DiaTech Oncology
Patient Specific Cancer Testing

CLIA ID # 99D1030993 CAP ID # #7186701

Patient: [redacted] Collected: [redacted]
Date of Birth: [redacted] Received: [redacted]
Specimen ID: [redacted] Physician: [redacted]
Specimen Type: [redacted] Institution: [redacted]

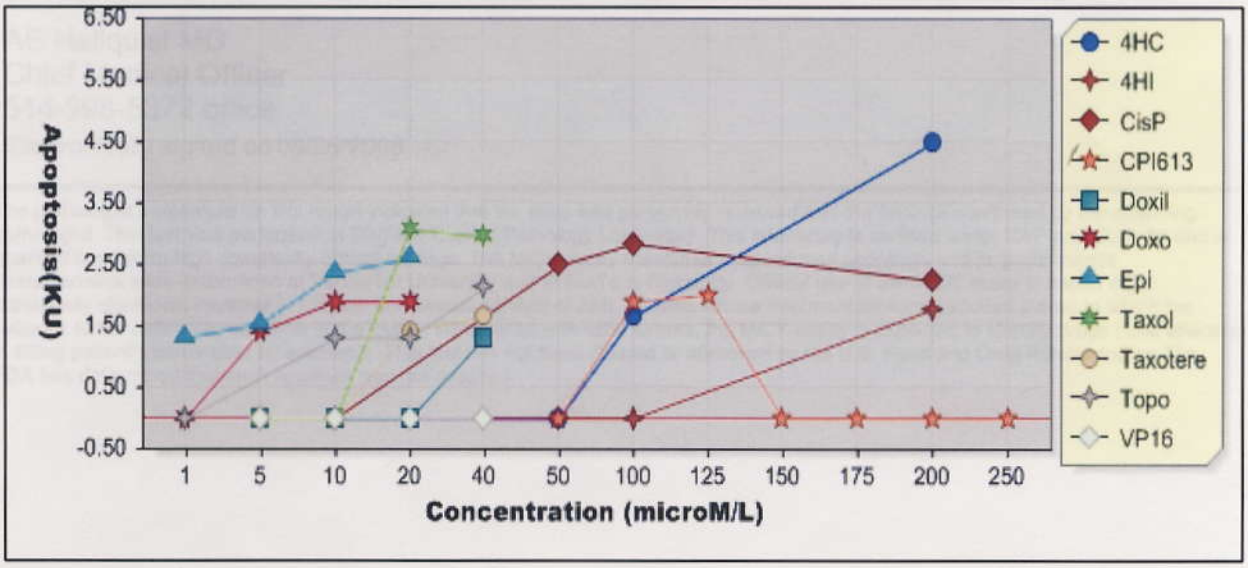
Clinical
81-year-old female with a diagnosis of endometrial cancer since 04/2008, first presentation, no prior chemotherapy.

INTERPRETATION:

Biopsy tissue:
1. Population of cells with morphological and immunocytochemical features consistent with an epithelial neoplasm is identified (see comment).
2. In the MiCK assay, the patient's tumor cells were most sensitive to Cytoxan(4HC) (see comment).
3. Extent of the response to Cytoxan was consistent with a moderate sensitivity (4.48KU) of the tumor cells to this compound (see comment).
4. The response to taxol, although lower than that seen with Cytoxan(4HC) were also in the moderate range(3.06KU).
5)Responses to Cispatin(2.83KU), Epirubicin(2.59KU),topotecan(2.12KU),and CPI613 (2.00KU) were in the low moderate range.
5. Other tested agents were consistent with lower sensitivity of the patient's tumor cells to these compounds (see comment).

Maximum Apoptotic Response (Kinetic Units):

4HC	Taxol	CisP	Epi	Topo	CPI613	Doxo	4HI	Taxotere	Doxil	VP16
4.48	3.06	2.83	2.59	2.12	2.00	1.89	1.77	1.65	1.30	0.00



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COMMENT:

Viable neoplastic cells collected from the specimen were tested for their sensitivity to multiple doses of the chemotherapeutic reagents listed below. A moderate level of sensitivity was shown by the tumor cells to Cytoxan, Taxol, Cisplatin, Epirubicin, Topotecan, as well as CPI613. This would suggest a significant response by the patient to these drugs. A lesser response was seen with the reagents listed. This would suggest a modest response by the tumor to these reagents.

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 agent Taxotere was the most effective inducer of apoptosis causing 2.86 KU maximal response, consistent with borderline moderate to moderately low sensitivity of the tumor cells to this compound. Of note, responses from 3 to 5 KU are consistent with a moderate drug sensitivity of tumor cells and have been previously seen in patients with partial clinical response to chemotherapy.

In conclusion, results of this study would support including Cytoxan, Taxol, Cisplatin, Epirubicin, (CPI613), and Topotecan in the patient's therapeutic regimen. Other reagents are predicted to be less successful.

MICROSCOPIC/IMMUNOPHENOTYPIC STUDIES:

Wright stained cytospin preparations of the disaggregated tissue showed predominantly large sized atypical epithelioid cells with deeply basophilic cytoplasm, nuclear irregularities, bi-nucleation, and prominent nucleoli, located singly and in small aggregates. ICC studies showed these atypical cells were positive for cytokeratin and negative for calretinin. a moderate number of the atypical cells expressed nuclear Ki-67. These findings are consistent with involvement by a malignant neoplasm of epithelial origin.
Wright

AE Hallquist MD
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Electronically signed on 08/26/2008

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.