

Genetics Associates, LLC Informed Consent for Genetics Testing

Availability of Genetic Counseling

Participation in genetic testing is completely voluntary. Patients or their authorized representative may wish to obtain genetic counseling prior to giving consent to fully understand what the risks and benefits are to having the testing completed. Genetic counseling may also be recommended after testing is completed.

Karyotype Analysis

Description: Karyotype analysis is a test that evaluates the number, size, and condition of chromosomes, the structures that contain the body's genetic blueprint.

Purpose: This test can help identify cytogenetic problems as the cause of a disorder or disease.

Limitations: Very small or cryptic abnormalities, complex aberrations, and marker chromosomes may not be accurately identified or fully characterized.

Fluorescence In Situ Hybridization (FISH)

Description: FISH is a specialized technique that uses fluorescently labeled DNA fragments that bind to a person's DNA to detect and locate the presence, number, or structure of a specific DNA sequence on a chromosome.

Purpose: This test is utilized to diagnose genetic diseases and identify chromosomal abnormalities. FISH can detect abnormalities that are too small to be detected by standard cytogenetic analysis.

Limitations: FISH can only detect deletions or duplication of regions specifically targeted by the probe used and which are larger than the probe used. It is recommended that FISH be used as an adjunct to chromosome analysis or chromosomal microarray.

Purpose for Test (to be filled in by the ordering healthcare provider)

Recommended Test: Karyotype Analysis FISH Analysis

The above marked test is performed to help diagnose: _____

Test Results

A positive test result is an indication that an individual may be predisposed to or have the specific disease(s) or condition(s) tested for.

A normal test result does not exclude the possibility that an individual has a genetic condition which is not evaluable by conventional cytogenetics or FISH.

There may be the possibility that the laboratory findings will be uninterpretable or of unknown significance. In rare circumstances, findings may be suggestive of a condition different than the diagnosis that was originally considered.

Upon receipt of results, an individual may consider further independent testing, consult their physician or pursue genetic counseling.

Disclosure of Test Results

All tests are confidential and will be disclosed only to the ordering provider or their designated representative unless otherwise authorized by the patient or patient's authorized representative in writing or required by law.

Retention and Additional Testing

Genetics Associates, LLC does not return any remaining sample to individuals or physicians unless requested.

No clinical tests other than those authorized shall be performed on the sample. The sample will be destroyed at the end of the testing process or not more than 60 days after the sample was collected unless a longer period of retention is expressly authorized in writing.

Additional testing may only be performed if written authorization is granted. If authorization is granted, the remaining sample may be retained longer than 60 days after collection and be used as a de-identified sample for test development and improvement, internal validation, quality assurance, and training purposes.

By checking this box and signing below, I consent for Genetics Associates, LLC keeping my sample indefinitely and to using the de-identified sample for test development and improvement, internal validation, quality assurance, and training purposes.

Patient and Ordering Provider Information

Patient Name: _____ Patient ID/Medical Record Number: _____

Patient Date of Birth: _____ Ordering Provider Name: _____

Consent for Testing

Patients (or their authorized representative) must provide their written informed consent prior to receiving genetic testing.

When signed and dated, this written consent is written authorization to participate in the genetic testing described above.

Signature of Patient: _____ Date: _____

Signature of Authorized Representative: _____ Date: _____

Relationship of Authorized Representative (if signing on behalf of patient): _____

Ordering Provider: I have explained this genetic test, its risks, benefits, and alternatives to the patient or authorized representative.

Signature of Ordering Provider: _____ Date: _____