

of a study. Numbers of cells to be scored is to be defined in the laboratory policy, in compliance with specific checklist requirements.



**CELL LINE/CLONE:** a population of cells with the same chromosome complement. Chromosome gain and structural aberrations are clonal when the gain or structural aberration is present in two or more cells. Chromosome loss is clonal when it is present in three or more cells. (ISCN).

**STEMLINE CLONE:** The stemline is the most basic clone of a tumor cell population.

**SIDELINE CLONE (SUBCLONE):** a population of cells with one or more of the same chromosome abnormalities seen in the stemline clone, but which has additional abnormalities not found in the stemline clone.

**COLONY:** a discrete focus of cells that is harvested and stained while attached to the cell culture growth substrate.

## Inspector Instructions:

	<ul style="list-style-type: none"> <li>Sampling of test procedures for specimen handling</li> </ul>
	<ul style="list-style-type: none"> <li>Observe how incubator/alarm systems are connected to power and compressed gas containers</li> <li>Confirm that prenatal cultures are split between at least two incubator systems</li> </ul>

### CYG.40000 Culture - Amniotic Fluid and Chorionic Villus

Phase II



**Amniotic fluid and chorionic villus cultures are split between two incubators with independent electrical circuits or emergency power systems, backup gas sources, and emergency alarms.**

*NOTE: If such arrangements are not feasible, a written protocol must ensure necessary growth requirements for all cultures and protection from power failures.*

### CYG.40100 Culture - All Specimen Types

Phase II



**Duplicate or independently established cultures are prepared for all specimen types, whenever possible.**

*NOTE: The intent is to provide backup cultures in the event of failures due to contamination, technical error and other problems, as well as providing the best opportunity to verify true mosaicism and maternal cell contamination.*

*In cancer studies, the clonal abnormality may be identified in only one culture system. The procedure manual should specify a prioritization scheme for what culture systems shall be set up when the sample volume or cellularity is insufficient to set up all cultures according to the laboratory's routine.*

#### Evidence of Compliance:

- ✓ Patient records/worksheets

### CYG.40200 Harvesting - Amniotic Fluid and Chorionic Villus

Phase II



**Duplicate amniotic fluid and chorionic villus flasks or dishes are harvested independently.**

*NOTE: To prevent failures due to contamination or technical error, all cultures from a patient should not be harvested in the same batch.*

**Evidence of Compliance:**

- ✓ Patient records/worksheets

## NUMBER OF CELLS COUNTED

### Inspector Instructions:



- Sampling of test procedures for cells counted
- Sampling of patient records/worksheets

### CYG.40500 Counting - Stimulated Blood Samples

Phase II



**For stimulated blood samples (non-neoplastic disorders), at least 20 cells are counted with the exception of abbreviated studies.**

*NOTE 1: Under special clinical circumstances (eg, rule out sex chromosome mosaicism or mosaicism of another numerical or structural abnormality), additional cells may need to be counted. The laboratory must have written criteria for these circumstances in which additional cells should be counted.*

*NOTE 2: Under other special clinical circumstances, fewer than 20 cells may be counted. 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 cells counted.*

**Evidence of Compliance:**

- ✓ Patient records/worksheets

**REFERENCES**

- 1) Wiktor AE, Bender G, Van Dyke DL. Identification of sex chromosome mosaicism: Is analysis of 20 metaphase cells sufficient? *Am J Med Genet Part A* 2009; 149A:257-259.
- 2) Wolff DJ, Van Dyke DL. Laboratory guideline for Turner syndrome. *Genet Med* 2010;12(1):52-55.
- 3) American College of Medical Genetics, Standards and Guidelines for Clinical Genetics Laboratories, 2021 edition, Section E5.1.2.

### CYG.40600 Counting - Amniotic Fluid or Chorionic Villus (In Situ) Samples

Phase II



**For amniotic fluid or chorionic villus (in situ) samples, at least 15 cells from 15 different colonies are counted, with cells from at least two cultures, with the exception of abbreviated studies.**

*NOTE: The number of cells counted should be distributed as equally as possible between independently established cultures. Under special circumstances, fewer than 15 cells may be counted. 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 cells counted.*

**Evidence of Compliance:**

- ✓ Patient records/worksheets

**REFERENCES**