GENE SOLUTIONS

SPOT-MAS

ADVANCED CTDNA BLOOD TEST

To Outsmart Multi-cancer

SPOT-MAS 10 analyzes cancer-associated signals in cell-free DNA found in the blood. Powered by multi-omics technology and AI, it screens for 10 common cancers from a single blood draw.



SPOT-MAS 10

has been granted FDA Breakthrough Device Designation.*

(*) Breakthrough Device Designation is not FDA approval, clearance, or marketing authorization. SPOT-MAS 10 remains subject to future FDA review.

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How does SPOT-MAS work?

SPOT-MAS 10 is a simple blood test that looks for DNA fragments released by cancer cells into the bloodstream. These fragments are called circulating tumor DNA (ctDNA).



A blood draw tube (10ml) → Next-Generation Sequencing + Multimodal AI → 1. ctDNA Signal Detection 2. Tumor Origin Prediction

This test incorporates **next-generation sequencing (NGS)** and AI technologies to analyze **the multi-omics features of ctDNA from a single tube of blood**[1].

What can SPOT-MAS screen for?

This test enales early detection of **10 common and aggressive cancer types**[2] including Multi-omics dataset from **75 subtypes**[1]:

- Breast
- Lung
- Colorectum
- Stomach
- Liver/ Biliary tract
- Ovary
- Pancreas
- Esophagus
- Head & Neck
- Uterine

● 7/10 cancers covered by SPOT-MAS currently have no standard–of–care screening program available[2].

What do SPOT-MAS results mean?[3,4]

SPOT-MAS 10 has **received FDA Breakthrough Device Designation as a multi-cancer screening test***. This test is backed by **strong clinical validation** and **real-world testing** experience worldwide.

9,000+
Participants in Prospective Validation Studies

150,000+
Early Cancer Detection Test Performs

Negative:
No cancer signal detected

99.9%
Negative predictive value (NPV)

In clinical studies, when the result was negative, the test was correct more than 99% of the time for the cancers it covers.

✓ High reassurance
✓Continue your regular health checks and screening tests as recommended by your doctor

Patient Support Programs**
If cancer is detected within 12 months after a negative result, eligible patients may receive partial reimbursement.

Positive:
Cancer signal detected

84%
Tumor-of-origin prediction value (TOO)

In clinical studies, the test correctly suggested the likely origin of the cancer in about 8 out of 10 positive cases.

✓ A positive result means a cancer signal was found in your blood. This is not a diagnosis of cancer.
✓Further testing is needed to confirm if cancer is present.

Patient Support Programs**
If follow-up imaging finds no tumor, eligible patients may receive a complimentary ctDNA testing repeat after 6 months. If a tumor is found, financial support for treatment may be available.

Who are SPOT-MAS for?

1. Adults aged <40 years but have high risks

- 20+ pack-years of smoking[5]
- 15 cans of beer/week for men; 8 cans/week for women[6]
- Hepatitis B or C infection[7]
- Inherited cancer genes as BRCA1, BRCA2, TP53[8]
- Family members diagnosed with cancer[9]

2. Adults aged ≥ 40 years

Proactive health monitoring

Limitations:
- This test does not find every type of cancer.
- A negative result does not rule out cancer.
- A positive result is not a diagnosis — more tests are needed to confirm if cancer is present.
- Use this test along with, not instead of, your usual screening tests.
- False positive and false negative results can occur.

Disclaimer:
This test is meant to add to, not replace, your regular cancer screening tests

Note:
(*) This designation is not FDA approval. The test is still under review.
(**) Patient Support Programs may vary by country and availability. Please consult your doctor or contact us to learn more.

Reference: (1) Nguyen, L.H.D. et al. Prospective validation study: a non-invasive circulating tumor DNA-based assay for simultaneous early detection of multiple cancers in asymptomatic adults. BMC Med 23, 90 (2025). doi:10.1186/s12916-025-03929-y.. (2) These 10 cancer types accounted for 56.2% of total new incidences and 59.9% of total mortality (WHO GLOBOCAN South-East Asia Report, 2022). (3) Nguyen THH, Nguyen LHD, Nguyen TH, et al. Comprehensive validation of a cell-free DNA-based assay for multi-cancer detection: A Vietnamese longitudinal prospective cohort study of 9,024 participants. J Clin Oncol. 2024;42(23_suppl):102. (4) These include a case-control study published in eLife Science, the K-DETEK clinical validation study published in BMC Medicine, and a real-world experience report of 10,577 tests conducted across South-East Asia (Vietnam, Singapore, Malaysia, Thailand, Indonesia, and the Philippines) reported in ESMO Annals of Oncology. (5) Chen et al., 2021. American Journal of Otolaryngology 42, 102915. (6) Connor et al., 2017. Addiction 112, 222–228. (7) Petruzziello et al., 2018. TOVJ 12, 26–32. (8) Petruzziello et al., 2018. TOVJ 12, 26–32. (9) Brewer et al., 2017. Breast Cancer Res Treat 165, 193–200.

Learn more about Gene Solutions Group

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