

## Inspector Instructions:



- 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