CCMG APPLICATION FOR ACCREDITATION OF CENTRE

CYTOGENETICS LABORATORY SERVICE

1. General

a. Complete this form for each cytogenetics laboratory which is considered an integral part of this genetics centre, and which contributes substantially to the centre's clinical service or CCMG training activities.

b. Provide the name of each laboratory, and its location _____

c. If this centre does not have affiliated cytogenetics lab(s) that provides prenatal, constitutional and oncology analysis, identify the lab(s) that are used, and for which tests. _____

2. Laboratory Geneticists

a. List all cytogeneticists (CCMG-certified or equivalent) who issue clinical reports for this laboratory.

Name	Qualifications	FTE

b. If there is only one cytogeneticist, who issues reports in her/his absence? Provide the name(s), qualifications, and locations.

_____

3. Other Laboratory Staff

In the table below, provide aggregate information for each category of staff.

Function	Degrees/Certification	FTEs
PhD laboratory Scientist / analyst		
MSc laboratory Scientist / analyst		
Genomic specialist/ bioinformatics/IT support		
Supervisory technologist		
Clinical Genetics technologist / Cytogenetics technologist*		
Laboratory assistant		
Genetic counsellor		
Clerical		
Other lab staff- specify		

* Specify the mandatory minimum qualifications for laboratory technologists:

4. Laboratory tests

a. In the table below, provide the number of tests analyzed in a recent 12-month period. Specify the time period that is described: _____
Provide average turnaround times (TAT) in days. Specify if working or calendar days.

	Total #	Abnormal #	Discontinued #	STAT TAT	Routine TAT
Blood (Constitutional)					
Karyotype					
FISH					
Microarray					
Other					
Fibroblast culture					
Karyotype					
FISH					
Microarray					
Culture and cryostorage					
Amniocytes					
Karyotype					
FISH					
Microarray					
RAD (qfPCR) **					
Culture and cryostorage					
CVS					
Karyotype					
FISH					
Microarray					
RAD (qfPCR) **					
Oncology - bone marrow					
Karyotype					
FISH					
Microarray					
Oncology – peripheral blood					
Karyotype					
FISH					
Microarray					
Oncology- solid tumour and lymph node					
Karyotype					
FISH					

Microarray					
Other: _please specify_tissue type and test_____					
Total					

** Please specify if qfPCR RAD tests are performed by cytogenetics or the molecular genetics laboratory in your institution.

_____

b. Are any samples sent out because of insufficient capacity in the laboratory?
Yes _____ Comment: _____
No _____

5. Tests performed

a. Do you do G banding in your laboratory? _____

b. On which specimen types? _____

c. Special tests performed:

Tests	Number per 12 months	Referral laboratory if not performed in-house
Fanconi		
Bloom		
Replication studies		
Other (1)- specify		
Other (2)- specify		

d. List the clinical indications for interphase FISH tests offered on constitutional specimens by the laboratory:

_____
_____

e. List the clinical indications for interphase FISH tests offered on oncological specimens by the laboratory:

_____
_____

6. Sendouts

a. Complete the following table for a recent 12-month period, including only those tests for which at least 10 samples were sent out in the last year.

Test or sample	# Sent out	Referral Laboratory

b. What is the source of funding for sendouts, and restrictions if any?

_____

7. Accreditation

a. Is this laboratory accredited by a provincial/other body?
No _____ Yes _____ Specify organization_____

b. When does the current accreditation expire? _____

8. External Quality Assurance

a. List all the EQA programs to which the laboratory subscribes:

Organization	Survey name	Number of interpretations per scheme (total for previous 5 years)	Number of unacceptable interpretations per scheme (total for previous 5 years)
IQMH			
CAP			
Other			

Please provide comments on the unacceptable interpretations listed in the above table.

b. Number of challenges performed in the last five years:
Chromosomes: _____
FISH: _____
Microarray: _____
Total: _____

c. List all tests or techniques NOT covered by the above EQA challenges, and describe how QA is accomplished for those.

Test without formal EQA challenge	QA activity to replace EQA challenge

9. Quality assurance

a. Does the laboratory have a quality manual?
Yes ____ No ____

b. Are there written procedures in place for the monitoring of tests and results?
Yes ____
No ____ Comment: _____

c. List the quality indicators other than TAT and EQA that are monitored in the laboratory.

Quality indicator	Benchmark	Acceptable QI?

d. Please complete table below and add lines as necessary, by providing a list of the quality activities that are monitored regularly and the quality improvement initiatives or projects that have been initiated in the last year.

Quality activities/ quality initiatives	Frequency of monitoring	Date last performed
Annual report		
Laboratory Client satisfaction survey		

In the event complaints or other opportunities for improvement were identified in the quality activities/quality initiatives, please provide comments on the issue(s) and corrective actions.

10. CCMG guidelines and recommendations

Does your laboratory comply with the following CCMG documents and recommendations? For any document that your centre answered as "NO", please elaborate.

a) Practice guidelines: joint CCMG/SOGC recommendations for the use of chromosomal microarray analysis for prenatal diagnosis and assessment of fetal loss in Canada, published in 2018
Yes ____ No _____

b) CCMG Guidelines for Genomic Microarray Testing, issued in 2016
Yes ____ No _____

c) CCMG guidelines for retention of cytogenetic specimens and genetic records, issued in 2014
Yes ____ No _____

d) CCMG Practice Guidelines for Prenatal QF-PCR, issued in 2010
Yes ____ No _____

e) Recommendations for the indications, analysis, and reporting of prenatal specimens, issued in 2010
Yes ____ No _____

f) Recommendations for the indications, analysis and reporting of constitutional specimens (peripheral blood, solid tissues), issued in 2010
Yes ____ No _____

g) Recommendations for the indications, analysis and reporting of cancer specimens, issued in 2010
Yes ____ No _____

h) CCMG endorsement of the CLSI FISH Guidelines, issued in 2006
Yes ____ No _____

11. Resources

Are the following adequate for safe and efficient delivery of service?

	Yes	**If no, please comment**
Space		
Staff		
Equipment		

12. Records

a) How are records, reports, and data stored?

_____

b) If records are stored off site, how quickly can they be accessed?

_____

c) Is there a procedure that provides the minimum requirement for the content of lab reports?
Yes ____ No _____

13. Development

a. Briefly describe the process for evaluating requests for service expansion.
_____

b. Provide a list of techniques/tests currently under development, with anticipated date of implementation. _____

14. Comments

If necessary, supply additional brief comments to describe the cytogenetic service provided by this laboratory.
_____
_____