(ACE I/D) INS/DEL POLYMORPHISM (ANGIOTENSIN-CONVERTING ENZYME)

For in vitro diagnostic use

CE IVD

ORDERING INFORMATIONS

REF: GEN-035-25 RDM Code: 2159760/R
Tests: 25 Reactions: 31
REF: GEN-035-50 RDM Code: 2165040/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 the nucleotide polymorphism insertion (allele I) or deletion (allele D) in intron 16 of the gene encoding the human angiotensin converting enzyme (ACE) by Real-Time PCR technique. Optimized kit for Real-Time PCR instrumentation Biorad CFX96 Dx, Biorad Opus Dx, Agilent AriaDx, Hyris bCUBE and Hyris bCUBE3 with Hyris bAPP.

SCIENTIFIC BACKGROUND

The renin-angiotensin-aldosterone system (SRAA) is a hormonal system that regulates blood pressure, circulating plasma volume, arterial muscle tone through various mechanisms and aldosterone secretion; it also plays an important role in the etiology of hypertension. There are numerous components of this system: renin, prorenin, angiotensin converting enzyme (ACE), angiotensinogen (AGT), angiotensin I and angiotensin II; the latter represents the final effector of the renin-angiotensin system and exerts its effects on the cardiovascular system through binding with specific receptors.

§ Gynecol Endocrinol 2017; 33 (sup1):32-35. doi: 10.1080/09513590.2017.1404237. Genetic and hemostasiological predictors of IVF pregnancy.

§Antihypertensive pharmacogenetic effect of fibrinogen-beta variant -455G>A on cardiovascular disease, end-stage renal disease, and mortality: the GenHAT study. Pharmacogenet Genomics. 2009 Jun; 19 (6):415-21.

§ Analysis of the effect of multiple genetic variants of cardiovascular disease risk on insulin concentration variability in healthy adults of the STANISLAS cohort. The role of FGB-455 G/A polymorphism. Atherosclerosis. 2007 Apr; 191 (2):369-76.

CLINICAL SIGNIFICANCE

The first step in the enzymatic cascade leading to the production of angiotensin II is the conversion of angiotensinogen to angiotensin I by the proteolytic enzyme renin. The second step in the process involves the conversion of angiotensin I to angiotensin II, via a reaction catalysed by ACE. Angiotensin II is the main active peptide of the RAAS which functions through at least four types of receptors. The AGTR1 receptor mediates cardiovascular effects, including vasoconstriction, aldosterone synthesis, vasopressin secretion, vascular smooth muscle cell proliferation, renal blood flow, regulation of renin activity, renal sodium absorption, modulation of sympathetic nervous system activity and cardiac function.The renin-angiotensin system (SRAA) also exerts local effects on cell proliferation, apoptosis, inflammation and angiogenesis in various tissues. Furthermore, there are data in the literature correlating SRAA with tumor tumorigenesis and angiogenesis. There are genetic polymorphisms in the various components of the RAS that may have clinical relevance.The insertion/deletion (I/D) of the ACE gene is directly associated with the circulatory level of the enzyme itself. Consequently, the I/D polymorphism influences the risk of cardiovascular complications, of developing diabetic nephropathy and obesity. A recent meta-analysis also reported a significant association between I/D polymorphisms and recurrent miscarriages. Women with the ACE “DD” or “ID” genotypes have a higher risk of experiencing recurrent pregnancy loss.

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ISO 9001:2015
ISO 13485:2016

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DESCRIPTION	LABEL	VOLUME		STORAGE
		GEN-035-25	GEN-035-50	
Mix oligonucleotides and probes	Mix PCR ACE I/D 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 HOMO DD	1 x 22 µl	1 x 22 µl	-20°C
Genomic DNA or recombinant DNA	Control +2 HET ID	1 x 22 µl	1 x 22 µl	-20°C
Genomic DNA or recombinant DNA	Control +3 HOMO II	1 x 22 µl	1 x 22 µl	-20°C

TECHNICAL CHARACTERISTICS

COD. GEN-035-25 / COD. GEN-035-50

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, Agilent AriaDx, Hyris bCUBE and Hyris bCUBE3 with Hyris bAPP.
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 at (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%

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