



## Y-chromosome microdeletion - PT program

### Objectives of the PT scheme:

- To maintain accurate Y chromosome microdeletions tests.
- Provide you feedback on your laboratory's Y chromosome microdeletions testing procedure.
- Provide you guidance and recommendations for your Y chromosome microdeletions testing and suggest possible procedure improvements.

### Y chromosome microdeletion PT Laboratory Practice

- The laboratory will treat the PT test item as if it was a routine Y deletion test in the laboratory
- The Y chromosome microdeletion testing procedure will be carried out by the materials and protocols, routinely used in the laboratory

### Y chromosome PT material storage instructions

- The DNA sample should be stored at 4°C

### The Y chromosome microdeletion PT Program

Twice a year, QualiGene sends one pre-characterized DNA sample in TE buffer, potentially harboring Y chromosomal microdeletion, which leads to spermatogenic impairment. The laboratory needs to determine the sample's specific microdeletion and submits the results to QualiGene for evaluation. QualiGene in-turn verifies the accuracy of the analysis and reports its findings back to the participating laboratory.

### The Y chromosome microdeletion 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 lab will submit the test's raw data attached to the result form (fsa files).
- The participating laboratory will receive QualiGene's evaluation and feedback within four weeks from the results submission deadline.
- The grades will not be reported back until all participants have submitted their results
- At the end of each year, the registered labs will receive a certificate attesting to their participation in the PT program.
- Following each PT round, QualiGene will publish a report containing Y chromosomal microdeletions PT- related statistics, general information and conclusions.

#### 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 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 lab's names are kept confidential.
- QualiGene's evaluation and grading is confidential and will be submitted back only to the laboratory manager.
- Statistics and grades published in the newsletter are anonymous.



- Grades of Israeli participating laboratories are reported to the MOH, annually

Grading (percent of total grade)

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|---|-----|
| • Correct identification of the Y chromosomal microdeletion | 50% |
| • Correct selection of markers and analysis quality         | 40% |
| • Timely submission of results                              | 10% |