SAGA DIAGNOSTICS

Pathlight™
Molecular Residual Disease

Redefining
the standard for ultra-sensitive and early MRD detection

Meeting the need for reliable monitoring

Breast cancer is the most common malignancy among women worldwide and the second leading cause of cancer death in U.S. women[1].

In the U.S. alone, approximately **300,000 women** are expected to be diagnosed with breast cancer in 2025[2], with roughly 90% presenting at early stages (I–III),[3] and 50% presenting in stages I-IIA[4].

Approximately **70–75%** of all breast cancers are estrogen receptor-positive (ER+), making it the most prevalent biologic subtype[4].

ER+ breast cancer can have a highly variable risk prognosis[5] — with **nearly 40%** characterized as high-risk Luminal B or Basal-like subtypes[6] — which requires long-term monitoring.

Pathlight is a next-generation, ultra-sensitive MRD test that intercepts cancer at the earliest stages when patients are most treatable.

Breaking barriers in clinical performance for breast cancer

Pathlight is a multi-tumor platform that sets a new standard for ultra-sensitive MRD testing with its first indication in breast cancer, delivering a 96% detection rate at baseline (pre-treatment) across all stages and subtypes, 94% in estrogen receptor-positive (ER+) breast cancer — a patient population in which first-generation MRD tests struggle to exceed 80%.

Pathlight also breaks the 1ppm sensitivity barrier — enabling the detection of early, small tumors while they're still treatable.

100%

sensitivity for distant recurrence[7]

100%

specificity across all timepoints[7]

13.7

month median lead time[7]

Personalized MRD test based on unparalleled knowledge of every tumor's source code

First-generation MRD tests rely on detecting single nucleotide variants (SNVs), which are susceptible to technical noise, leading to false positives that impact specificity and false negatives that decrease sensitivity, leading to shorter lead times across many tumor types.

Pathlight works differently, built on proprietary bioinformatics that use patient- and tumor-specific genetic alterations called structural variants (SVs), which are much less susceptible to detection noise.

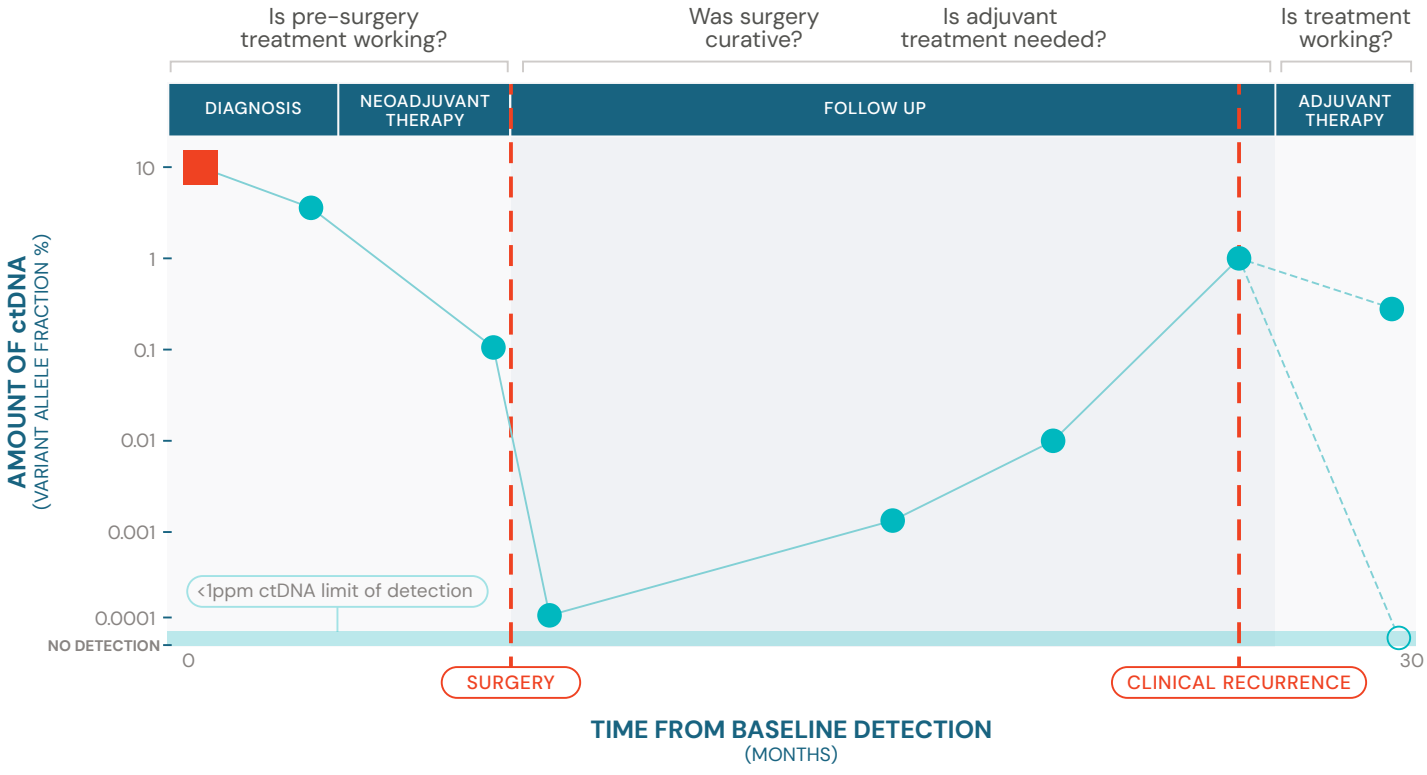
Personalized tumor fingerprint development and initial blood test

Results will be available **3–4 weeks** from receipt of both tissue and blood at the laboratory.

Subsequent blood tests

Results will be available **3–5 days** from receipt of blood at the laboratory.

Using ultrasensitive MRD detection to inform recurrence monitoring and treatment response



Pathlight MRD testing

- Fingerprint development and baseline ctDNA detection

Pathlight test status

- Positive (ctDNA detected)
- Negative (ctDNA not detected)

Patient Support Program

We believe financial constraints should never be a barrier to the care you need. Our Pathlight Patient Support Program is designed to support uninsured and underinsured financially eligible patients.

Support may include:

- Full or partial financial assistance based on household income and financial hardship
- Help with insurance appeals for denied claims
- Interest-free payment plans for eligible balances

If you have questions – We are here to help.

A trusted partner selected by pharma for clinical trials

Pathlight is being used in clinical studies by multiple top 10 pharmaceutical companies and leading academic institutions and national cancer centers.

Order Pathlight

Setting up your account is easy. Contact our dedicated client services team to create your clinician account and start ordering Pathlight for your patients.

Contact us

References

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