QF-PCR Proficiency Testing Program- for prenatal testing

The Objectives of the Pre-natal QF-PCR PT scheme:

- To maintain a high level of QF-PCR based tests.
- To monitor flaws in the testing procedure by using pre-characterized DNA samples.
- To provide feedback on the lab's QF-PCR testing procedure.
- To provide guidance and recommendations for the QF-PCR procedure improvements.

The Pre-natal QF-PCR PT Program

Twice a year, QualiGene sends one pre-characterized DNA sample diluted in TE buffer, potentially harboring specific chromosomal aberration (detectable by QF-PCR), and instructions. The laboratory determines the sample's genotype and gender and submits the results and raw data to QualiGene for evaluation. QualiGene in-turn verifies the accuracy of the analysis and will report its findings back to the participating laboratory.

QF-PCR PT Laboratory Practice

- The laboratory needs to treat the PT test samples as if these were routine QF-PCR tests
- The QF-PCR test will be carried out with the reagents and protocols, routinely used in the laboratory

QF-PCR PT material storage instructions

- The DNA samples should be stored at 4°C.

The QF-PCR PT Protocol

- QualiGene will inform all participating laboratories two weeks before sample shipment.
- A submission date will be set for **90 days from delivery day.** (The delivery day will be announced and **late submission, without a prior approval for extension by QualiGene, will result in grade reduction**)
- The results will be submitted by fax or e-mail, on a result form provided by QualiGene.

- The fsa files (raw data) of the tested DNA sample, will be submitted with the filled-in result form
- The lab will receive QualiGene's evaluation and feed-back four weeks after the results submission deadline.
- At the end of each year, the registered labs will receive a certificate attesting their participation in QualiGene's PT program.
- Following each PT round, QualiGene will publish a report containing announcements, QF-PCR PT related statistics, general information and conclusions, which were drawn from the past PT schemes.

Appeals

- Each participating laboratory may appeal the grade, reported back by QualiGene, up to one week from result receipt
- Appeals should be submitted by e-mail, specifying the reasons for the appeal and supporting arguments appeal arguments and reasons
- QualiGene will re-evaluate the results submitted by the participating laboratory, and will report its decision to the laboratory up to 10 days from appeal receipt.

Confidentiality

- All participating laboratories' names are kept strictly confidential.
- QualiGene's evaluation and grading of your results is confidential and will be submitted back only to the laboratory manager.
- Statistics and grades published in QualiGene's report are always anonymous.
- Grades of Israeli laboratories are reported annually to the Israeli MOH.

Grading Criteria (percent of total grade)

• Correct identification of the chromosomal aberrations	50%
• marker analysis quality	30%
• Correct identification of the gender	10%
• Timely submission of results	10%