Inspector Instructions:

READ

- Sampling of gas monitoring records for gas-dependent equipment

CYG.33700 Gas-Dependent Equipment **Phase II**

All gas-dependent equipment (eg, incubators) is monitored and the gas concentration is recorded each day of use, with records of corrective action when values fall outside the acceptable range.

NOTE: Gas concentrations in equipment using modified atmospheres must be monitored and recorded on each day of use. External methods of monitoring (eg, Fyrite) must be performed monthly and recorded.

The two acceptable ways of recording gas levels are: 1) recording the numerical value, or 2) placing a mark on a graph that corresponds to a numerical value (either manually, or using a graphical recording device). The identity of the individual recording the gas levels must be documented (recording the initials of the individual is adequate).

The use of automated (including remote) gas monitoring systems is acceptable, providing that laboratory personnel have immediate access to the monitoring data, so that appropriate corrective action can be taken if the recorded values are out of the acceptable range. There must be records showing daily functionality of the system.

CYG.33950 ISH Slide Processing System Temperature Checks **Phase II**

Individual slide slots (or a representative sample thereof) of in situ hybridization (ISH) temperature controlled slide processing systems are checked for temperature accuracy before being placed in service and at least annually thereafter.

Evidence of Compliance:

✓ Records of equipment verification

PROCEDURES AND TESTS

DEFINITION OF TERMS

The following definitions of terms are offered as a guide to inspectors and laboratories:

ANALYZED CELLS: banded metaphase cells in which the individual chromosomes are counted and evaluated in their entirety, either at the microscope or from intact digitized images or photographic prints.

COUNTED CELLS: the number of metaphase cells evaluated for chromosome number.

KARYOGRAM: the cutout and paired chromosomes from a photograph or the arranged computer-generated image.

SCORED CELLS: cells assessed for the presence or absence of a specific cytogenetic feature, usually indicated either by a particular clinical history or by the finding of one or two abnormal cells during the course

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:

	• Sampling of test procedures for specimen handling
	• Observe how incubator/alarm systems are connected to power and compressed gas containers • Confirm that prenatal cultures are split between at least two incubator systems

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**