CYG.32250 Recommendations in Final Report **Phase I**

The final report contains recommendations for genetic consultation or additional studies, when appropriate.

REFERENCES
1) American Board of Medical Genetics and Genomics http://www.abmgg.org/
2) National Society of Genetic Counselors http://www.nsgc.org/
3) American Board of Genetic Counseling http://www.abgc.net/

RECORDS

Inspector Instructions:

- Record/specimen retention policy
- Sampling of patient records and materials

CYG.32500 Laboratory Record Information **Phase II**

The laboratory record includes the number of cells counted, analyzed microscopically and the number from which photographic or digitized karyograms were prepared.

REFERENCES
1) Department of Health and Human Services, Centers for Medicare and Medicaid Services, Clinical laboratory improvement amendments of 1988; final rule. Fed Register. 2003(Jan 24): [42CFR493.1276(b)(1)]

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CYG.32700 Record and Material Retention - Cytogenetics **Phase II**

Records and materials are retained in compliance with applicable national, federal, state (or provincial), and local laws and regulations and as defined in the table below:

Type of Record/Material	Retention Period
Original specimen and cultures	Until release of the final report
Processed specimens or cell pellets	2 weeks after final report
Permanently stained slides	3 years
Fluorochrome-stained slides	At the discretion of the laboratory director
Chromosomal microarray slides	At the discretion of the laboratory director
Images of ISH and non-ISH (eg, G-banded) studies - hard copy (negatives or prints) and/or in retrievable digitized formats	10 years for neoplastic disorders 20 years for non-neoplastic/constitutional disorders (see NOTE 3 below)
Chromosomal microarray data	At least two weeks after the final report is released for the original scan At least two years of sufficient original data to support primary results generation and re-analysis
Final Report (electronic versions are acceptable)	10 years for neoplastic disorders 20 years for constitutional conditions

NOTE 1: The intent is to retain 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 continue to change, access to some digitally archived material may be lost. However, reasonable due diligence should be exercised to maintain access for the full retention period.

NOTE 3: There is no retention requirement for retaining images of slide preparations when the source slides remain readable for the required retention period. If slides are expected to become unreadable before the end of the required retention periods (for example, FISH slides), then images that adequately represent findings on the slides must be retained.

If representative images of chromosome ISH slides are retained, those with a normal result must include an image of at least one cell illustrating the normal probe signal pattern, and those with an abnormal result must include images of at least two cells illustrating each relevant abnormal probe signal pattern.

REFERENCES
1) American College of Medical Genetics, Standards and Guidelines for Clinical Genetics Laboratories, 2021 edition.
2) South ST, Lee C, Lamb AN, Higgins AW, Kearney HM, Working Group for the American College of Medical Genetics and Genomics Laboratory Quality Assurance Committee. ACMG standards and guidelines for constitutional cytogenomic microarray analysis, including postnatal and prenatal applications: revision 2013. *Genet Med.* 2013; 15(11):901-9.
3) Shao L, Akkari Y, Cooley LD, et al. Chromosomal microarray analysis, including constitutional and neoplastic disease applications, 2021 revision: a technical standard of the American College of Medical Genetics and Genomics (ACMG). *Genet Med.* 2021;23(10):1818-1829.

REAGENTS

Inspector Instructions:

- Sampling of records of media checks

Additional requirements are in the REAGENTS section of the All Common Checklist.

CYG.33300 Media QC **Phase II**

Each lot of culture medium is checked onsite for sterility and the ability to support growth.

NOTE: Each laboratory must perform its own QC on new lots of culture media. It is not acceptable practice to rely on QC testing performed at another site.

Evidence of Compliance:

✓ Records of media checks and actions taken when media is unsuitable

INSTRUMENTS AND EQUIPMENT

The checklist requirements in this section should be used in conjunction with the requirements in the All Common Checklist relating to instruments and equipment.