

## NUMBER OF KARYOGRAMS

### Inspector Instructions:



- Sampling of test procedures for number of karyograms
- Sampling of patient records/worksheets

#### CYG.41600 Karyograms per Case

Phase II



**There is a minimum of two karyograms per case, with at least one karyogram per cell line, for the following specimen types.**

1. PHA-stimulated blood cells
2. Amniotic fluid (in situ or flasks)
3. Chorionic villus
4. Solid tissue (non-neoplastic)

*NOTE: For abbreviated studies, a minimum of one karyogram is required. Examples of such circumstances are confirmation of an abnormal prenatal chromosome result, or peripheral blood chromosome studies on family members to exclude a previously identified chromosome rearrangement. The laboratory must have written criteria for the circumstances under which an abbreviated study can be performed. Criteria should address the rationale for such studies, the clinical reason for referral, and the minimum number of karyograms.*

#### Evidence of Compliance:

- ✓ Patient records/worksheets

#### REFERENCES

- 1) American College of Medical Genetics, Standards and Guidelines for Clinical Genetics Laboratories, 2021 edition.

#### CYG.42000 Karyograms - Neoplastic Disorders

Phase II



**For neoplastic disorders studied in marrow, blood or solid tumor specimens, there are at least two karyograms per stemline, one karyogram from each sideline (subclone) and one karyogram of a normal cell (if observed in the analysis).**

#### Evidence of Compliance:

- ✓ Patient records/worksheets

## BAND RESOLUTION

### Inspector Instructions:



- Sampling of test procedures for band resolution

	<ul style="list-style-type: none"> <li>Under what circumstances might your laboratory use a lower band resolution?</li> </ul>
	<ul style="list-style-type: none"> <li>Examine the karyograms from cases. Determine whether the band level is sufficient to provide the rendered interpretation.</li> </ul>

**CYG.42200 Band Level - Constitutional Cases****Phase II****The band level for constitutional cases is at least at the 400-band level of resolution.**

*NOTE: Constitutional cases must be banded at least at the 400-band level (International System for Human Cytogenetic Nomenclature - ISCN).*

**Evidence of Compliance:**

- ✓ Karyograms with appropriate band resolution

**REFERENCES**

- 1) American College of Medical Genetics, Standards and Guidelines for Clinical Genetics Laboratories, 2021 edition.
- 2) McGowan-Jordan J, Hastings R, Moore S, eds; International Standing Committee on Human Cytogenomic Nomenclature. *ISCN: An International System for Human Cytogenomic Nomenclature* (2020). Basel, New York: Karger; 2020.
- 3) 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)(2)]

**CYG.42300 Band Level - Blood Samples****Phase II****At least the 550-band level of resolution is achieved in appropriate blood samples.**

*NOTE: The 550-band level is the minimum goal of all such studies, particularly in cases of developmental delay/intellectual disability, dysmorphology and birth defects.*

**Evidence of Compliance:**

- ✓ Karyograms with appropriate band resolution

**REFERENCES**

- 1) American College of Medical Genetics, Standards and Guidelines for Clinical Genetics Laboratories, 2021 edition.
- 2) McGowan-Jordan J, Hastings R, Moore S, eds; International Standing Committee on Human Cytogenomic Nomenclature. *ISCN: An International System for Human Cytogenomic Nomenclature* (2020). Basel, New York: Karger; 2020.

**CYG.42400 Banding and Resolution****Phase II****The quality of banding and resolution is sufficient to render the reported interpretation.****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)(3)]

## IN SITU HYBRIDIZATION

*The use of the term *in situ hybridization (ISH)* in this section applies to all ISH methods, including fluorescence (FISH), chromogenic (CISH), silver (SISH), and brightfield (BISH) *in situ* hybridization.*

*Please refer to the Definition of Terms section of the All Common (COM) Checklist for definitions of analytical validation and analytical verification.*