

CAP ID # 7186701

CLIA ID # 99D1030993

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SAMPLE REPORT

Clinical:

73-year-old female with a diagnosis of breast cancer since 2006, currently in relapse. Prior chemotherapy with Cytoxan, Taxol and 5-FU.

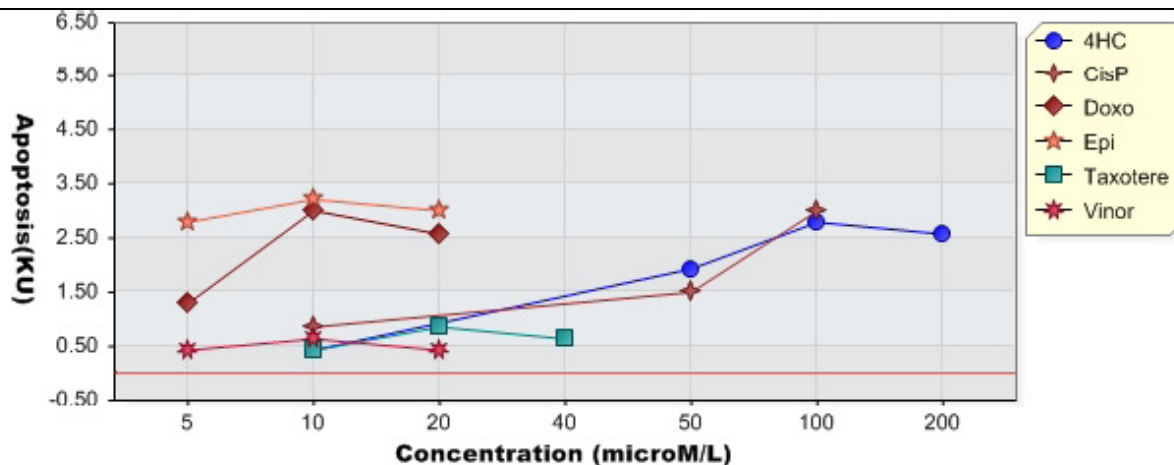
INTERPRETATION:

Lymph node, site not specified, biopsy:

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 Epirubicin (see comment).
3. Extent of the response to Epirubicin was consistent with a moderate sensitivity of the tumor cells to this compound (see comment).
4. Responses to other tested agents were consistent with lower sensitivity of the patient's tumor cells to these compounds (see comment).

Maximum Apoptotic Response (Kinetic Units):

Epi	CisP	Doxo	4HC	Taxotere	Vinor
3.21	3.00	3.00	2.79	0.86	0.64



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COMMENT:

The number of viable neoplastic cells collected from the specimen was sufficient for testing their sensitivity to multiple doses of Cytoxan(4HC), Cisplatin(CisP), Doxorubicin(Doxo), Epirubicin(Epi), Taxotere and Vinorelbine(Vinor) as single agents. Of note, alkylating agent Cyclofosfamide (Cytoxan) requires metabolic transformation by hepatocytes and, thus, cannot be tested in vitro. Synthetic active metabolite of Cyclofosfamide (4HC) was used in this study.

The MiCK assay identifies drugs that are 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 Epirubicin was the most effective inducer of apoptosis causing 3.21KU maximal response. Of note, responses from 3 to 5 KU are consistent with a moderate drug sensitivity of tumor cells and have been seen in patients with partial clinical response to chemotherapy. Responses to Cisplatin and Doxorubicin were consistent with a borderline moderate to moderately low sensitivity of the tumor cells to these agents. Response to Cytoxan (4HC) was consistent with a moderately low sensitivity of the tumor cells to this agent. Neither Taxotere nor Vinorelbine induced any significant apoptosis in the patient's tumor cells. A table in the "Interpretation" section shows maximal apoptotic responses achieved with each of the tested agents.

In conclusion, results of this study would support including Epirubicin in the treatment protocol if clinically indicated. Combinations of Epirubicin/Cisplatin or Epirubicin/Cytoxan could also be considered.

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

MICROSCOPIC/IMMUNOPHENOTYPIC STUDIES:

Wright stained cytospin preparations of the disaggregated tissue showed predominantly large sized atypical epithelioid cells with deeply basophilic cytoplasm and nuclear irregularities, located singly and in small aggregates. ICC studies showed these atypical cells were positive for cytokeratin. Approximately 20-25% atypical cells expressed nuclear Ki-67.

The report was faxed to Doctor on 00/00/0000.

Attending Pathologist
Phone: 123-456-7890

Electronically signed on 00/00/0000

R.Garry Latimer
CEO
Office:615-377-9668
Toll free: 1-877-434-2832
Fax: 615-221-4387
rglatimer@diatech-oncology.com

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.