

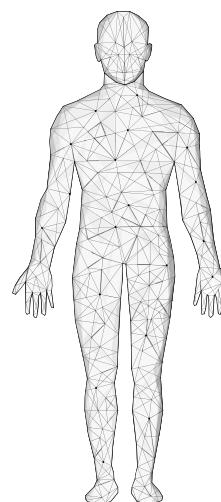
Solid Tumor NTRK Gene Fusion Assay

NTRK Gene Fusions are now recognized as an important pan-cancer, histology agnostic biomarker relevant to routine clinical oncology practice.

- **HIGHLY RECURRENT IN RARE TUMOR TYPES** including mammary analogue secretory carcinoma, and congenital fibrosarcoma.
- **IDENTIFIED AT LOW FREQUENCIES AMONG WIDE RANGE OF COMMON CANCER TYPES** including NSCLC, GIST, CNS tumors and Melanoma.
- **RNA-BASED NEXT GENERATION SEQUENCING (NGS) IS THE TECHNOLOGY OF CHOICE** to definitively identify the numerous gene fusion events involving NTRK1, 2 or 3, and overcome the limitations of traditional testing approaches that may be associated with false negatives or nonspecific results.

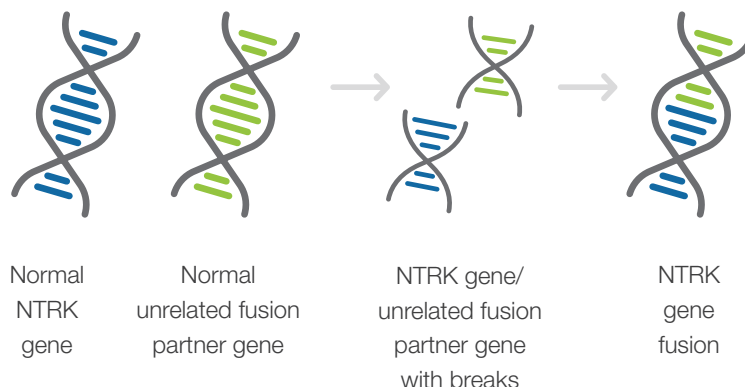
Estimated frequency of NTRK gene fusion in specific tumor types

Infantile fibrosarcoma	91%-100%
Secretory breast carcinoma	92%
Spitzoid melanoma	16%
Thyroid cancer	2%-12%
High-grade gliomas (pediatric)	10%
Melanoma, high-grade glioma, renal cell carcinoma, sarcoma; pancreatic and breast cancer	<5%
Cholangiocarcinoma	4%
Astrocytoma	3%
Lung cancer	0.2%-3%
Colon cancer	1%
Sarcoma	1%
Glioblastoma	1%
Head and neck squamous cell carcinoma	0.5%



Source: Tropomyosin-Related Kinases (TRK) Making Headway in Head and Neck Cancers. P Sciavolina. Targeted Oncology. Nov 2015; NTRK fusion-positive cancers and TRK inhibitor therapy. E Cocco, M Scaltriti, A Drilon. Nature Reviews Clinical Oncology. Oct 2018.

NTRK gene fusion testing is a strongly recommended component of comprehensive genomic profiling of newly diagnosed solid tumors. NCCN and other expert society consensus recommendations indicate that NTRK gene fusion testing should be performed as part of a broad, panel-based approach.



Advantages of GenPath's Solid Tumor NTRK Gene Fusion Assay

- **Optimized to directly detect translocation event** between NTRK gene and partner gene.
- **Requires minimal tissue** to test for a variety of genes.
- **Quick TAT** 7-10 days upon receipt of specimen.

Clinical Utility:

NTRK fusions are clinically actionable. The detection of NTRK gene fusion can assist in selecting patients that may benefit from TRK inhibitor therapies.

Test Information:

Test Code	Test Name	Methodology	Specimen Type	TAT
J355-9	Solid Tumor Gene Fusion Assay (<i>ALK, AXL, BRAF, CCND1, EGFR, FGFR1, FGFR2, FGFR3, MET, NRG1, NTRK1, NTRK2, NTRK3, PPARG, RAF1, RET, ROS1, THADA</i>)	Next-Generation Sequencing (NGS)	FFPE: Specimen Block Preferred Slides: 15 unstained slides cut at 5 microns containing a minimum 10% tumor cellularity	7-10 days

GenPath, a division of BioReference Laboratories, Inc., is a full service oncology/pathology laboratory with over 15 years of diagnostic experience. GenPath employs specialized pathologists and offers a comprehensive test menu. From routine clinical and special coagulation testing to complex genomic testing for tumor sequencing and hereditary cancer syndromes, the full spectrum of a cancer patient work-up is covered in one laboratory.



GenPath Oncology Profile:

Screening		Diagnostic		Treatment and Prognostic
Hereditary Cancer Program	Solid Tumor/Anatomic Pathology	Hematology/Coagulation	Cancer Genomics	
<ul style="list-style-type: none"> Breast & GYN panels Panels for multiple cancer types (Pancreatic, Colorectal, Melanoma, MDS/Leukemia, Prostate, Renal, etc.) Tumor specific panels 	<ul style="list-style-type: none"> Cytogenetics FISH Histology Immunohistochemistry Special Stains Sub-specialized pathology solutions 	<ul style="list-style-type: none"> Cytogenetics FISH Flow Cytometry Immunohistochemistry Morphology/ Histology Special Coagulation Testing 	<ul style="list-style-type: none"> Companion Diagnostics Hematologic NGS Solid Tumor NGS Precision Medicine 	

References

- Amatu A, SartoreBianchi A, Siena S. NTRK gene fusions as novel targets of cancer therapy across multiple tumour types. ESMO Open 2016;1:e000023. doi:10.1136/esmoopen-2015-000023.
- Hsiao S.J et al Detection of Tumor NTRK Gene Fusions to identify patients who may benefit from Tyrosine Kinase (TRK) Inhibitor Therapy.
- NCCN Guidelines, Non-Small Cell Lung Cancer, Version 3.2020.
- Drilon et al. Efficacy of Larotrectinib in TRK Fusion-Positive Cancers in Adults and Children. N Engl J Med. 2018 Feb 22;378(8):731-739.