

CAP ID # 7186701  
CLIA ID # 99D1030993  
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## SAMPLE REPORT

**Clinical:**

60-year-old male diagnosed with non-small cell lung cancer with bone, liver and CNS metastasis, Stage IV, since 06/2006. Previous chemotherapy included Taxol, Carboplatin, Taxotere and Alimta. Response to Alimta. Most recent chemotherapy was 3 weeks ago.

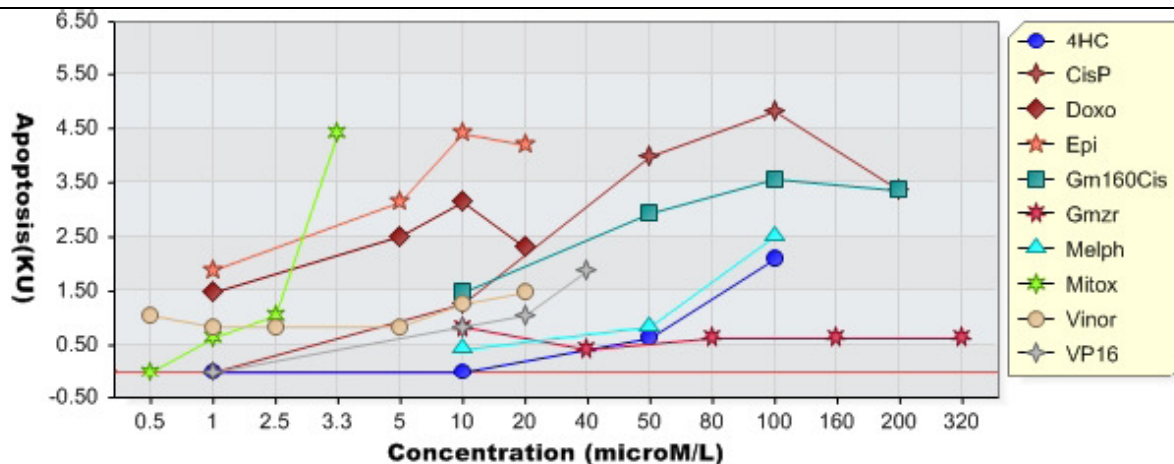
**INTERPRETATION:**

Pleural effusion, drainage:

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

**Maximum Apoptotic Response (Kinetic Units):**

CisP	Epi	Mitox	Gm160 Cis	Doxo	Melph	4HC	VP16	Vinor	Gmzr
4.81	4.40	4.40	3.56	3.14	2.51	2.09	1.88	1.47	0.84



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## COMMENT:

Purified viable neoplastic cells were tested for their sensitivity to multiple doses of Cytoxan(4HC), Cisplatin(CisP), Doxorubicin(Doxo), Epirubicin(Epi), Melphalan(Melph), Mitoxantrone(Mitox), Vinorelbine(Vinor), Etoposide(VP16) as single agents, and to a combination of Gemzar/Cisplatin (Gm160Cis). Of note, alkylating agent Cytoxan (Cyclofosfamide) 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 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 Cisplatin was the most effective inducer of apoptosis causing 4.81 KU maximal response. 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. Responses to Mitoxantrone (4.4 KU), Epirubicin (4.4 KU), the combination of Gemzar/Cisplatin (3.56 KU), and Doxorubicin (3.14 KU) also were consistent with a moderate sensitivity of the tumor cells to these compounds. 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 Cisplatin in the treatment protocol if clinically indicated. Combination of Cisplatin with Mitoxantrone or Epirubicin would also be reasonable to consider.

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, nuclear irregularities, increased N:C ratio, located singly and in small aggregates. ICC studies showed these atypical cells were positive for cytokeratin and TTF1, and negative for calretinin. Approximately 60-65% atypical cells expressed nuclear Ki-67. These findings are consistent with involvement by a malignant neoplasm of epithelial origin.

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

Attending Pathologist  
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Electronically signed on 00/00/0000

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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.