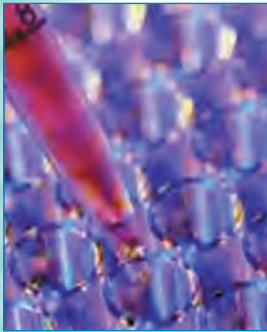




ONCOTECH

EDR[®] ASSAY

Extreme Drug Resistance Assay



“Biochemical resistance to chemotherapy
is the major impediment to successful treatment.”

Vincent T. DeVita, Jr., MD

Cancer: Principles & Practice of Oncology, 4th ed.



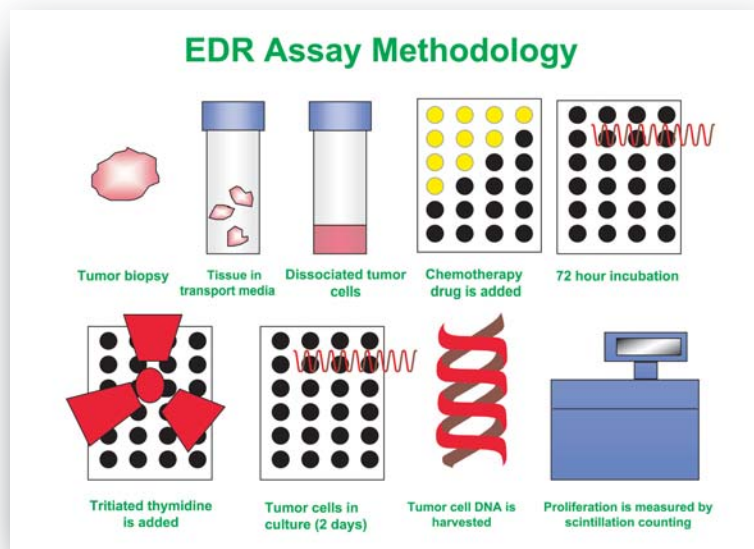
Oncotech’s EDR Assay predicts the clinical failure
of drug therapy with 99.2% accuracy.¹

Studies show patients receiving chemotherapy drugs that were
found to be in the extreme drug resistance category for their tumor
had significantly shorter disease-free and overall survival rates.^{2, 4, 5}

Oncotech EDR® Assay for Solid Tumors

EDR® Assay Methodology

- Fresh viable tumor tissue is minced and enzymed to disaggregate the tumor cells.
- The tumor cells are plated in soft agar which preferentially favors tumor cell proliferation.
- Cells are exposed to tumor type-specific anti-neoplastic agents for five days in a carefully controlled environment.
- Drug exposures in excess of the maximum tolerated are used. Due to the reduced rate of drug metabolism, *in vitro* tumor exposure is 5 to 80 times greater than *in vivo*.
- Tritiated thymidine is introduced during the last two days of culture as a measure of cell proliferation.
- Treated cells are compared to untreated controls.
- If malignant cells proliferate *in vitro* under such extreme chemotherapeutic exposure conditions, then *in vivo* exposures will be ineffective, with a probability greater than 99%.¹
- Patient survival has been shown to be directly correlated with EDR results.^{2, 4, 5}



Oncotech EDR Assay Validation

This graph displays 450 double-blinded correlations between EDR Assay results and clinical response to chemotherapy, with each dot representing an individual patient correlation.¹

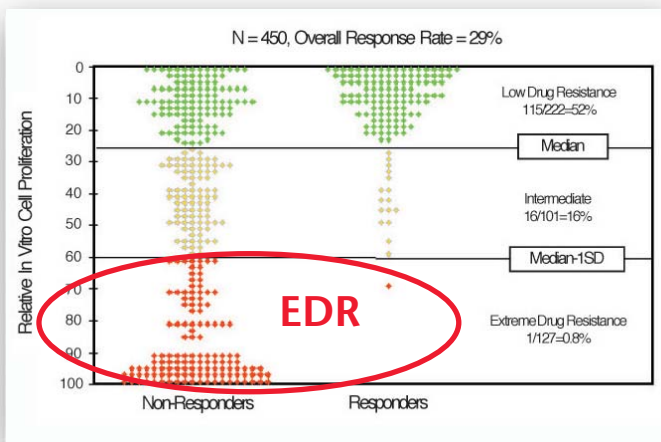
The patient's *in vitro* assay result is shown on the Y-axis and the clinical response to the tested drug is shown on the X-axis.

Assay results were divided into three categories:

Extreme Drug Resistance (EDR): Tumor cell growth was greater than 1 standard deviation above the median. Of 127 patients whose tumors had Extreme Drug Resistance to the drugs given clinically, 126 (99%) had no response to chemotherapy.

Intermediate Drug Resistance (IDR): Tumor cell growth was greater than the median growth but less than 1 standard deviation above the median.

Low Drug Resistance (LDR): Tumor cell growth was less than the median growth.



¹ Kern and Weisenthal, Highly specific prediction of antineoplastic drug resistance with an *in vitro* assay using suprapharmacologic drug doses. *J. Natl. Cancer Inst*; 82:582; 1990.

² Mehta et al., Breast cancer survival and *in vitro* tumor response in the extreme drug resistance assay. *Breast Cancer Research and Treatment* 66:225-237, 2001.

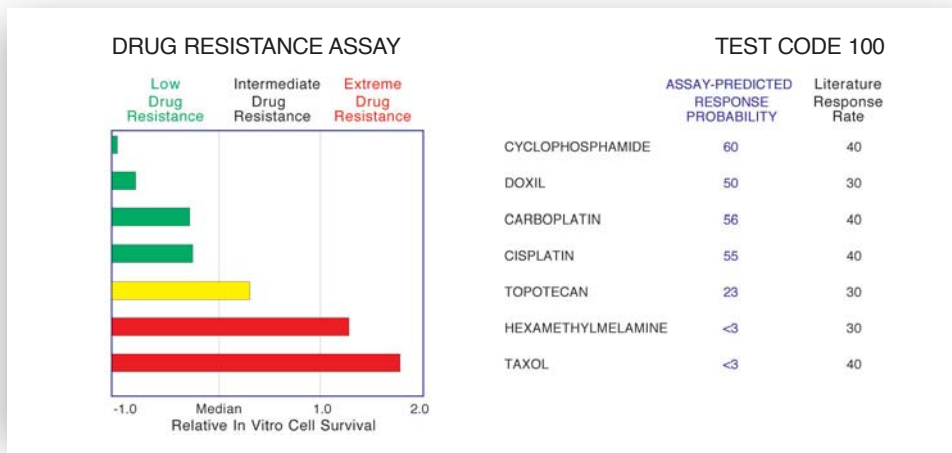
³ Brem, et al. Extreme drug resistance in primary brain tumors: *in vitro* analysis of 64 resection specimens. *Journal of Neuro-Oncology*, 2002, 58: 115-123.

⁴ Holloway et al., Association Between *In Vitro* Platinum Resistance in the EDR Assay and Clinical Outcome for Ovarian Cancer Patients. *Gynecologic Oncology*, Vol 87:1, 8-16, 2002.

⁵ Loizzi, et al: Survival outcomes in patients with recurrent ovarian cancer who were treated with chemoresistance assay-guided therapy. *Am J Obstet Gynecol* 189:5, 1301-1307, 2003.

⁶ Parker, et al. A prospective blinded study of the predictive value of an extreme drug resistance assay in patients receiving CPT-11 for recurrent glioma. *Journal of Neuro-Oncology*, 2004, 66: 365-375.

Oncotech EDR[®] Assay Report



Extreme Drug Resistance (EDR)

Extreme Drug Resistance (EDR) indicates that tumor cell growth was virtually unaffected by the high chemotherapeutic agent exposure. Data published in the April 1990 edition of the Journal of the National Cancer Institute (JNCI) and other published data show that patients had less than 1% chance of responding to EDR agents.

Intermediate Drug Resistance

Intermediate Drug Resistance (IDR) indicates moderate tumor growth. In published studies, patients treated with agents in the IDR category had response rates that were about half of the rates reported in the medical literature.

Low Drug Resistance

Low Drug Resistance (LDR) indicates that tumor cell proliferation was inhibited by the tested agent and that tumor cells demonstrated less than median growth. Patients treated with agents in the LDR category had response rates that were approximately 1 1/2 to 2-fold greater than the literature reported rates in published studies.

Literature Response Rate

Determined from an extensive review of clinical trials in which each drug was administered as single agent therapy to specific tumor type.

Assay Predicted Response Probability

Derived from an algorithm involving *in vitro* tumor cell proliferation, literature response rate, patient treatment status, and a comparison with a growing database of over 80,000 *in vitro* assays, in accordance with the Bayesian mathematical model.

EDR[®] Assay Features and Benefits

Accurate

- Over 99% accuracy for identifying ineffective (resistant) agents¹
- Independent of host factors

Cost Effective

- Avoids direct costs of ineffective therapies
- Avoids costs of managing treatment related morbidity

Humane

- Spares patients unnecessary toxicity
- Saves valuable treatment time
- Avoids the potential of inducing cross resistance to other effective agents

Reliable

- Approximately 90% of tumor specimens submitted yield successful assay results

Fast

- Test results are available in 7 days

Assay Specimen Preparation Guidelines

Solid Tumor (including Lymphoma):

- Obtain fresh biopsy specimen. Ideally, the specimen should contain at least 2 grams of viable tumor tissue. Smaller specimens will be processed, but they may not yield sufficient cells to test a full panel of drugs. Do not mince, fix or freeze specimen.
- Rinse specimen in sterile saline or lactated Ringer's solution.
- Immediately place sample into the inner specimen transport vial which contains Oncotech transport media. In the absence of Oncotech transport media, use sterile lactated Ringer's solution or RPMI 1640.

Divide specimens larger than 2 grams into separate vials.

- Secure inner and outer specimen vials tightly.
- Place specimen vial assembly into the center of the Oncotech box. Place ice pack on top of vial assembly.
- Place closed box and completed Requisition Form into Federal Express Diagnostic Pack for shipment.
- Call 1-800-ONCOTECH to notify Client Services that you are sending a specimen.

Malignant Effusions:

- Collect 250 - 1000 ml of fluid in a sterile evacuation bottle or polyethylene bag. Do not use Pleur-Evac system containers.
- Immediately add 3 units of heparin per 1 ml of fluid. This step is highly recommended but not required.
- Retain a portion of the fluid for your cytology department.
- Refrigerate the specimen until shipment.
- Use an Oncotech leakproof, protective shipping container (available at no charge).

Important Reminders:

- Refrigerate transport vial until use.
- Freeze Oncotech transport box at least 24 hours before use.
- Patients must not have had chemotherapy or radiation therapy within 3 weeks of specimen collection.

Selected Oncotech EDR® Assay Standard Test Panels*

Current Test Panels as of March 2006

BRAIN

1. Temozolomide
2. Carmustine
3. Cisplatin
4. Cyclophosphamide
5. Vincristine
6. Doxorubicin
7. Etoposide

BREAST

1. Doxorubicin
2. Cyclophosphamide
3. Taxol
4. Fluorouracil
5. Navelbine
6. Taxotere
7. Gemcitabine
8. Cisplatin
9. Capecitabine

COLORECTAL

1. 5 FU + Leucovorin
2. Irinotecan
3. 5 FU + Irinotecan
4. Oxaliplatin
5. Topotecan
6. Capecitabine
7. Floxuridine

ENDOMETRIAL

1. Cisplatin
2. Taxol
3. Doxorubicin
4. Ifosfamide
5. Etoposide
6. Cyclophosphamide
7. Topotecan

KIDNEY (Renal Cell)

1. Interleukin 2
2. Alpha Interferon
3. Fluorouracil
4. Gemcitabine
5. Doxil
6. Vinblastine
7. Interferon + Vinblastine
8. Mitomycin C
9. Cyclophosphamide

LUNG (Non-Small Cell)

1. Carboplatin
2. Taxol
3. Navelbine
4. Etoposide
5. Gemcitabine
6. Topotecan
7. Cisplatin
8. Taxotere

MELANOMA

1. Cisplatin
2. Temozolomide
3. Vinblastine
4. Taxotere
5. Navelbine
6. Gemcitabine
7. Taxotere + Navelbine
8. Alpha Interferon
9. Carmustine

OVARIAN

1. Carboplatin
2. Taxol
3. Topotecan
4. Doxil
5. Etoposide
6. Gemcitabine
7. Taxotere
8. Cisplatin
9. Cisplatin + Gemcitabine
10. Cyclophosphamide

PANCREATIC

1. Gemcitabine
2. Fluorouracil
3. Ifosfamide
4. Doxorubicin
5. Irinotecan
6. Mitomycin C
7. Taxotere

SARCOMA (Soft Tissue)

1. Doxorubicin
2. Ifosfamide
3. Temozolomide
4. Cisplatin
5. Taxotere
6. Gemcitabine
7. Topotecan

STOMACH

1. Fluorouracil
2. Mitomycin C
3. Doxorubicin
4. Cisplatin
5. Etoposide
6. Gemcitabine
7. Taxol

UNKNOWN PRIMARY

1. Cisplatin
2. Doxorubicin
3. Fluorouracil
4. Cyclophosphamide
5. Taxol
6. Topotecan
7. Etoposide

* Custom drug panels available upon physician request. Standard drug panels are reviewed frequently and are subject to change.

Billing Policies

- Oncotech bills insurance directly and does not balance bill the patient. Patients may be responsible for co-payments or unmet deductible amounts where required by law or insurance contract.
- Oncotech has negotiated reimbursement contracts with many of the country's leading insurance carriers, including many managed care organizations.
- A Social Security Administration Administrative Law Judge has determined that Extreme Drug Resistance Assays are "part of the generally accepted medical practice" and are "not experimental." Oncotech bills Medicare directly on an accept assignment basis.
- Oncotech will assist patients in obtaining reimbursement and may provide indigent coverage where appropriate.



ONCOTECH, INC.

15501 Red Hill Avenue, Tustin, CA 92780

1-800-576-6326 • www.oncotech.com