Y CHROMOSOME MICRODELETIONS (AZFa, AZFb, AZFbc, AZFc)

For in vitro diagnostic use

CE IVD

ORDERING INFORMATIONS

REF: GR-011-25-AG
RDM Code: 1694068/R
Tests: 25
Reactions: 31 x 2
CND Code: W01060299
Manufacturer: BioMol Laboratories s.r.l.

CONTENT OF THE KIT

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

PRODUCT CHARACTERISTICS

Detgection of presence/absence of the Y chromosome microdeletions (AZFa, AZFb, AZFbc, AZFc) and detection on agarose gel or capillary electrophoresis. Kit optimized for any CE-IVD marked thermal cycler and on capillary electrophoresis QIAxcel Advanced System (Qiagen).

SCIENTIFIC BACKGROUND

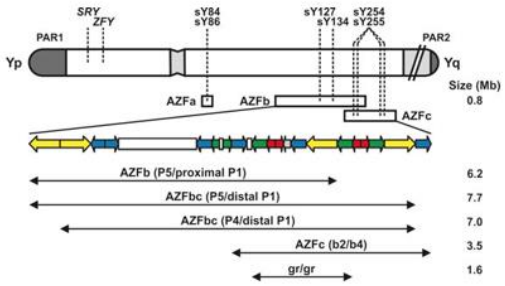
Male infertility can be attributed to several factors such as cryptorchidism, varicocele, endocrinological disorders, obstruction/absence of seminal ducts, infections, alcohol consumption or chemotherapy. However, genetic alterations have also emerged as a major cause of male infertility. Genetic defects commonly seen in infertile males include karyotypic abnormalities, gene copy number variations, single gene mutations/polymorphisms, and deletions on the long arm of the Y chromosome. Y chromosomal microdeletions are the second most frequent genetic cause of male infertility. Microdeletions occur in approximately one in 4,000 men in the general population, but their frequency is significantly increased among infertile men. Molecular diagnosis of Y chromosomal microdeletions is a genetic test that is part of routine diagnostics in the study of azoospermic and severe oligozoospermic men.

The following recurrent Y chromosome microdeletions are clinically relevant and have been found in men with severe oligo- or azoospermia: AZFa, AZFb (P5/proximal P1),AZFbc (P5/distal P1 or P4/distal P1), AZFc (b2/ b4). The most frequent type of microdeletion is that of the AZFc region (~80%) followed by the microdeletions AZFa (0.5-4%, AZFb (1-5%) and AZFbc (1-3%).

CLINICAL SIGNIFICANCE

Y chromosome microdeletions are the second most frequent cause of failure of spermatogenesis in infertile men. The incidence of these microdeletions in infertile subjects reported in the literature is about 2-10%. However, it is higher in azoospermic men than in oligozoospermic men.

It is clinically appropriate to consider Y deletions as a cause of oligo/azoospermia rather than a cause of "infertility", fertility being possible even with a low sperm count.



§ EAA/EMQN best practice guidelines for molecular diagnosis of y-chromosomal microdeletions. State of the art 2004. Int J Androl 27, 240–249.

§ EAA/EMQN best practice guidelines for molecular diagnosis of Y-chromosomal microdeletions: state-of-the-art 2013. Andrology. 2014 Jan;2(1):5-19. doi:

10.1111/j.2047-2927.2013.00173.x. Review.

§ Genetics of the human Y chromosome and its association with male infertility. Reprod Biol Endocrinol. 2018 Feb 17;16(1):14.

doi: 10.1186/s12958-018-0330-5

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ISO 9001:2015
ISO 13485:2016

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DESCRIPTION	LABEL	VOLUME	STORAGE
		GR-011-25-AG	-20°C
Oligonucleotides mix	Mix Multiplex A 2X	1 x 450 µl	-20°C
Oligonucleotides mix	Mix Multiplex B 2X	1 x 450 µl	-20°C
Amplifying enzyme	Taq polymerase (5U/µl)	1 x 35 µl	-20°C
Deionized H_20	Deionized H_20	2 x 1 ml	-20°C
Genomic DNA or recombinant DNA	Positive control XX	22 µl	-20°C
Genomic DNA or recombinant DNA	Positive control XY	22 µl	-20°C
Disclosure kit	Ready to use 3% Nusieve agarose gel, TBE buffer, molecular weight markers		RT

TECHNICAL CHARACTERISTICS

COD. GR-011-25-AG

STABILITY	18 months
REAGENTS STATUS	Ready to use
BIOLOGICAL MATRIX	Genomic DNA from whole blood, tissue, cells
POSITIVE CONTROL	Recombinant DNA for at least 3 analytical sessions
VALIDATED INSTRUMENTS	Thermal cycler for end-point PCR, heated cap
TECHNOLOGY	PCR (polymerization chain reaction)
RUNNING ON AGAROSE GEL	Electrophoretic running equipment
THERMAL CYCLING PROFILE	1 cycle at 95 °C (15 min); 35 cycles at 95 °C (30 sec) +57 °C at (90 sec) + 72 °C at (60 sec); 1 cycle 72 °C (10 min)
ANALYTICAL SPECIFICITY	Absence of non-specific primer pairings; absence of cross-reactivity
ANALYTICAL SENSITIVITY: LIMIT OF DETECTION (LOD)	≥ 2,5 ng of DNA
ANALYTICAL SENSITIVITY: LIMIT OF BLANK (LOB)	0% NCN
REPRODUCIBILITY	99,9%
DIAGNOSTIC SPECIFICITY / DIAGNOSTIC SENSITIVITY	100%/98%

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