

# Functional Tumor Profiling: A Guide to Certified Laboratory Options

An independent comparison of CLIA-certified labs offering ex vivo chemosensitivity and functional profiling tests for cancer patients

## WHAT YOU NEED TO KNOW ABOUT THIS CLASS OF TESTS

- A

**These tests measure how your tumor actually responds to therapy -- something genomic testing cannot do.** Functional profiling exposes your living tumor cells to specific drugs in the laboratory and directly observes the result. Genomic testing, by contrast, looks for mutations that may predict drug response; however, actionable mutations are found in only about one in four patients with advanced cancer. Functional assays can assess the effectiveness of most standard chemotherapies and, in some cases, a broad range of targeted therapies as well -- particularly when the assay measures both cell death and cancer growth inhibition.
- B

**All functional profiling assays require a fresh, living tumor sample.** Because the test must observe how your actual cancer cells respond to therapy, the tumor tissue must be alive at the time of testing. Fresh tissue is typically collected during surgery, a biopsy, or a fluid-drainage procedure (such as thoracentesis or paracentesis), and must be shipped promptly to the laboratory. This is an important practical consideration when planning your care.
- C

**The evidence is substantial, but these tests are not yet mainstream -- and most require out-of-pocket payment.** Dozens of published studies have demonstrated the accuracy and clinical relevance of functional profiling assays. Nevertheless, they remain contested within academic oncology and have not yet received endorsement from the NCCN (National Comprehensive Cancer Network) or most insurance plans. Opposition has come primarily from academicians oncologists who cite a lack of large prospective randomized trials -- a standard that has rarely been applied to genomic testing. As a result, the majority of functional profiling tests currently require out-of-pocket payment.

| PHYSICIAN-LED, CLIA-CERTIFIED LAB                                      | ASSAY READOUT                                                                   | WHAT IS MEASURED                                                                                         | NOTES                                                                                                                                                                                                                                                       |
|------------------------------------------------------------------------|---------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>SageMedic Corp.</b><br>SAGE Oncotest™ (Reveal™ + Prevail™)          | <b>DUAL READOUT</b><br>Native 3D cytotoxicity + antiproliferation, 7 to 10 days | Cell death AND cancer growth inhibition -- both measured in a preserved native 3D tumor microenvironment | <b>MOST ADVANCED ASSAY</b><br>The only platform in this class offering both cytotoxicity and antiproliferation readouts, enabling reliable testing of a broad range of targeted therapies alongside standard chemotherapy. Works for all solid tumor types. |
| <b>Nagourney Cancer Institute</b>                                      | <b>CYTOTOXICITY</b><br>Cell death testing, 7 to 10 days                         | Whether cancer cells die when exposed to a drug                                                          | <b>PRACTICING ONCOLOGIST</b><br>Decades of clinical experience; the physician-founder can order the test and treat his own patients accordingly -- an unusual integrated model.                                                                             |
| <b>Weisenthal Cancer Group</b>                                         | <b>CYTOTOXICITY</b><br>Native 3D cell death testing, 7 to 10 days               | Whether cancer cells die; tumor tested in a native 3D configuration                                      | Dr. Weisenthal is an oncologist and hematologist who pioneered the Differential Staining Cytotoxicity (DiSC) assay -- a foundational contribution to functional tumor profiling -- establishing the scientific and clinical basis for it.                   |
| <b>CureFirst</b><br>formerly SEngine; University of Washington spinout | <b>CYTOTOXICITY</b><br>3D organoid-based testing, several weeks to months       | Whether cancer cells die, after growing a mini-tumor (organoid) in the laboratory                        | 501(c)(3) nonprofit with a patient-centered mission. Organoids do not always grow successfully, which may delay or prevent results. Longer lead time is an important practical limitation.                                                                  |

| OTHER CERTIFIED LABS              | ASSAY READOUT                                                            | WHAT IS MEASURED                                                             | NOTES                                                                                                                                                                                                                                                           |
|-----------------------------------|--------------------------------------------------------------------------|------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Cordgenics</b><br>ChemolD test | <b>CYTOTOXICITY</b><br><br>Single-cell testing, 2 to 3 weeks             | Whether individual cancer cells (including stem-like cells) die              | <b>STRONG OUTCOME STUDIES</b><br><br>Claims to test both bulk tumor cells and stem-like cancer cells. Published clinical studies in recurrent glioblastoma and platinum-resistant ovarian cancer showing improvements in progression-free and overall survival. |
| <b>First Ascent Biomedical</b>    | <b>CYTOTOXICITY</b><br><br>Native 3D cell death testing, 10 days or less | Whether cancer cells die; some preservation of the natural tumor structure   | Academic spinout; maintains elements of the native tumor microenvironment. Emphasizes integration of AI and genomic data alongside the functional readout.                                                                                                      |
| <b>Kiyatec</b>                    | <b>CYTOTOXICITY</b><br><br>3D cell death testing, 7 to 10 days           | Whether cancer cells die                                                     | Laboratory service only; approach is similar to Nagourney's. Coverage may be limited primarily to standard chemotherapy agents. Less published experience than other physician-led labs.                                                                        |
| <b>Travera</b>                    | <b>GRAVIMETRIC</b><br><br>Single-cell weight measurement, 2 to 3 days    | Picogram-scale weight changes in individual cancer cells after drug exposure | MIT-developed; measures weight change of individual cancer cells with sub-picogram precision. Whether transient drug-induced weight changes reliably predict cytotoxicity remains an open question.                                                             |

**A note on insurance and access:** As described above, functional profiling tests are not currently covered by most insurance plans. Patients typically pay out of pocket. Costs, sample-collection logistics, and the clinical scenarios in which each lab operates vary. We recommend discussing these factors with your oncologist or contacting the laboratory directly before proceeding.

**How to read the "Assay Readout" column:** A *cytotoxicity* assay measures whether cancer cells die when exposed to a drug -- a readout suited primarily to chemotherapy. An assay that also measures *antiproliferation* (cancer growth inhibition) can additionally evaluate the large class of targeted therapies that work by slowing or stopping cell division rather than directly killing cells. The difference in scope between a single-readout and a dual-readout platform is clinically significant.

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