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CCMG GUIDELINE FOR RETENTION OF:

A) CYTOGENETIC SPECIMENS AND GENETIC ANALYSIS RECORDS AND B) MOLECULAR SPECIMENS AND GENETIC ANALYSIS RECORDS

Prepared and Submitted by: CCMG Cytogenetics Committee, October 30, 2014
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Approved by: CCMG Board of Directors, **March 4, 2021**

The aim of this guideline is to provide recommendations for the minimum retention of cytogenetic, molecular genetic and genomics analysis records. Each genetic laboratory should develop policies and procedures detailing their retention of specimens, secondary material (aliquots, slides, cell pellets, DNA) and testing results records, ensuring that they are meeting the requirements for retention records for their province.

NOTE 1: The intent of record retention 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 in this document.

A. CYTOGENETIC RETENTION OF SPECIMENS AND RECORDS

1. Original specimen: at least until it is verified that metaphases are available for analysis

2. Back-up cultures: at least until adequate metaphase cells are obtained for analysis

3. Cell pellets: at least 2 weeks after release of the final report and as defined in laboratory policy/procedure

4. Slides
   - Permanently stained slides - 2 years
   - Slides stained with fluorochromes - retention time as defined in laboratory policy/procedure
   - Cytogenomic array slides - retention time as defined in laboratory policy/procedure

5. Images - maintained in hard copy (negatives or prints) and/or in retrievable digitized formats as described below:

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● FISH - 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 from relevant clones.
● 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 for neoplastic and non-neoplastic disorders.

6. Cytogenomic array data - Laboratories should establish a policy for the retention of raw data (for example retain the original scan for at least 2 weeks after the report is completed). Retain sufficient original data to support the final report for at least 20 years for constitutional and neoplastic disorders.

7. Paper and/or electronic final reports for constitutional and neoplastic conditions are retained for at least 20 years.

B. MOLECULAR GENETIC AND GENOMIC RETENTION OF SPECIMENS AND ANALYSIS RECORDS

1. For DNA retention, refer to the CCMG Guidelines on DNA Retention and Banking.

2. Molecular tests data digitalized or hard copy (such as, but not limited to, gel images, Sanger sequencing traces, fragment analysis traces, quantitative PCR file): as per local policy for raw data. And at least 2 years for annotated data, sufficient to support the final report.

3. NGS (next generation sequencing) VCF/FASQ/SAM/BAM files: Refer to the CCMG Laboratory Guidelines for Next-Generation Sequencing https://www.ccmg-ccgm.org/documents/Policies_etc/Pract_Guidelines/CCMG-NGS-Guidelines_jmedgenet-2019-106152.full.pdf (Also refer to: J Med Genet. 2019 Dec;56(12):792-800, PMID: 31300550)

4. Paper and/or electronic final reports for neoplastic and constitutional conditions are retained for at least 20 years.