CMA - PT program Protocol

Objectives of the PT scheme:

- To help the laboratory maintain accurate CMA testing
- To provide feedback on the quality/accuracy of your laboratory's CMA testing.
- To provide guidance and recommendations for your laboratory's CMA test and suggest possible improvements.

The CMA PT Program

Twice a year, QualiGene will send one DNA sample, diluted in TE buffer, potentially harboring chromosomal gains or losses detectable by CMA, together with a short case report. The laboratory will report all pathogenic abnormalities greater than 200Kb for losses and 500Kb for gains. The results will be reported to QualiGene for evaluation using the International System for Human Cytogenetic Nomenclature (ISCN), (Only report pathogenic CNV's). QualiGene will in-turn verify the accuracy of the analysis and will report its findings back to the participating laboratory. Laboratories that wish to receive feedback on their data, may upload. cell or, cychp files.
QualiGene will evaluate the results together with other participating laboratories.

CMA PT Laboratory Practice

- The laboratory should treat the PT test sample as a routine CMA test.
- The result analysis will be carried out using the software routinely used in the lab, to analyse CMA results

CMA PT material storage instructions

The DNA samples should be stored at 4°C

The CMA PT Protocol

- QualiGene will inform all participating laboratories one week before sample shipment.
- A submission date will be set for **60 days from delivery day.** (The delivery day will be announced and **late submission, without a prior approval for extension by QualiGene, will result in a grade reduction**)
- The results will be submitted by fax or e-mail, on a result form provided by QualiGene.

- The participating laboratory will receive QualiGene's evaluation and feed-back within four weeks from the submission of results.
- At the end of each year, the registered labs will receive a certificate attesting to their participation in the PT program.
- QualiGene will publish a summary report, twice a year, containing announcements, CMA PT- related statistics, and general information and conclusions, drawn from past PT schemes.
- The grades will not be reported back to the participating laboratories, before all participant have submitted their result

Appeals

- The laboratory may appeal the grade given by QualiGene, up to one week after the result is received.
- Appeals should be submitted by e-mail along with the arguments/ reasons for the appeal.
- QualiGene will re-evaluate the results submitted by the participating laboratory and will report its decision to the laboratory up to 10 days after receiving the appeal.

Confidentiality

- All participating lab's names are kept confidential.
- QualiGene's evaluation and grading is confidential and will only be given to the laboratory manager.
- Statistics and grades published in the newsletter are anonymous.
- Grades of Israeli participating laboratories are reported to the ministry of health, annually
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Grading (percent of total grade)

- Correct identification of the gain\loss 80%
- Nomenclature according to the ISCN 10%
- Timely submission of results 10%