

FLO.31350 G0/G1 Peak**Phase II**

Control cells of known DNA content are run with each specimen or batch of specimens to establish an acceptable CV for the G0/G1 peak and to determine the DNA index.

NOTE: Repetitive analysis of the reference cells allows reference intervals to be established to determine an acceptable range of results. This can be used as a control for DNA staining and instrumental parameters used in the analysis.

Evidence of Compliance:

- ✓ Records of QC results

REFERENCES

- 1) Hiddemann W, et al. Convention on nomenclature for DNA cytometry. *Cytometry*. 1984;5:445-446

FLO.31400 Aneuploid Cell Population ID**Phase II**

Analytical criteria are established for identification of an aneuploid cell population in the test specimen.

NOTE: The ability to detect DNA aneuploidy by flow cytometric measurement depends upon the resolution of the DNA measurements, usually assessed by the coefficient of variation (CV) of the peaks. CVs should be reported for all clinical studies. The range of CVs is highly dependent on the tissue type and the way it is prepared. Histograms observed for clinical specimens often represent complex overlapping patterns because most tumor specimens contain a mixture of tumor cells, stromal cells, and inflammatory cells. Analysis of control cells is necessary to establish the CV for a normal diploid, G0/G1 peak. Periodic review of the CVs for control cells is necessary to ensure adequate functioning of the analytic procedure.

An international workshop recommended that cells (or nuclei) should be termed as having an "abnormal DNA stemline" or "DNA aneuploidy" when at least two separate G0/G1 peaks are demonstrated.

REFERENCES

- 1) Hiddemann W, et al. Convention on nomenclature for DNA cytometry. *Cytometry*. 1984;5:445-446
- 2) Coon JS, et al. Advances in flow cytometry for diagnostic pathology. *Lab Invest*. 1987;57:453-479