

the temperatures of identical samples after microwave processing. For those microwave devices (particularly those incorporated into histology processing equipment) that use temperature-independent methods to evaluate reproducibility, the reproducibility must be assessed following instrument manufacturer's instructions.

The microwave device must be tested for radiation leakage if there is visible damage to the device. A description of the specific damage along with the result of the test must be recorded.

Evidence of Compliance:

- ✓ Records of monitoring the diagnostic quality of specimens processed using microwaves

ANP.28860 Microwave Container Venting

Phase I



All containers used in microwave devices are vented or are used in compliance with manufacturer's instructions for the microwave instrumentation used.

NOTE: Venting of containers is necessary so that processing occurs at atmospheric pressure, to prevent explosion. For procedures using pressure above that of the atmosphere, specialized containers must be used, with strict adherence to manufacturer's instructions.

ANP.29430 Microwave Venting

Phase I

Microwave devices are properly vented and the effectiveness of ventilation is monitored at least annually.

NOTE: Some types of microwave devices need to be operated in an appropriate ventilation hood to contain airborne chemical contaminants and potentially infectious agents. Before operation of the microwave device, flammable and corrosive reagents must be removed from the hood to prevent fire or chemical damage to the electronic components of the device. Microwave devices used outside a fume hood must have an integral fume extractor certified by the manufacturer for use in a clinical laboratory.

This checklist item does not apply to microwave devices that are designed by the manufacturer to operate without venting. It also does not apply if only non-hazardous reagents (as defined in the safety data sheets) and non-infectious specimens (eg, paraffin specimens) are used in the device.

Evidence of Compliance:

- ✓ Records of annual evaluation of ventilation effectiveness

CIRCULATING TUMOR CELL ANALYSIS (CTC)

This section applies to laboratories using a test system to prepare, analyze, and quantify circulating tumor cells in whole blood, including immunomagnetic separation and labeling using antibodies and fluorescent stain.

VALIDATION AND CALIBRATION

Inspector Instructions:



- Sampling of validation and calibration policies and procedures
- Sampling of validation/calibration records