

DiaTech Oncology

Patient Specific Cancer Testing

SAMPLE REPORT

CLIA ID # 99D1030993

CAP ID # 7186701

Patient : Patient X.
 Date of birth : 08/30/1953
 Specimen ID : HP11-2342
 Specimen type : Peripheral blood

Collected : 06/29/2011
 Received : 06/30/2011
 Physician : Linda Bosserman
 Institution : Wilshire Oncology

Clinical

57-year-old male with a diagnosis of stage IV NHL-low grade/CLL since 04/1999, currently in relapse. Previous chemotherapy with Leukeran(resistant), MINE-Rituxan, Fludarabine-Cytosan-Rituxan (resistant), Campath (complete response 2005), bendamustine (delayed response), arsenic (partial response) .

Recommendation

The MiCK assay identified numerous drugs (most non traditional) for successful treatment of the patient. Since we were able to isolate many malignant lymphocytes we tested normal CLL drugs as well as those that would be "off label". Because of this we identified numerous drugs and drug combinations which were highly successful in inducing apoptosis in the malignant lymphocyte population. Any of the drugs/drug combinations that had a KU reading above 5.0KU would be expected to be successful in treating the patient. The specific drug/ drug combination is best determined based on the patient's physical status and ability to tolerate the specific drug(s).

MiCK Assay Results

Drug tested	Max. Resp. (KU)	Resp. level	Drug tested	Max. Resp. (KU)	Resp. level
Idarubicin	9.3	Sensitive	Cisplatin	2.6	Low to moderate
Daunorubicin	7.8		Cisplatin+Gemcitabine	2.4	
Oxaliplatin	7.0		NitrogenMustard	2.3	
4HI(ifosfamide)+Carboplatin+Et...	6.6		Vincristine	2.2	
4HC(cytosan)+Vincristine	6.6		Thioguanine	2.1	
Vinorelbine	5.9		Procarbazine	2.1	
Vinblastine	5.8		4HC(cytosan)+Fludarabine	2.1	
4HC(cytosan)+Doxorubicin+Vinc...	5.7		Tarceva	1.9	
Velcade	5.4		Cytarabine+Oxaliplatin+Fludara...	1.8	
Vidaza	4.8		Hydroxyurea	1.7	
Bendamustine	4.8	Mitoxantrone+Fludarabine	1.6		
Epirubicin	4.3	Decitabine	1.5		
Cisplatin+Vincristine	4.3	Mitomycin	1.3		
Mitoxantrone	3.8	Moderate	Chlorambucil	0.9	Nonsensitive
Gleevec(imatinib)	3.6		Gemcitabine	0.8	
Doxorubicin	3.6		Carboplatin	0.6	
4HI(ifosfamide)	3.3		Methotrexate	0.6	
4HC(cytosan)	3.2		Cytarabine	0.4	
4HC(cytosan)+pentostatin	3.1		Fludarabine	0.4	
Sunitinib	2.8		Etoposide	0.2	
4HC(cytosan)+Fludarabine+Mito...	2.7		ArsenicO3	0.2	
5-Fluorouracil	2.6		Temozolomide	0.1	
Cisplatin+Cytarabine	2.6		Low to moderate	Sorafenib	
		pentostatin		0.0	

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Interpretation

Refractory CLL, peripheral blood:

1. A population of lymphocytes with cytologic features and immunologic characteristics of CLL is present.
2. In the MiCK assay, the patient's lymphocytes were highly sensitive to numerous drugs/ drug combinations, many of these drugs would be considered "off label". As much as 9.3KU of apoptosis were recorded. The Table below shows all of the drugs which gave greater than 5.0KU of apoptosis.
3. Based on the MICK assay the extent of the response of those drugs/drug combinations with a KU reading of 5.0 or greater was consistent with high sensitivity of the tumor to these drugs.
4. Responses to other reagents were consistent with lower sensitivity to these reagents.
5. The Table and Graph below show all reagents tested, their concentrations, and the MICK assay results.

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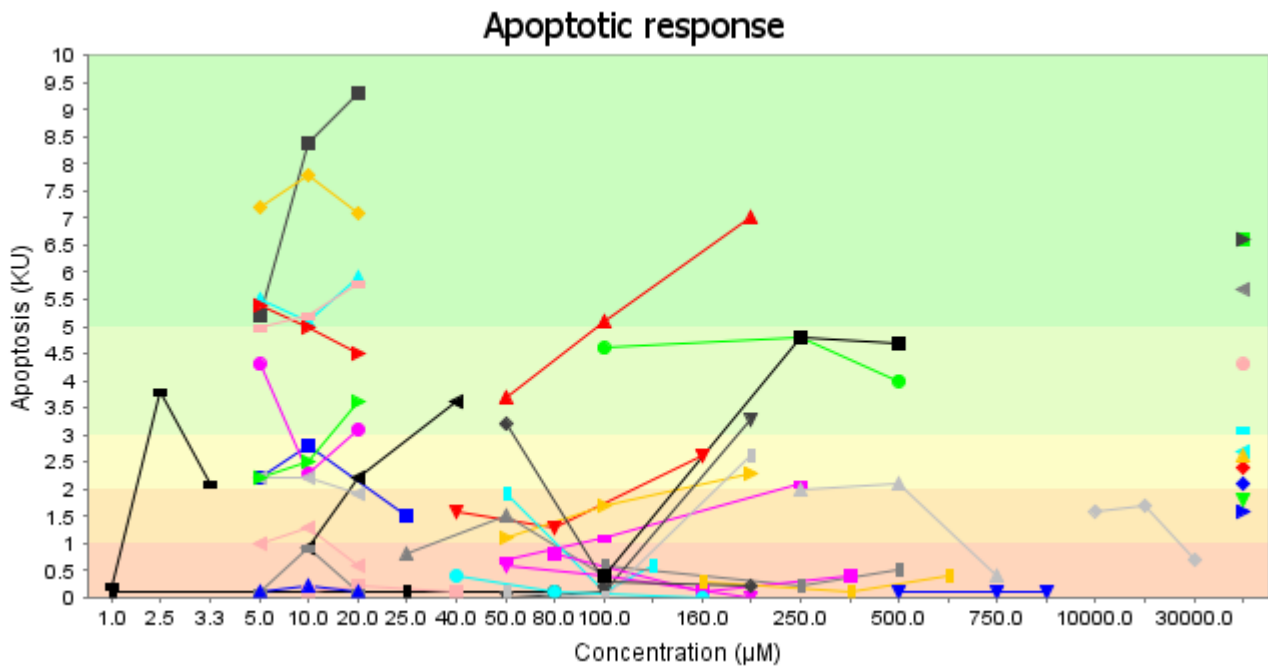
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Legend:		ND: data not displayed	NS: not sensitive					
■	Idarubicin	9.3	▽	4Hl(ifosfamide)	3.3	◊	Mitomycin	1.3
◆	Daunorubicin	7.8	◆	4HC(cytoxan)	3.2	■	Chlorambucil	0.9
▲	Oxaliplatin	7.0	■	Sunitinib	2.8	■	Gemcitabine	0.8
▲	Vinorelbine	5.9	▼	5-Fluorouracil	2.6	■	Carboplatin	0.6
■	Vinblastine	5.8	■	Cisplatin	2.6	▼	Methotrexate	0.6
▲	Velcade	5.4	▲	NitrogenMustard	2.3	▲	Cytarabine	0.4
●	Vidaza	4.8	■	Vincristine	2.2	■	Fludarabine	0.4
■	Bendamustine	4.8	■	Thioguanine	2.1	■	Etoposide	0.2
■	Epirubicin	4.3	■	Procarbazine	2.1	■	ArsenicO3	0.2
■	Mitoxantrone	3.8	■	Tarceva	1.9	■	Temozolomide	0.1
■	Gleevec(imatinib)	3.6	■	Hydroxyurea	1.7	■	Sorafenib	0.0
■	Doxorubicin	3.6	■	Decitabine	1.5	■	pentostatin	0.0
■	4Hl(ifosfamide)+ Carboplatin+Etoposide	6.6	▲	Cisplatin+Cytarabine	2.6	■		
■	4HC(cytoxan)+Vincristine	6.6	■	Cisplatin+Gemcitabine	2.4	■		
■	4HC(cytoxan)+Doxorubicin+Vincristine	5.7	■	4HC(cytoxan)+Fludarabine	2.1	■		
■	Cisplatin+Vincristine	4.3	■	Cytarabine+Oxaliplatin+Fludarabine	1.8	■		
■	4HC(cytoxan)+pentostatin	3.1	■	Mitoxantrone+Fludarabine	1.6	■		
■	4HC(cytoxan)+Fludarabine+Mitoxantrone	2.7						

Comments

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Viable neoplastic cells collected from the specimen were tested for their sensitivity to multiple drugs and drug combinations at multiple concentrations. Of note, the alkylating agents Cytosan and ifosfamide require hepatic metabolic transformation to the active metabolites, 4HC and 4HI respectively, and therefore cannot be tested directly in vitro. For the MICK assay the active metabolites, 4HC and 4HI, were used.

The MICK assay identifies chemotherapy reagents that are most effective in killing malignant cells by inducing apoptosis, it specifically identifies and quantitates apoptotic cells. In this study, numerous drugs and drug combinations were highly effective in inducing apoptosis causing as much as 9.3KU maximal response which is consistent with high sensitivity of the tumor cells to this reagent. Of note, a response of greater than 5.0KU is consistent with a high drug sensitivity and has previously been associated with a complete clinical response to chemotherapy. Other tested reagents induced lower levels of apoptosis. All tested chemotherapy reagents induced apoptosis in appropriate control cell lines.

Microscopic/Immunophenotypic studies

The Wright's stained peripheral smear contains numerous lymphoid cells which are small, mature appearing, and have "blocky" chromatin. Nucleoli are not noted. RBCs are noted to have many Howell-Jolly bodies.

Attending Pathologist

Medical Director

DiaTech Oncology, LLC

Electronically signed on 07-07-2011

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.

DiaTech Oncology, 740 Dr. Penfield Ave. Suite 4200, Montreal, Quebec, Canada www.diatech-oncology.com