

Recurrent Pregnancy Loss Screening

Yourgene® QST*^R Pregnancy Loss



The Yourgene® QST*^R Pregnancy Loss assay is used for the routine *in vitro* quantitative diagnosis of the six most common autosomal trisomies associated with pregnancy loss: Patau's syndrome (T13), T15, T16, Edwards' syndrome (T18), Down's syndrome (T21) and T22. The kit also includes X and Y chromosome markers and the TAF9L marker for the determination of sex status. The results obtained from the Yourgene® QST*^R Pregnancy Loss assay will determine the aneuploidy status of the fetus and may be useful in the management of the consequences resulting from the spontaneous miscarriage and for modification of risk calculations for future pregnancies. Yourgene® QST*^R Pregnancy Loss employs the commonly used QF-PCR (Quantitative Fluorescence-Polymerase Chain Reaction) technique. The kit is intended to be used on DNA extracted from Products of Conception.

Key Benefits

Simple to set up

- Using established Applied Biosystem instrumentation and dye sets
- One tube per sample, reduced risk of sample mix up
- One step protocol, fewer consumables and reduced cost

Rapid turnaround time

- Individual results can be obtained within a few hours of receipt of samples

Simple analysis

- No post-PCR manipulation required
- Highly informative – multiplexed 5 dye chemistry
- Easy to understand single page report using GeneMapper™ or GeneMarker® software within minutes

QF-PCR based assay

- Simple to use
- Low failure rates
- Ability to identify material genome contamination

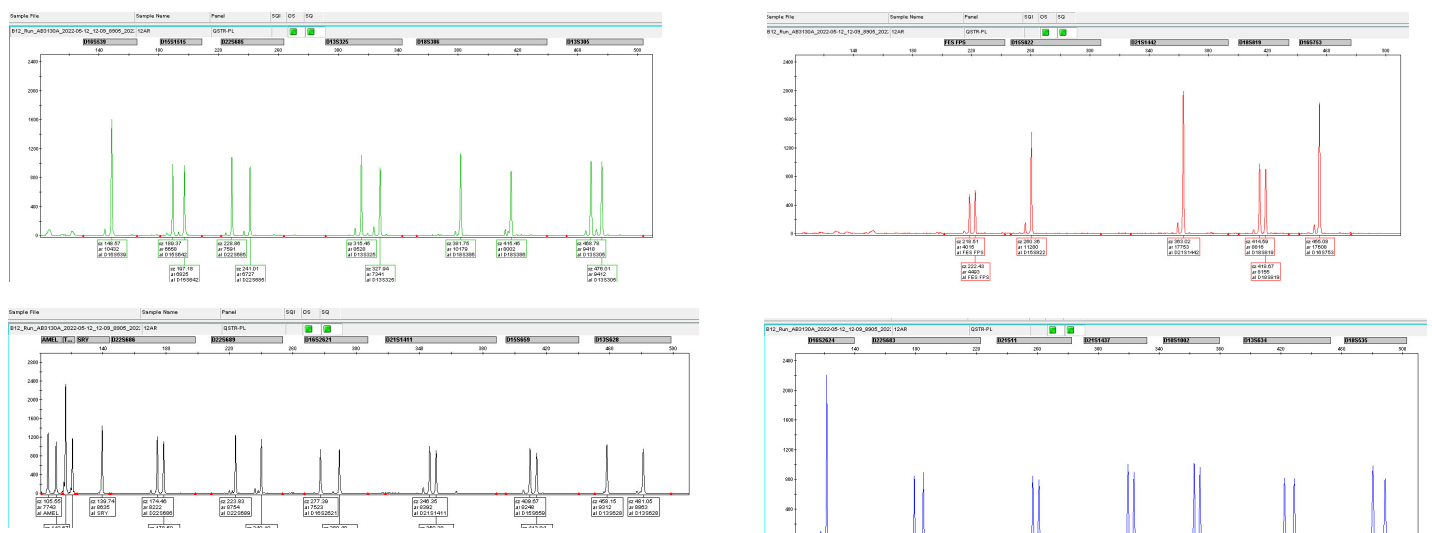
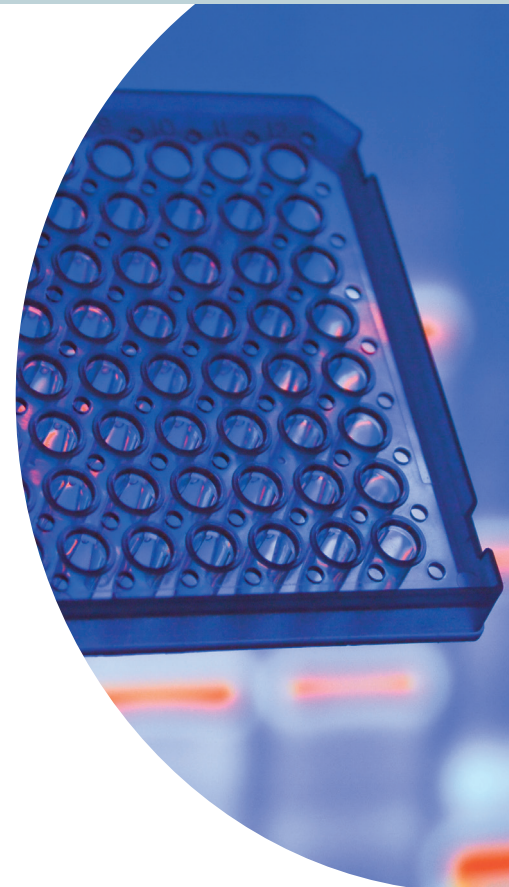


Figure 1. Yourgene® QST*^R Pregnancy Loss assay (previously known as Elucigene® QST*^R-PL) Analysis Profile

FAQs

What is the test for?

For the routine *in vitro* quantitative diagnosis of the six most common autosomal trisomies associated with pregnancy loss: Patau's syndrome (T13), T15, T16, Edwards' syndrome (T18), Down's syndrome (T21) and T22. The kit also includes X and Y chromosome markers and the TAF9L marker for the determination of sex chromosome aneuploidies.

What specific chromosomes are analyzed?

The Yourgene® QST*R Pregnancy Loss assay detects aneuploidy of autosomal chromosomes 13, 15, 16, 18, 21, 22 using 4 heterozygous short tandem repeat (STR) markers per chromosome. The assay also contains X and Y specific non-STR markers for sex determination of sex chromosome aneuploidy.

Why these chromosomes?

These autosomal chromosomes are associated with the six most common autosomal trisomies associated with first trimester pregnancy loss: Patau's syndrome (T13), T15, T16, Edwards' syndrome (T18), Down's syndrome (T21) and T22.

When can it be used?

The Yourgene® QST*R Pregnancy Loss assay is designed to be used on DNA

extracted from the products of conception and fetally derived tissue. The results obtained from the Yourgene® QST*R Pregnancy Loss assay will help determine the aneuploidy status of the fetus and may be useful in the management of the consequences resulting from the spontaneous miscarriage and for modification of risk calculations for future pregnancies.

What equipment is required?

The Yourgene® QST*R Pregnancy Loss assay is a QF-PCR based assay. Accordingly, it will require an amplicon-free environment for assay set up. The PCR is performed on a thermal cycler (equivalency testing has been performed on a limited range of thermal cyclers to assess and evaluate the robustness of the Yourgene® QST*R Pregnancy Loss assay). Fragment analysis will require the use of an ABI Genetic Analyzer 3130/3500 instrument.

How long does the test take?

The assay has been developed as a single tube reaction. Accordingly, hands on time during assay set up is kept to a minimum. Assay set up time for 16 samples (1 injection on a 3130xl/3500xl Genetic Analyzer) takes approximately 20 mins. The PCR stage of the assay takes approximately 2 hrs 45 mins

to complete, depending on platform in use. For a single injection (16 samples) sample preparation and injection on the 3130xl Genetic Analyzer takes approximately 60 mins from start to finish.

How is the analysis carried out?

Data analysis for the Yourgene® QST*R Pregnancy Loss assay is carried out using either GeneMapper™ (Life Technologies) or GeneMarker® (SoftGenetics) analysis software packages. Like all Yourgene® QST*R assays, the Yourgene® QST*R Pregnancy Loss assay has been developed with both platforms in mind. We provide the necessary analysis files for both software packages, therefore allowing Yourgene® QST*R Pregnancy Loss analysis to integrate seamlessly with existing Yourgene® QST*R analysis.

How well does it work?

From product concept through to IVD release, QST*R-PL has undergone extensive development and rigorous testing resulting in an extremely robust assay. Consequently you can have complete confidence with the analysis findings.

Ordering Information

Assay	Product Number	Description	Kit Size
Yourgene® QST*R Pregnancy Loss assay	AN6XYB2	Yourgene QST*R Pregnancy Loss test for quantitative diagnosis of the 6 most common autosomal trisomies (13, 15, 16, 18, 21, 22) associated with pregnancy loss. The test also contains X and Y chromosome markers and the TAF9L marker for the determination of sex status.	25 Tests

Yourgene® Pregnancy Loss assay previously known as Elucigene® QST*R Kit

About

YOURGENE HEALTH

Yourgene Health is an international molecular diagnostics group which develops integrated genomic technologies and services enabling genomic medicine.

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