

CAP ID # 7186701
CLIA ID # 99D1030993
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SAMPLE REPORT

Clinical:

59-year-old female with a recent diagnosis of ovarian cancer, first presentation.

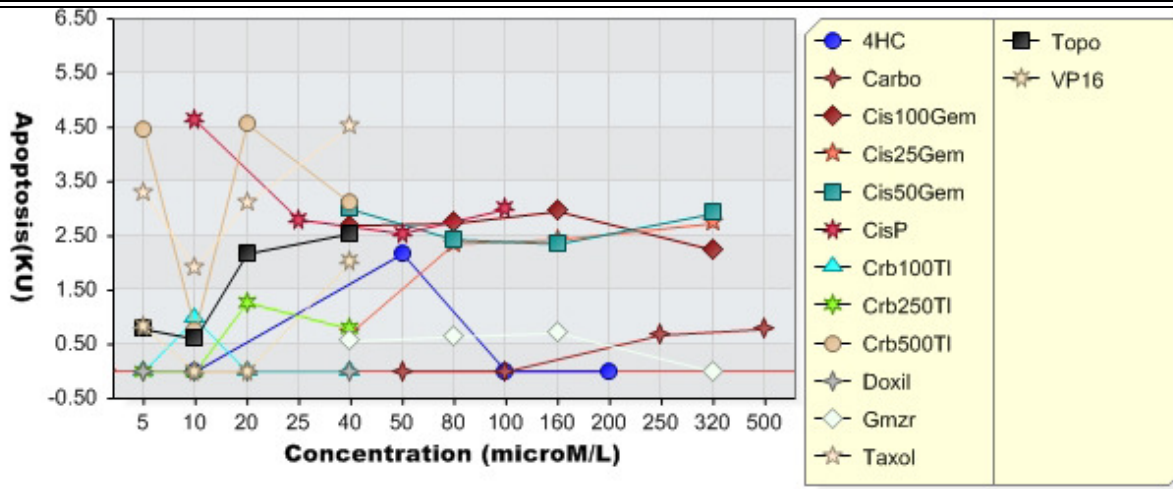
INTERPRETATION:

Primary endometrial tumor tissue biopsy:

- 1 A population of cells with morphologic and immunocytochemical features of an epithelial neoplasm is present.
2. In the MICK assay the tumor cells were equally sensitive to the combinations of carboplatin with taxol and cisplatin with gemcitabine as well as single agent taxol.
3. In the MICK assay the extent of the response was consistent with a moderate sensitivity of the tumor cells to these combinations. Please see the Comment section for further detail.
- 4 Responses to the other tested reagents were consistent with lower sensitivity of the tumor cells to these reagents.
- 5 The Table and Graph below show all tested reagents, concentrations, and the MICK assay results.

Maximum Apoptotic Response (Kinetic Units):

CisP	Crb500TI	Taxol	Cis50Gem	Cis100Gem	Cis25Gem	Topo	4HC	VP16	Crb250TI	Crb100TI	Carbo	Gmzr	Doxil
4.63	4.56	4.52	2.99	2.95	2.73	2.54	2.17	2.02	1.27	0.97	0.78	0.71	0.00



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COMMENT:

Viable neoplastic cells collected from the specimen were tested for their sensitivity to multiple single agents and combinations of agents at multiple concentrations.

Of note, the alkylating agents cyclophosphamide requires hepatic metabolic transformation to the active metabolite, 4HC, and therefore cannot be tested directly in vitro. For the MICK assay the active metabolites, 4HC, was 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, the combinations of carboplatin with taxol and cisplatin with gemcitabine as well as single agent taxol were equally effective in inducing apoptosis causing 4.5 to 4.6KU maximal response which is consistent with moderate sensitivity of the tumor cells to these reagent. Of note, responses from 3.0 to 5.0 are consistent with a moderate drug sensitivity and have previously been associated with a partial 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:

Cytospin preparations of the tumor contain primarily small, single cells with a moderate amount of basophilic cytoplasm. Single ovoid nuclei with uniformly distributed chromatin and a macronucleolus are present. The tumor is cytokeratin positive, weakly positive for CA125, and negative for calretinin. Ki67 is positive in >50% of the cells.

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.