008

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.