MIB Testing & Research Directory

UNDERSTANDING TUMOR CHARACTERISTICS AND DRIVERS

STUDY/TEST	CONTACT	DESCRIPTION
Invitae Sarcoma Panel	(800) 436-3037 clientservices@invitae.com San Francisco, CA	Identifies hereditary predispositions to cancer (hereditary genetic sequence changes, deletions/duplications), which could reveal other cancer risks and indicate a more aggressive treatment plan. Does not look at genomic profile of the tumor. This test analyzes up to 41 genes that are associated with a hereditary predisposition to the development of sarcomas, a type of connective tissue tumor that can occur anywhere in the body. These genes were selected based on the available evidence to date to provide Invitae's most comprehensive hereditary sarcoma panel. Many of these genes are also associated with an increased risk of other cancer types. Genetic testing of these genes may confirm a diagnosis and help guide treatment and management decisions. Identification of a disease-causing variant would also guide testing and diagnosis of at-risk relatives. This test is specifically designed for heritable germline mutations and is not appropriate for the detection of somatic mutations in tumor tissue.
Dana-Farber/Boston Children's Pediatric Cancer Genetic Risk Program	617-632-4298 pedi_genetics@dfci.harvard.edu Boston, MA	The Pediatric Cancer Genetic Risk Program at Dana-Farber/Boston Children's provides cancer risk assessment for children, comprehensive recommendations for managing cancer risk in children, and psychosocial support for families affected by hereditary cancer. We also conduct research into many aspects of cancer risk and its management. We are one of the few cancer genetic risk programs in the U.S. focused specifically on pediatric cancer risk. Our goal is to help you determine whether your children are at risk of cancer – and if so, what can be done either to help prevent cancer in your children or to catch it early and address it quickly for the best possible outcome. (Note this is a clinical program)
NCI & Children's Oncology Group - Pediatric MATCH Trial (Molecular Analysis for Therapy Choice)	Check "Locations & Contacts"	NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice), also known as Pediatric MATCH, is a pediatric precision medicine cancer treatment trial that explores whether targeted therapies can be effective for children and adolescents with solid tumors that harbor specific gene mutations. Pediatric MATCH is a phase 2 trial that will investigate more than eight different study drugs, each targeting a defined set of gene mutations, in order to match patients with therapies aimed at the molecular abnormalities in his or her tumor. The trial has two enrollment steps. Each patient will initially enroll for a screening study, in which a sample of his or her relapsed tumor will undergo DNA and RNA sequencing to detect genetic abnormalities that could be targeted by one or more of the drugs being studied. Archived tumor samples can be used as long as they were obtained after the tumor progressed following initial treatment. If there is a genetic abnormality identified in the tumor and a drug in Pediatric MATCH that targets that abnormality, the patient can then enroll in the corresponding treatment arm if he or she meets the eligibility criteria. Pediatric MATCH will use a single sequencing test to screen for many molecular abnormalities at once. The test, which is also being used for the adult NCI-MATCH trial, was developed by the NCI Molecular Characterization Laboratory at the NCI Frederick National Laboratory for Cancer Research in Frederick, Maryland. The latest version of this test looks for alterations in more than 160 genes associated with cancer.
Dana-Farber/Boston Children's GAIN Consortium iCat2 study OncoPanel	617-632-4994 GainConsortium@dfci.harvard.edu 12 locations in the US	This research study is evaluating the use of specialized testing of solid tumors including sequencing. The process of performing these specialized tests is called tumor profiling. The tumor profiling may result in identifying changes in genes of the tumor that indicate that a particular therapy may have activity. This is called an individualized cancer therapy (iCat) recommendation. We have developed a cancer genomic assay to detect somatic mutations, copy number variations and structural variants in tumor DNA extracted from fresh, frozen or formalin-fixed paraffin-embedded samples. The OncoPanel assay surveys exonic DNA sequences of 447 cancer genes and 191 regions across 60 genes for rearrangement detection. This test is able to identify TP53 rearrangements, a gene change unique to osteosarcomas. Over 100 osteosarcoma patients have had sequencing performed and interpreted by the group leading this study.
Baylor College of Medicine/TX Children's Cancer Center Texas KidsCanSeq	832-824-4643 dwparson@txch.org 5 sites in TX	The Texas KidsCanSeq Study is building upon the previous success of the Baylor College of Medicine BASIC3 exome sequencing study to further investigate the application and utility of both germline and tumor sequencing tests in the care of childhood cancer patients. The study will compare the results of targeted cancer panel sequencing versus genome-scale testing (germline exome sequencing; tumor exome and transcriptome sequencing plus copy number array in high-risk and relapsed patients) across heterogeneous clinical settings in Texas. We will explore the clinical utility of these tests on treatment decisions (tumor testing), and the impact of diagnostic and/or actionable findings (germline testing) on cancer surveillance, genetic testing and healthcare utilization of first degree relatives. Our project, which encompasses the diverse patient population in Texas (emphasis on Hispanic individuals), will evaluate novel, culturally sensitive methods for consent and communication of complex genomic information to families and physicians. Results from the targeted DNA/RNA tumor mutation panels are available in ~2 weeks, while germline testing and integrated tumor testing (exome, transcriptome, copy number array) have a 2-3 month turnaround time Participating institutions (currently): Texas Children's Hospital (Houston), Vannie Cook Jr. Clinic (McAllen, TX), Cook Children's Hospital (Fort Worth), Children's Hospital of San Antonio, University of Texas Health San Antonio.
Children's Hospital Los Angeles OncoKids® Cancer Panel	323-361-7520 jrista@chla.usc.edu Los Angeles, CA	OncoKids® is a targeted gene panel intended to guide the diagnosis and treatment of cancer in pediatric patients based on the genomic alterations specific to their tumor. The DNA content of the OncoKids® panel consists of over 3,000 amplicons and covers the full coding regions of 44 cancer predisposition loci, tumor suppressor genes and oncogenes; hotspots for mutations in 82 genes; and amplification events in 24 genes. The RNA content includes over 1,400 targeted gene fusions associated with acute myeloid leukemia, acute lymphoblastic leukemia, childhood sarcomas, pediatric brain tumors and soft tissue tumors.
Ashion GEM ExTra®	844-539-3309 customerservice@ashion.com Phoenix, AZ	Ashion, a TGen® clinical lab, is a CAP-accredited and CLIA-certified clinical genomics testing laboratory. GEM ExTra® is a tumor profiling assay for solid tumors that characterizes the sequences of the patient's entire exome using a paired tumor/germline approach. DNA sequencing captures 19,396 genes as well as 169 introns, with double coverage of existing druggable gene targets. RNA sequencing of the entire transcriptome achieves sensitive detection of fusions and select special transcripts. Due to sequencing coverage and depth, it provides the most accurate and comprehensive genomic analysis available for clinical cancer testing, allowing the identification of all common and rare tumor alterations. In addition, the tumor mutational burden (TMB) and Microsatellite Instability (MSI) is reported, lending valuable information for immune-response interventions. The report provides the most comprehensive and up to date information on clinically actionable tumor mutations, copy number alterations, transcript variants, and fusions detected in the patient's DNA or RNA. This information is provided in a 14-day turnaround via an easy to interpret report indicating FDA approved therapies or clinical trial options appropriate to the patient. Ashion is an active partner with health systems to return data and participate in clinical trial research.
Caris Life Sciences Caris Molecular Intelligence	1-888-979-8669 Irving, TX CustomerSupport@carisls.com	The Caris Molecular Intelligence® comprehensive tumor profiling approach to assess DNA, RNA and Proteins reveals the highest quality molecular blueprint to guide more precise and individualized treatment decisions that is proven to extend overall survival. As the first and most experienced tumor profiling service, we provide results back in about 10-14 days* and to help you find better answers when you need it most. Caris Molecular Intelligence uses multiple tumor profiling technologies to decode cancer. This technology agnostic, panomic approach allows our medical teams to more fully understand the biology of the tumor – therefore helping oncologists' better plan their attack. MI Tumor Seek™ includes NGS (DNA mutations, copy number alterations*, insertions/deletions, genomic signatures: MSI, TMB*), whole transcriptome sequencing* (RNA fusions and variant transcripts), pyro sequencing, IHC, in situ hybridization. MI Profile™ includes those services plus pyro sequencing, IHC, and in situ hybridization. ** Not available in New York State.*
Foundation Medicine Foundation One Heme	(888) 988-3639 client.services@foundationmedicine.com Cambridge, MA	FoundationOne®Heme is a comprehensive genomic profiling test designed to identify genomic alterations in patients with hematologic malignancies and sarcomas. Test results provide information about clinically relevant alterations and biomarkers, potential targeted therapies or immunotherapies, and available clinical trials. FoundationOne Heme combines DNA and RNA sequencing. The DNA panel includes 406 genes and the RNA panel includes 265 genes. The combination of DNA and RNA sequencing enables efficient detection of fusions. The test is validated to detect the four main classes of genomic alterations (substitutions, indels, CNAs and rearrangements). For additional patient resources, please go to: www.foundationmedicine.com/patients.
Foundation Medicine Foundation One Liquid	(888) 988-3639 client.services@foundationmedicine.com Cambridge, MA	FoundationOne Liquid helps guide cancer care from a simple blood draw. This liquid biopsy test provides targeted gene and microsatellite instability (MSI) results that can help direct therapy selection and clinical trial options for advanced-stage cancer patients using a minimally invasive sample type. By analyzing ctDNA with our comprehensive genomic profiling approach (70 genes) and providing expertly curated reports, FoundationOne Liquid empowers providers to make more informed clinical decisions even when tissue is not ideal. While tissue DNA samples are recommended for osteosarcoma patients, in cases where there is progressive disease and tissue is unavailable (unresectable tumor), a blood sample to sequence DNA via liquid biopsy may provide and opportunity for genomic sequencing insight.
Guardant360	855.698.8887 Redwood City, CA clientservices@guardanthealth.com	For oncologists, Guardant360 provides comprehensive genomic results from a simple blood draw in approximately seven days, helping them move beyond the limitations of tissue biopsies to match patients with the best treatments. Obtaining clinically relevant genomic information through a blood draw helps them avoid an additional tissue or surgical biopsy and moves beyond the limitations of tissue specimens. Guardant360 covers all genes recommended for profiling by the National Comprehensive Cancer Network, including the 74 genes most relevant to clinical care. While tissue DNA samples are recommended for osteosarcoma patients, in cases where there is progressive disease and tissue is unavailable (unresectable tumor), a blood sample to sequence DNA via liquid biopsy may provide and opportunity for genomic sequencing insight.
Tempus xT	833.514.4187 Chicago, IL support@tempus.com	The Tempus xT somatic variant calling assay is a targeted sequencing panel designed to detect actionable oncological targets by sequencing tumor samples and matched normal saliva or blood samples, when available. The third version of the xT assay (v3) detects 648 total genes spanning 3.6 Mb of genomic space. This includes coverage for single nucleotide variants (SNVs) and insertions/deletions (indels) events, fusion events in 24 genes, two gene promoters (PMS2 and TERT) and 239 sites for microsatellite instability. The fusion events target all current biomarkers for FDA approved drugs and several drugs in clinical trials. From whole transcriptome RNA sequencing, additional gene fusions are detected in a clinically validated, comprehensive and unbiased manner (all genes fused with known and novel partners). In addition, tumor mutational burden (TMB) and microsatellite Instability (MSI) status are also reported. Some viral sequences, such as HPV and EBV, can be reported as an insight when deemed appropriate.
Tempus xE	833.514.4187 Chicago, IL support@tempus.com	Tempus xE is a whole-exome DNA sequencing assay that analyzes the entire coding region (exome) of ~19,400 genes in the patient tumor and matched normal specimens (spanning ~39 Mb of genomic space) combined with whole transcriptome RNA sequencing in tumor specimen only. It is optimized for formalin fixed paraffin embedded (FFPE) tumor tissue samples. The FFPE tumor tissue is matched to a normal blood or saliva sample to ensure fidelity of somatic variant calling. The xE assay identifies actionable both oncogenic variants and resistance mutations. From DNA sequencing, the xE bioinformatics pipeline calls both somatic and incidentally detected germline single nucleotide variants (SNVs), insertions and deletions (indels), and copy number alterations (CNAs). From RNA sequencing, gene fusions in tumor specimens are detected in an unbiased and comprehensive manner (all genes fused with known and novel partners). In addition, tumor mutational burden (TMB) is reported in a clinically validated manner. However, microsatellite Instability (MSI) status has not been clinically validated with the Tempus xE assay, but is available in the portal for clinical orders as a research use only metric.
Tempus xF	833.514.4187 Chicago, IL support@tempus.com	The non-invasive Tempus xF liquid biopsy assay detects cell-free, circulating tumor DNA (ctDNA) in blood specimens of advanced solid tumor patients. The assay is capable of detecting mutations in two variant classes in 105 genes, including: single nucleotide variants (SNVs) and insertion-deletions (indels), as well as copy number variants (CNVs) in 6 genes, and chromosomal rearrangements in 7 genes, covering ~0.3 Mb of genomic space. Microsatellite instability High (MSI-H) status is also reported when detected. The panel is designed to provide clinical decision support for patients with solid tumors and is focused on the identification of oncogenic and resistance mutations.

STUDY/TEST	Institution		Test Type				Eligibility				Sample Accepted					Lead Time			Cost			
	Commercial	Research	Germline	Targeted Panel	WES	RNA-Seq	Open	Physician Order	Patient of Record*	Age Restriction	Blood	Saliva	FFPE	Fresh Tissue	Frozen Tissue	≥2 weeks	≥1 month	≥3 months	None	Some Out of Pocket	Financial Assistance	Insurance Billed**
Invitae Sarcoma Panel	●		●					●			●	●					●			●		●
Dana-Farber/Boston Children's Pediatric Cancer Genetic Risk Program		●	●				●				●						●		●			●
NCI & Children's Oncology Group - Pediatric MATCH Trial (Molecular Analysis for Therapy Choice)		●	●	●						≤21 yrs	●		●			●			●			
Dana-Farber/Boston Children's GAIN Consortium iCat2 study OncoPanel		●	●	●						≤30 yrs	●		●	●	●		●		●			
Baylor College of Medicine/TX Children's Cancer Center Texas KidsCanSeq		●		●	●	●			●	<18 yrs	●		●			●		●	●			
Children's Hospital Los Angeles OncoKids® Cancer Panel		●		●				●	●		●		●	●	●		●					●
Ashion GEM ExTra®	●				●	●		●			●	●	●	●	●	●				●	●	●
Caris Life Sciences Caris Molecular Intelligence	●		●	●	●	●		●			●		●	●		●				●	●	●
Foundation Medicine Foundation One Heme	●			●		●		●			●		●			●				●	●	●
Foundation Medicine Foundation One Liquid	●			●				●			●					●				●	●	●
Guardant360	●			●				●			●					●				●	●	●
Tempus xT	●			●		●		●			●	●	●	●	●	●				●	●	●
Tempus xE	●				●	●		●			●	●	●	●	●		●			●	●	●
Tempus xF	●			●				●			●					●				●	●	●

**Must be registered patient at that institution*

***Note that while the provider may attempt to bill insurance, it is helpful to understand your insurance coverage to avoid unexpected bills as the insurance company may deny coverage and the patient would be responsible for any costs.*

IMPORTANT NOTE: *MIB does not independently verify information submitted to the MIB; it relies on submitters to provide information that is accurate and not misleading. MIB makes no endorsements of tests or laboratories listed in the MIB Testing & Data Directory. MIB is not a substitute for medical advice. Patients and families with specific questions about a genetic test should contact a healthcare provider or a genetics professional.*

MIB AGENTS — MAKE IT BETTER FOR KIDS WITH OSTEOSARCOMA

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