

CAP ID # 7186701
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SAMPLE REPORT

Clinical:

32-year-old male with a diagnosis of acute myeloid leukemia (AML) since 05/02/2006, currently in relapse. Prior induction chemotherapy with Idarubicin and ARA-C resulted in CR.

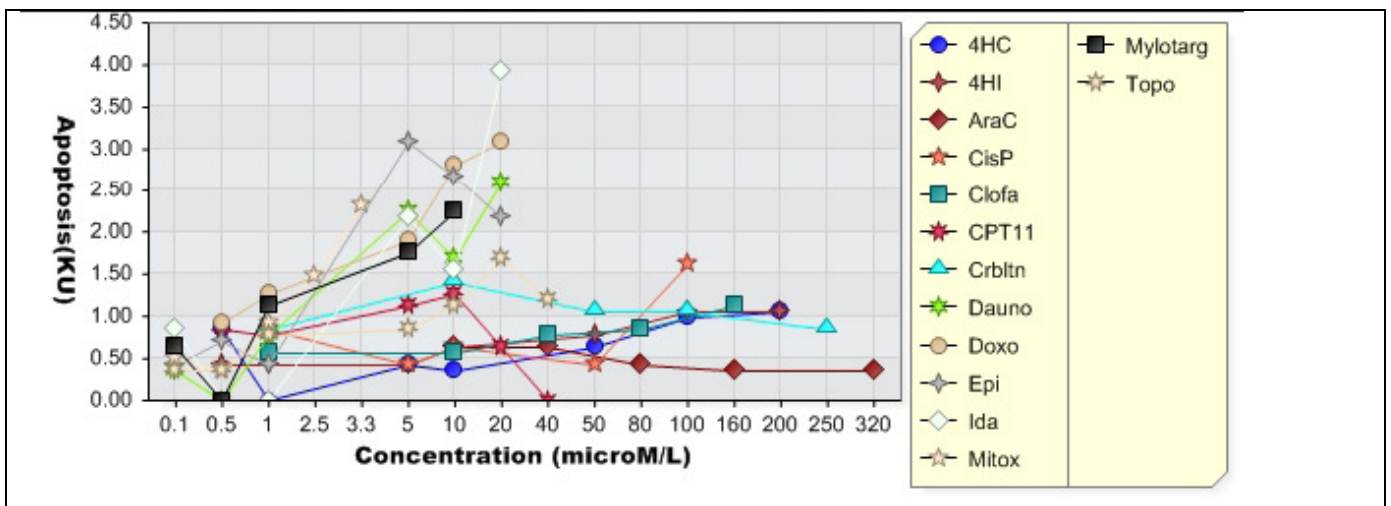
INTERPRETATION:

Bone marrow, aspirate:

1. Population of cells with morphological and immunophenotypic features consistent with abnormal myeloid blasts is identified (see comment).
2. In the MiCK assay, the patient's tumor cells were most sensitive to Idarubicin (see comment).
3. Sensitivity of the patient's tumor cells to drug combinations is being tested and will be reported separately.

Maximum Apoptotic Response (Kinetic Units):

Ida	Doxo	Epi	Dauno	Mitox	Mylot	Topo	CisP	Crbltn	CPT11	Clofa	4HC	4HI	AraC
3.92	3.08	3.08	2.59	2.31	2.24	1.68	1.61	1.40	1.26	1.12	1.05	1.05	0.63



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COMMENT:

Purified viable leukemic blasts were tested for their sensitivity to multiple doses of Cytoxan(4HC), Ifosfamide(4HI), Cytarabine(AraC), Cisplatin(CisP), Clofarabine(Clofa), Irinotecan(CPT11), Daunorubicin(Dauno), Doxorubicin(Doxo), Epirubicin(Epi), Idarubicin(Ids), Melphalan(Melph), Mitoxantrone(Mitox), Topotecan(Topo), Etoposide(VP16) as single agents. Of note, alkylating agents Cyclofosfamide and Ifosfamide require metabolic transformation by hepatocytes and, thus, cannot be tested in vitro. Synthetic active metabolites of Cyclofosfamide (4HC) and Ifosfamide (4HI) were 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, Idarubicin was the most effective inducer of apoptosis causing 3.92 KU maximal apoptotic response while Mitoxantrone caused 2.31 KU maximal response. Of note, responses of more than 3 KU to Idarubicin and more than 2 KU to Mitoxantrone have been previously seen in acute myeloid leukemia patients achieving complete remission after induction chemotherapy (see ref). Of the three other tested anthracycline antibiotics, Doxorubicin and Epirubicin caused 3.08 KU maximal response each while Daunorubicin was least effective causing 2.59 KU maximal response. Of other tested agents, Mylotarg was the most effective against patient's blasts causing 2.24 KU maximal response. A table in the "Interpretation" section shows maximal apoptotic responses achieved with tested agents. Responses to Melphalan and Etoposide were less than 1 KU and are not shown in the table.

In conclusion, based on the results of this study, Idarubicin would be most reasonably to include in the treatment protocol if clinically indicated. Of other tested agents, use of Mitoxantrone, Epirubicin, Doxorubicin, or Mylotarg may be considered.

Ref.: V.Kravtsov, J. Greer, Y. Shyr, J. Whitlock, T., T.McCurley, Goodman, R. Stein, S.Krantz, M. Koury (2001) Prediction of survival in acute non-lymphocytic leukemia (AML). Blood,98:214b

MICROSCOPIC/IMMUNOPHENOTYPIC STUDIES:

Wright stained bone marrow aspirate smear showed expanded population of immature myeloid cells morphologically consistent with blasts. By flow cytometry after lysis of the erythroid cells, myeloid blasts accounted for 84.3% of the white blood cells. The blasts showed homogeneous expression of HLA-DR, CD13, CD33, CD34 and variably expressed CD11b, CD56, CD117, and CD38. The immunophenotype and morphologic features of the blasts are consistent with involvement by acute myeloid leukemia, favor M4 in the FAB classification.

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.