FXIII G103T POLYMORPHISM

For in vitro diagnostic use

CE IVD

ORDERING INFORMATIONS

REF: GEN-012-25 RDM Code: 1737859/R
Tests: 25 Reactions: 31
REF: GEN-012-50 RDM Code: 2164384/R
Tests: 50 Reactions: 62
CND Code: W0106010499
Manufacturer: BioMol Laboratories s.r.l.

CONTENTS OF THE KIT

The kit consists of: reagents for Real-Time PCR amplification
**reagents for the extraction of genomic DNA are not supplied in the kit*

PRODUCT CHARACTERISTICS

Detection of G103T polymorphism of the FXIII gene by Real-Time PCR technique. Kit optimized for Real-Time PCR instrumentation Biorad CFX96 Dx, Biorad Opus Dx and Agilent AriaDx.

SCIENTIFIC BACKGROUND

Several genetic alterations, in particular those affecting physiological anticoagulants (antithrombin III, proteins C and S) and the procoagulant systems (factor V Leiden, prothrombin, fibrinogen), have been identified as risk factors for venous thromboembolism.
Coagulation factor XIII (FXIII) is a transglutaminase that plays an important role in the final stage of blood coagulation, where it catalyzes the formation of covalent bonds between fibrin monomers to produce clot stabilization and resistance to fibrinolysis.
Hereditary FXIII deficiency causes severe bleeding and a high risk of miscarriage in women with the homozygous mutation.
Although several polymorphisms have been identified in the gene encoding the FXIII A subunit (Val34Leu, Pro564Leu, Val650Ile and Glu651Gln), the Val34Leu polymorphism is the most important functional polymorphism capable of influencing FXIII activation. This polymorphism is a G>T substitution at position 103 in exon 2, three amino acids away from the thrombin cleavage site that occurs in Arg37-Gly38. The release of the activating peptide is accelerated in this genetic condition. The less frequent allele (Leu34) has been described as a protective factor against myocardial infarction and venous thrombosis.

CLINICAL SIGNIFICANCE

Venous thromboembolism (VTE), usually involving deep vein thrombosis, pulmonary embolism, or both, is a complex, multifactorial disorder in which a number of conditions interact and contribute to increased individual risk culminating in the development of venous occlusives. Thrombophilia is commonly defined as a propensity to develop venous thromboembolism based on a hypercoagulable condition attributable to inherited or acquired disorders involving blood clotting or fibrinolysis.

§ Association of the F13A1 Val34Leu polymorphism and recurrent pregnancy loss: A meta-analysis. Eur J Obstet Gynecol Reprod Biol. 2017 Aug;215:234-240. doi: 10.1016/j.ejogrb.2017.06.032. Epub 2017 Jun 23.

§ Genetic association between FXIII and β-fibrinogen genes and women with recurrent spontaneous abortion: a meta- analysis. J Assist Reprod Genet. 2015 May;32(5):817-25. doi: 10.1007/s10815-015-0471-9. Epub 2015 Apr 11.

§ Risk for early pregnancy loss by factor XIII Val34Leu: the impact of fibrinogen concentration. J Clin Lab Anal. 2013 Nov;27(6):444-9. doi: 10.1002/jcla.21626.

§ Effect of factor XIII levels and polymorphisms on the risk of myocardial infarction in young patient. Balogh L, Mol Cell Biochem. 2018 Feb 26.

§ Association of the F13A1 Val34Leu polymorphism and recurrent pregnancy loss: A meta-analysis. Eur J Obstet Gynecol Reprod Biol. 2017 Aug;215:234-240

§ Blood coagulation factor XIII-A subunit Val34Leu polymorphisms and intracerebral hemorrhage risk: A meta-analysis of case-control studies. Br J Neurosurg. 2015;29(5):672-7.

BIOMOL LABORATORIES S.R.L.
Via Arcora 110 (Palazzo Gecos)
80013 Casalnuovo di Napoli, NA
info@biomollaboratories.com
biomollaboratories.it

ISO 9001:2015
ISO 13485:2016

BioMol LABORATORIES

FXIII G103T POLYMORPHISM

For in vitro diagnostic use

CE IVD

ORDERING INFORMATIONS

REF: GEN-012-25 RDM Code: 1737859/R
Tests: 25 Reactions: 31
REF: GEN-012-50 RDM Code: 2164384/R
Tests: 50 Reactions: 62
CND Code: W0106010499
Manufacturer: BioMol Laboratories s.r.l.

CONTENTS OF THE KIT

The kit consists of: reagents for Real-Time PCR amplification
**reagents for the extraction of genomic DNA are not supplied in the kit*

CONTENTS OF THE KIT

DESCRIPTION	LABEL	VOLUME		STORAGE
		GEN-012-25	GEN-012-50	
Mix oligonucleotides and probes	Mix Val34Leu FXIII 10X	1 x 85 µl	1 x 170 µl	-20°C
Mix buffer and Taq-polymerase enzyme	Mix Real-Time PCR 2X	1 x 425 µl	1 x 850 µl	-20°C
Deionized H_20	Deionized H_20	2 x 1 ml	2 x 1 ml	-20°C
Genomic DNA or recombinant DNA	Control +1	1 x 22µl	1 x 22 µl	-20°C
Genomic DNA or recombinant DNA	Control +2	1 x 22µl	1 x 22µl	-20°C
Genomic DNA or recombinant DNA	Control +3	1 x 22 µl	1 x 22 µl	-20°C

TECHNICAL CHARACTERISTICS

COD. GEN-012-25 / COD. GEN-012-50

STABILITY	18 months
REAGENTS STATUS	Ready to use
BIOLOGICAL MATRIX	Genomic DNA extracted from whole blood, tissue, cells
POSITIVE CONTROL	Recombinant DNA for at least 3 analytical sessions
VALIDATED INSTRUMENTS	Biorad CFX96 Dx, Biorad Opus Dx e Agilent AriaDx
TECHNOLOGY	Real-time PCR; oligonucleotides and specific probes; 2 FAM/HEX fluorescence channels
RUNNING TIME	85 min
THERMAL CYCLING PROFILE	1 cycle at 95 °C (10 min); 45 cycles at 95 °C (15 sec) + 60 °C (60 sec)
ANALYTICAL SPECIFICITY	Absence of non-specific pairings of oligonucleotides and probes; absence of cross-reactivity
ANALYTICAL SENSITIVITY : LIMIT OF DETECTION (LOD)	≥ 0,016 ng of DNA
ANALYTICAL SENSITIVITY : LIMIT OF BLANK (LOB)	0% NCN
REPRODUCIBILITY	99,9%
DIAGNOSTIC SPECIFICITY / DIAGNOSTIC SENSITIVITY	100%/98%

BIOMOL LABORATORIES S.R.L.
Via Arcora 110 (Palazzo Gecos)
80013 Casalnuovo di Napoli, NA
info@biomollaboratories.com
biomollaboratories.it

ISO 9001:2015
ISO 13485:2016

BioMol LABORATORIES