CCMG GUIDELINES FOR RETENTION OF:
A) CYTOGENETIC SPECIMENS AND GENETIC RECORDS
AND
B) MOLECULAR SPECIMENS AND GENETIC RECORDS

Submitted by:
CCMG Laboratory Practice Committee
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Approved by:
CCMG Board of Directors
November 5, 2014

The CCMG has agreed to sanction the CAP (College of American Pathologists) guidelines for the retention of cytogenetic and molecular genetic records, as per the April 21, 2014 CAP revision for the Cytogenetic and Molecular Pathology Checklists with amendments to sections CYG.32700 and MOL.49640 outlined in red. The appropriate pages are indicated for each section. CCMG current practice for molecular retention times and DNA banking guidelines are outlined in green.

The following are guidelines for the minimum retention of cytogenetic and molecular genetic records. Each genetic laboratory should ensure that they are meeting the requirements for retention records for their province.
A. CYTOGENETIC RETENTION OF SPECIMENS AND RECORDS

as per
College of American Pathologists (CAP) Cytogenetics Checklist
**REVISED** 04/21/2014 (pp. 10-11)
CYG.32700 Material Retention-Conventional Cytogenetic Assays Phase II*

1. Original specimen and cultures – at least until adequate metaphase cells are obtained for analysis.
2. Processed specimens or cell pellets – 2 weeks after release of the final report
3. Slides
   - Permanently stained slides - 3 years
   - Slides stained with fluorochromes - retention time as defined in laboratory policy/procedure
   - Cytogenomic array slides - retention time as defined in laboratory policy/procedure
4. Images - maintained in hard copy (negatives or prints) and/or in retrievable digitized formats as described below:
   - FISH for neoplastic disorders - 10 years. For an assay with a normal result, retain an image of at least one interphase or metaphase cell illustrating the normal probe signal pattern. For an assay with an abnormal result, retain images of at least two interphase or metaphase cells illustrating each abnormal probe signal pattern from relevant clones.
   - FISH for non-neoplastic disorders - 20 years. For an assay with a normal result, retain an image of at least one interphase or metaphase cell illustrating the normal probe signal pattern. For an assay with an abnormal result, retain images of at least two interphase or metaphase cells illustrating each abnormal probe signal pattern.
   - At least two representative metaphase cells/karyograms from each normal and abnormal cell line or clone from all other light and non-FISH fluorescence microscopy - 20 years
5. Cytogenomic array data - retain the original scan for at least 2 weeks after the report is completed. Retain sufficient original data to support the final report (e.g. the feature extracted data file) for 20 years
6. Final reports for neoplastic conditions for at least 10 years and for constitutional/genetic conditions for at least 20 years. Electronic versions are acceptable.

NOTE 1: The intent is to maintain evidence of case results for any future need, such as further family studies, monitoring disease, legal issues, etc.
NOTE 2: Because information technology software and hardware continues to change, access to some digitally archived material may be lost. However, reasonable due diligence should be exercised to maintain access during the retention guidelines described above.

B. MOLECULAR GENETIC RETENTION OF SPECIMENS AND RECORDS

as per
College of American Pathologists (CAP) Molecular Pathology Checklist
**REVISED** 04/21/2014 (p. 59)

MOL.33250 Specimen Retention Phase II*
Specimens are retained in compliance with applicable laws and regulations.

C. CCMG Guidelines for DNA Banking Policy (2008; p. 4)
Decisions regarding length of sample storage should be based on the initial reason for banking, and anticipated future use. Length of storage for long-term banking should be at least two generations (50 years45). Length of storage for residual clinical samples is at the discretion of the laboratory, and may range from a minimal but defined interval after reporting of current clinical testing to indefinite storage. Laboratories should establish and clearly disseminate their respective policies to referring health care providers. A suggested default policy is storage of residual clinical samples for one year after the laboratory has reported test results.

MOL.49635 Laboratory Records Phase II*
The laboratory record includes sufficient information regarding the individual specimen and assay conditions.

NOTE: Appropriate information may include the quantity and quality of nucleic acid isolated and the amount used in the assay; the lot numbers of the restriction endonucleases, probes or primers used and any assay variables.

MOL.49640 Record Retention Phase II*
A copy of each final report, all records of results, membranes, autoradiographs, gel photographs, and in situ hybridization slides, are retained in compliance with applicable provincial accreditation agency regulations.

NOTE: CAP requires that test reports for neoplastic conditions be retained for 10 years, and that test reports for constitutional/genetic conditions be retained for 20 years. Electronic versions are acceptable.

MOL.49645 Labeling/Cross-Referenced Phase II*
All autoradiographs, gel photographs and in situ hybridization slides are adequately labeled for identification and adequately cross-referenced in the case records.
Please refer to the 2013 CCMG molecular survey (Table 3) for current retention practices of Canadian molecular laboratories.

* Phase 0, Phase I, and Phase II Deficiencies

Each checklist requirement bears a designation of Phase 0, Phase I, or Phase II. A Phase 0 item may be included in the checklists for administrative purposes. It is not a requirement and does not require a formal response. Deficiencies to Phase I requirements compromise the quality of the services without endangering the health and safety of patients, clients, or personnel. If a laboratory is cited with a Phase I deficiency, correction and a written response to the CAP are required, but supportive documentation of deficiency correction is not required. Deficiencies to Phase II requirements may have a serious impact on the quality of services or may endanger the health and safety of patients, clients, or personnel. All Phase II deficiencies must be corrected before the Accreditation Committee grants accreditation. Correction requires that the laboratory provide to the CAP both a plan of action and supporting documentation that the plan has been implemented.