

Expanding the eligible patient populations for targeted therapies

The CELsignia test diagnoses new cancer sub-types molecular-based approaches cannot detect.

Instead of identifying genetic variants in fixed tumor cell samples, our diagnostic tests measure dynamic pathway signaling activity in a cancer patient's living cancer cells *ex vivo*. Our CELsignia Test measures dynamic HER2, c-Met, and PI3K-node involved signaling activity in the living tumor cells of HER2-negative breast cancer patients.

Most patients lack actionable mutations.

Roughly 80% of cancer patients lack actionable genetic mutations and are not eligible for targeted therapies.



A new way to identify patients eligible for targeted therapies.

CELsignia tests diagnose dysregulated signaling cancer drivers that molecular based approaches cannot detect. Why? The nature of cell signaling is too dynamic and complex to be characterized by static analysis of fixed cells.



These patients are likely drug responders.

The patients diagnosed with a dysregulated signaling pathway have a disease mechanism that directly corresponds to the matching targeted therapy's mechanism of action.



CELsignia tests can help drug sponsors obtain new indications for their targeted therapies.

CELsignia tests provide pharmaceutical companies a new type of biomarker, dysregulated signaling activity, to identify additional patients eligible for their targeted therapies.

Analytical validation studies of the CELsignia Test have been completed, and two Investigational Device Exemptions have been approved to conduct two Phase II interventional clinical trials to evaluate the efficacy of targeted therapeutics in patients selected with the CELsignia Test. Celcuity is now collaborating with pharmaceutical companies to obtain FDA approvals for targeted therapeutics that treat the new patient populations selected by the CELsignia Test.

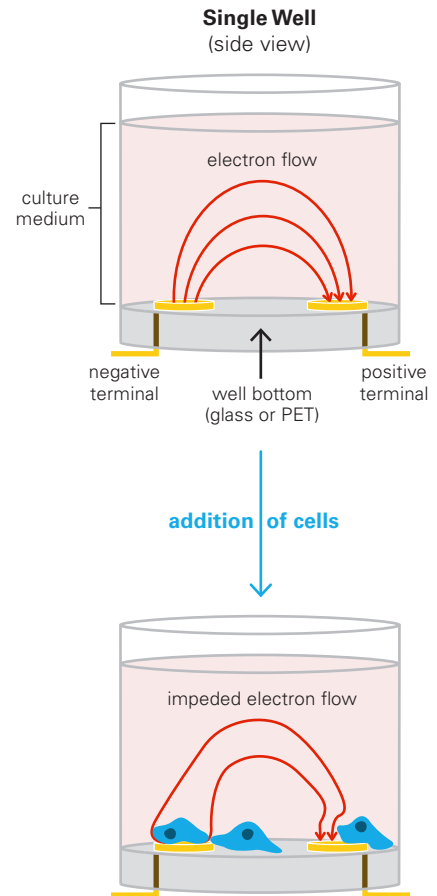
The CELsignia platform uses live patient tumor cells to measure dynamic cell signaling activity.

1 **Our technology is the first to isolate and culture patient tumor cells.**

- + Fresh patient tumor tissue is used to derive cell samples
- + Only requires tissue from a single core biopsy
- + Cell samples represent the entire specimen received
- + Zero passage short term cultures better preserve viable tumor heterogeneity
- + Site-friendly collection kits are provided
- + No blackout collection or receipt days

2 **Our cell signaling quantification technology is also the first to measure dynamic signaling activity in live patient tumor cells.**

- + The CELsignia Test leverages the well-established biological link between cell signaling and cell adhesion processes
- + Measuring cell adhesion activities can serve as a metric for cell signaling activity
- + Live cells are attached to a microelectrode on a biosensor that measures impedance levels
- + Signaling activity affects impedance levels by causing cell adhesion changes
- + CELsignia measures the impedance changes to quantify cumulative signaling activity induced by pathway agonists or antagonists over a four-hour period



The result:

- + Dysregulated signaling pathways are clearly differentiated from normally signaling pathways
 - Signaling activity levels are bi-modally distributed within the population of patients lacking actionable mutations.
 - 5 standard deviations separate mean results for normal signaling sub-group from dysregulated signaling sub-group
- + Three distinct breast cancer disease subgroups, comprising 25%-35% of HER2-negative patients, are now identified with a single test:
 - Hyperactive HER2 signaling tumors
 - Hyperactive HER2 and c-MET signaling tumors
 - Hyperactive PI3K-involved signaling tumors

25-35%
more cancer patients diagnosed with an actionable biomarker