

CAP ID # 7186701

CLIA ID # 99D1030993

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## SAMPLE REPORT

### Clinical:

55-year-old male with an history of stage I CLL (1992). Previous chemotherapy included Vincristine, Cytosan/Fludarabine, most recent with Rituxan/Oncovin/Cytosan X 6 and with Fludarabine, then with Adriamycin X 2.

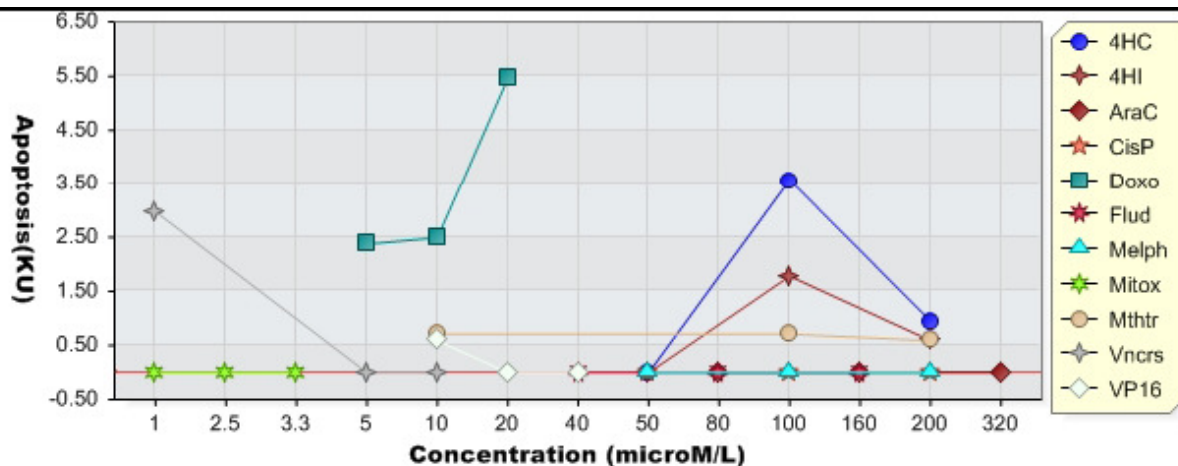
### INTERPRETATION:

Peripheral blood:

1. A population of cytologically normal but immunophenotypically abnormal lambda chain-restricted CD5-positive B lymphocytes identified, consistent with chronic lymphocytic leukemia/small lymphocytic lymphoma is present (as per studies section).
2. In the MiCK assay, the patient's tumor cells were most sensitive to doxorubicin (please see the comment section), showing a high degree of sensitivity.
3. Responses cytosin (tested as the active metabolite 4HC) and vincristine showed a lesser, but still significant, level of induced apoptosis. The response to other tested agents were consistent with lower sensitivity of the patient's neoplastic cells to these compounds (please see the see comment).

### Maximum Apoptotic Response (Kinetic Units):

Doxo	4HC	Vncrs	4HI	Mthtr	VP16	AraC	CisP	Flud	Melph	Mitox
5.46	3.56	2.97	1.78	0.71	0.59	0.00	0.00	0.00	0.00	0.00



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## COMMENT:

Viable neoplastic cells isolated from the peripheral blood specimen were tested for their sensitivity to multiple doses of chemotherapy agents as single agents (as listed in the chart above). The malignant lymphocytes showed the greatest measured apoptosis in response to doxorubicin, 5.46KU which is a high degree of sensitivity. The lymphocytes were less sensitive to cytoxan (tested as the active metabolite 4HC) with 3.56KU and vincristine with 2.97KU of induced apoptosis. These figures are considered to be in the moderate range of sensitivity for the MiCK assay.

The MiCK assay identifies drugs that are most effective in killing patient's tumor cells by apoptosis. The extent of drug-induced apoptosis is measured in Kinetic Units (see table in the "Interpretation" section). In this study, doxorubicin was the most effective inducer of apoptosis causing 5.46KU maximal response. With epithelial malignancies responses greater than 5KU are considered highly sensitive, responses of 3-5KU are considered moderately sensitive. It must be noted that for CLL patients, statistical correlation between the extent of the drug-induced apoptosis and treatment outcome has not been established.

A table in the "Interpretation" section shows maximal apoptotic responses achieved with each agent.

In conclusion, of the tested agents, doxorubicin should be considered for including in the treatment protocol if clinically indicated. Cytoxan and vincristine, although the patient has progressed with prior therapy with these agents, still showed a moderate level of activity. All tested agents induced apoptosis in a control cell line.

## MICROSCOPIC/IMMUNOPHENOTYPIC STUDIES:

Wright stained smears of the peripheral blood showed a low percentage of small, mature appearing lymphocytes in the peripheral blood. A significant population of prolymphocytes and malignant, large lymphocytes was not identified on the smears nor by flow cytometry. Flow cytometric studies identified a low percentage (~38%) population of immunophenotypically abnormal lymphocytes that were CD19 and CD5 positive with lambda light chain restriction. This population of lymphocytes was also ZAP70 positive.

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

Attending Pathologist  
Phone: 123-456-7890

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.