Elucigene®
Clarity without complexity

QST*R-PL

Analysis of six autosomes
Sex chromosome analysis
Single tube reaction

elucigene.com

Recurrent Pregnancy Loss

Recurrent Pregnancy Loss

Miscarriage is defined as the spontaneous loss of pregnancy before the fetus reaches viability and includes all pregnancy losses from the time of conception until 24 weeks of gestation. Recurrent miscarriage is the loss of three or more consecutive pregnancies, and affects nearly 1% of couples trying to conceive.

50% of first trimester recurrent miscarriage cases have been shown to be caused by a chromosome abnormality (primarily aneuploidy); the most commonly noted are trisomies, which account for 60% of all chromosome abnormalities in miscarriage.

The most frequent trisomy found in products of conception (POC) is trisomy for chromosome 16. However, trisomies for chromosomes 13, 15, 18, 21 and 22 are also common. Other aneuploidies commonly seen include monosomy X and triploidy which account for approximately 20% and 15% of all abnormalities, respectively (Figure 1).

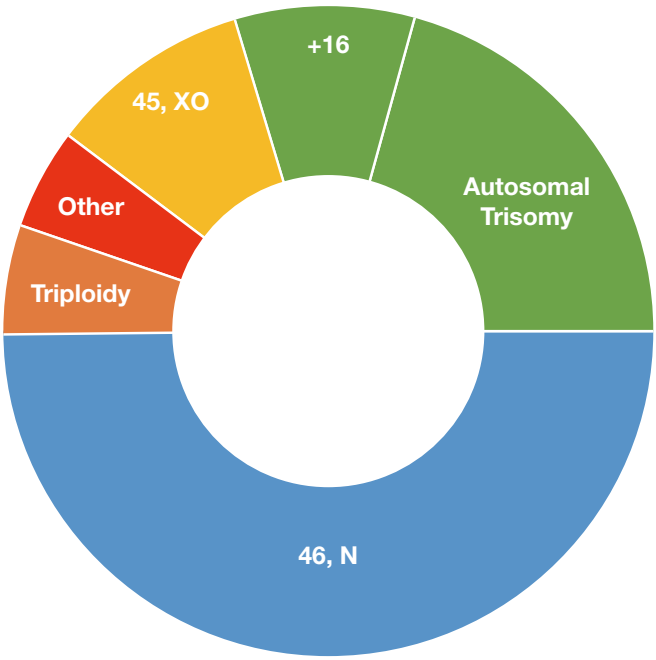

Figure 1: Showing the chromosomal findings in products of conception with 46N representing normal results. (adapted from Gardner and Sutherland, 3rd Edition)

QST*R-PL (Pregnancy Loss Kit)

The QST*R-PL Kit is for the routine in vitro quantitative diagnosis of the six most common autosomal trisomies associated with pregnancy loss: trisomy 13 (Patau syndrome), trisomy 15, trisomy 16, trisomy 18 (Edwards syndrome), trisomy 21 (Down syndrome) and trisomy 22. The kit also includes X and Y chromosome markers and the TAF9L marker for the determination of sex status. The results obtained from QST*R-PL Kit 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.

- QST*R-PL contains 4 x STR markers for chromosomes 13, 15, 16, 18, 21, 22
- QST*R-PL contains X specific counting marker TAF9
- QST*R-PL contains X and Y specific markers AMEL and SRY

Why QF-PCR?

Elucigene Diagnostics has developed QST*R-PL for the fast, simple to use and accurate diagnosis of the six most common autosomal trisomies associated with pregnancy loss. QST*R-PL employs the commonly used QF-PCR (Quantitative Fluorescence-Polymerase Chain Reaction) technique, which has a number of advantages over other techniques for analyzing recurrent pregnancy loss.

- Simple to use method
- Low failure rates
- Fast 1 day sample to diagnosis
- Ability to identify maternal genome contamination

How does the QST*R-PL kit work?

Using PCR amplification, fluorescent dye labelled primers target highly polymorphic regions of DNA sequence called short tandem repeats (STRs) that are located on the chromosomes of interest.

Amplified products of the QF-PCR technique are analyzed quantitatively on a capillary electrophoresis Genetic Analyzer to determine the copy number of the analyzed STR markers.

Figure 2. Overview of QF-PCR procedure

Simple to set up

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

Simple analysis

- No post-PCR manipulation required
- Highly informative – multiplexed 5 dye chemistry
- Reporting times of less than 24 hours from sample receipt
- Easy to understand single page report using GeneMapper® or GeneMarker® software within minutes

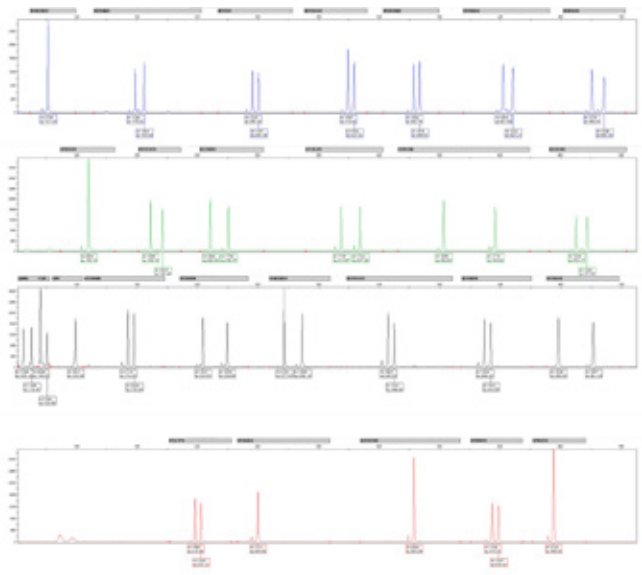

Figure 3. QST*R-PL Analysis Profile

FAQs

What is the test for?

For the routine in vitro quantitative diagnosis of the six most common autosomal trisomies associated with pregnancy loss: trisomy 13 (Patau syndrome), trisomy 15, trisomy 16, trisomy 18 (Edwards syndrome), trisomy 21 (Down syndrome) and trisomy 22. 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?

QST*R-PL 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: trisomy 13 (Patau syndrome), trisomy 15, trisomy 16, trisomy 18 (Edwards syndrome), trisomy 21 (Down syndrome) and trisomy 22.

When can it be used?

QST*R-PL is designed to be used on DNA extracted from the products of conception and fetally derived tissue. The results obtained from QST*R-PL kit 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 Elucigene QST*R-PL 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 Elucigene QST*R-PL 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 QST*R-PL is carried out using either GeneMapper (Life Technologies) or GeneMarker (SoftGenetics) analysis software packages. Like all QST*R products, QST*R-PL has been developed with both platforms in mind. Elucigene Diagnostics provides the necessary analysis files for both software packages, therefore allowing QST*R-PL analysis to integrate seamlessly with existing 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.

Product Details

Catalogue No.	Product	Kit Size
AN6XYB2	Elucigene QST*R-PL Pregnancy Loss Kit	25 Tests

Elucigene®
Clarity without complexity

DIAGNÓSTICA LONGWOOD

www.dlongwood.com
Camino del Pilón, 86-Casa 7. 50011 - Zaragoza
e-mail: dlw@dlongwood.com
Tel. 976 320 638 · Fax. 976 32 06 60

MAR0010 001 SEP14