FAQs

What is the test for?

Tests for the the presence of microdeletions of AZFa, AZFb and AZFc regions of Y chromosome.

Why more than 6 STSs detection is not necessary?

* Based on the experience of many laboratories, the results of external quality control and considering the multiplex PCR format, the first choice of STS primers recommended in the previous versions of the guidelines remains valid. These primers include:

For AZFa: sY84, sY86 For AZFb: sY127, sY134

For AZFc: sY254, sY255 (both in the DAZ gene)

- * Novel methods and kits with excessively high number of markers do not improve the sensitivity of the test, may even complicate the interpretation of the results and are not recommended.
- * There are commercial kits on the market, which, however, almost all contain an unnecessary high number of markers. This may lead to detection of 'false' deletions, especially if the DNA quality and PCR conditions are suboptimal.

How to collect the specimen?

At least 2.5ml whole blood in an EDTA (Lavender top) tube, store the blood at 2-8°C for 1 week or at -18-20°C for 6 weeks.

Why Real-time PCR method?

- * The Diagnostics of Y-chromosomal microdeletions should be performed by multiplex(at least duplex) PCR amplification of genomic DNA, using the ZFX/ZFY as internal PCR control. A DNA sample from a fertile male and from a women and a blank(water) control should be run in parallel with each multiplex.
- * Real time PCR has the advantage of being relatively fast because the protocal does not involve running an agrose gel.
- Higher cost-effective than micro-array technology.

What is the indications for testing?

- Male infertility
- Azoospermia or oligozoospermia
- Abnormality of sperm morphology
- Abnormality of sperm motility
- Spouse with unexplained habitual miscarriage.

Why no AZFd detection?

* What is important for the diagnosis is that the panel of STS primers is derived from regions of the Y chromosome which are not polymorphic and are well-known to be deleted specifically in men affected by oligo-/azoospermia according to the known, clinically relevant microdeletion pattern. The sequence of the MSY and the mechanism underlying the microdeletions have shown definitely that a putative fourth AZFd region postulated by Kent-First et al. (1999) (and considered in a popular commercial kit) does not exist.

What is the advantages of testing?

Influence clinical management

- Men with deletions in AZFa, AZFb,AZFb+c, AZFa+b+c should be fully informed about the very low /virtually zero chance to retrieve spermatozoa.
- Men with deletions in AZFc causing a zoospermia have 50% success rate for sperm retrieval.

Determines risks to offspring

- Male offspring of men with AZFc deletions conceived following sperm retrieval will inherit their father's microdeletion and will have a high risk for infertility.
- * Content is from the EAA/EMQN best guideline 2013

Product Details

| Catalogue No. | Product | Kit Size | Store |
|---------------|--|--------------|------------------|
| PGA7001Y4 | Y6(Y-Chromosomal Microdeletions Detection Kit) | 20 tests/kit | Room temperature |

Patent Application Number: CN201510141295



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Y-Chromosomal Microdeletions Detection Kit Real-Time PCR method



Y-Chromosomal Microdeletions Detection Kit

Y-Chromosomal Microdeletions are the second most frequent genetic cause of male infertility.

*According to WHO statistics that 15% couples were suffering from infertility.

*Over 30% of them are caused by genetic abnormalities.

*After the Klinefelter syndrome, Y-chromosomal microdeletions are the second most frequent genetic cause of male infertility

*Y chromosome infertility occurs in approximately 1 in 2000 to 1 in 3000 males of all ethnic groups, This condition accounts for between 5 percent and 10 percent of cases of azoospermia or severe-oligospermia.





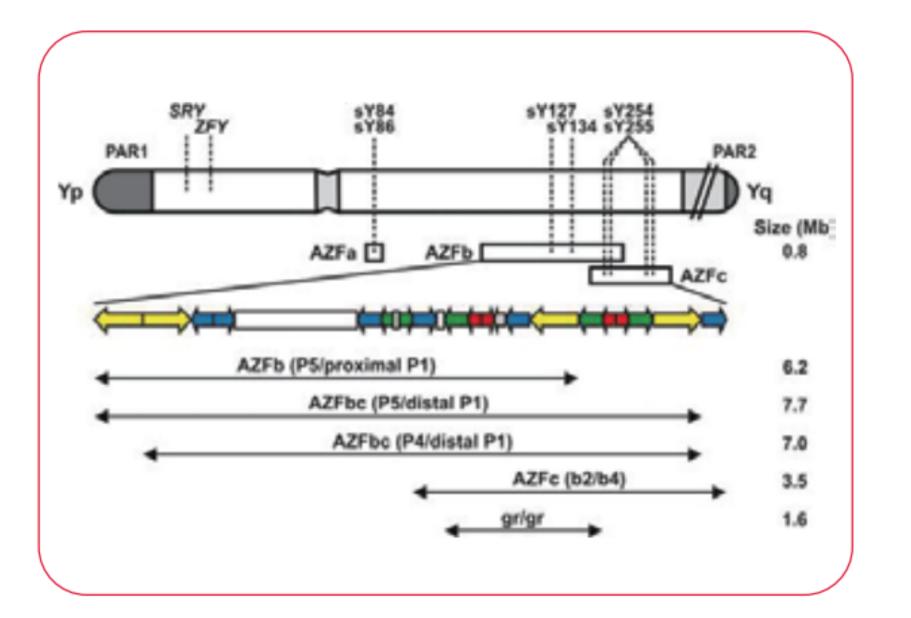


Microdeletions of any AZFa,AZFb,AZFc regions associated with spermatogenic function on Y chromosome will caused the spermatogenesis dysfunction.

According to the present knowledge, the following recurrent microdeletions of the Y chromosome are clinically relevant and are 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 deletion type is the AZFc region deletion (~80%) followed by AZFa (0.5–4%), AZFb (1–5%) and AZFbc(1–3%) deletion. Deletions which are detected as AZFabc are most likely related to abnormal karyotype such as 46,XX male or iso(Y).



Tellgen Y6

Detection sites

In 2013, the European Academy Of Andrology (EAA) and European Molecular Genetic Quality Network(EMQN) have published the now best practice guidelines for Y-chromosome microdeletion testing.

| STS | sY84 | sY86 | sY127 | sY134 | sY254 | sY255 |
|------------|----------|----------|-------|----------|----------|-------|
| EAA/EMQN | • | ~ | ~ | 1 | 1 | ~ |
| Tellgen Y6 | V | " | ~ | / | V | ~ |



Detection method

Real-time PCR

Control set up

Kit include a control (normal male sample), a negative control (ddH20)

Internal control

ZFX/ZFY \ SRY gene: Monitor the whole procedure from sample extraction to PCR result.

Compatible instrument

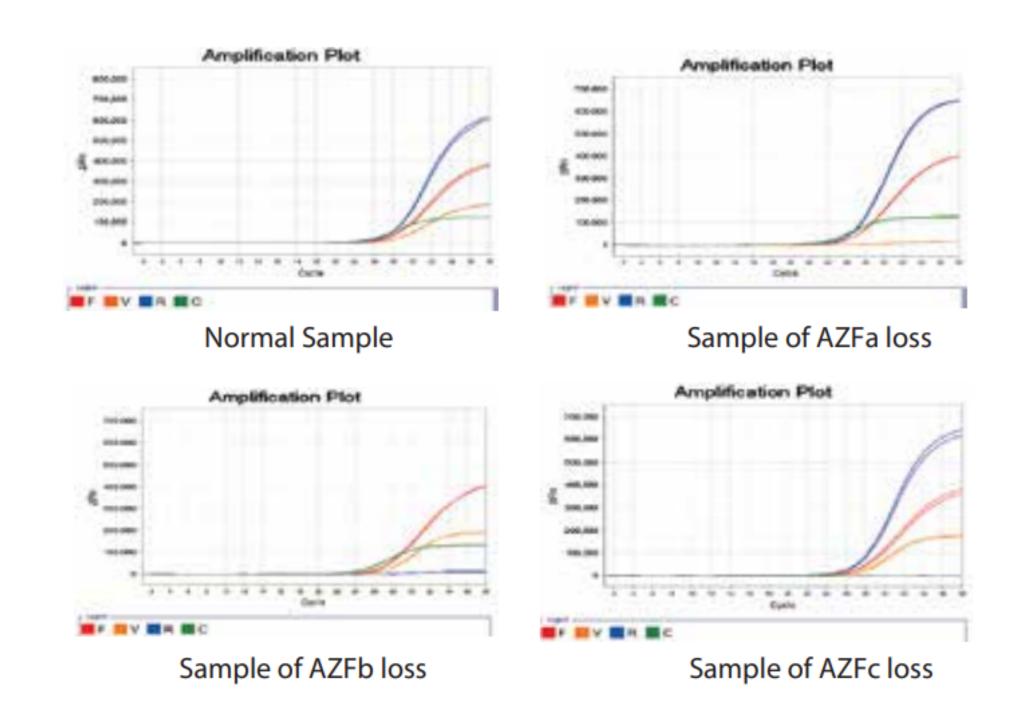
The kit can work on the open real time PCR machine with following florescence channels:

* FAM * VIC/HEX * ROX * CY5

Simple operation



Detection result reading



Product Details

| | Channel | Detection Site | Remark | |
|---------|---------|----------------|---------|--|
| Group A | FAM | SRY | Control | |
| | VIC | sY84 | AZFa | |
| | ROX | sY127 | AZFb | |
| | Cy5 | sY255 | AZFc | |
| Group B | FAM | ZFX/ZFY | Control | |
| | VIC | sY86 | AZFa | |
| | ROX | sY134 | AZFb | |
| | Cy5 | sY254 | AZFc | |