Microwave Device Use in the Histology Laboratory; Approved Guideline

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Abstract

This document provides recommendations for quality assurance and safety procedures for microwave equipment use, and provides a means to understand and troubleshoot conditions that contribute to variability in microwave-accelerated procedures in human clinical, veterinary, and research histopathology laboratories. Safety issues unique to microwave instrumentation in histopathology laboratory settings are emphasized. In addition, the document discusses microwave device process control, procedure validation, and results verification.

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Foreword

The ease and rapid pace with which microwaves have entered the clinical laboratory are raising many questions for laboratory administrators. Are laboratory personnel aware of and trained in safety issues unique to microwaves? Do laboratory directors have a quality assurance program for microwave procedures? Does the leadership of the national societies that represent medical and research communities have the information they need to respond to local and national regulatory agencies regarding the safe and efficacious use of microwave technology? Are equipment manufacturers promoting equipment that meets the highest safety standards?

Several basic science and clinical research laboratories in North America, Europe, Asia, and Australia working independently during the past 31 years have identified important principles for using microwave technology reliably in laboratory medicine. This guideline emphasizes the scientific principles and practices involving the safe and effective use of microwave ovens in the histology laboratory. However, it is also important to be aware of national and local governmental regulatory requirements before microwave ovens are selected and used in clinical laboratories. The guideline only provides examples of the regulatory requirements that are current in the United States. Users in other countries are advised to consult with their national and local authorities for requirements.

Readers wishing for a quick start are directed to the following sections:

- Table 4, Safe Laboratory Use of Microwave Devices;
- Section 9, Template for Documentation of Microwave Methods; and
- Section 10, Troubleshooting Results.

Key Words

Antigen retrieval, biopsy, electron microscopy, fixation, histology, immunocytochemistry, immunohistochemistry, light microscopy, microwave, processing, resin curing, staining
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1 Scope

This CLSI guideline is written for multiple audiences, including: laboratory technicians, microwave device manufacturers, microwave device resellers, compliance and safety officials, and administrators. The goals of this document are to 1) provide a scientific basis for reproducible sample preparation of biological specimens for diagnostic purposes; 2) advise laboratory personnel on the best safety guidelines; and 3) discuss the limitations of domestic microwave ovens in a hospital laboratory. Original sources are cited in the References section for those individuals seeking additional information.

NOTE: The reader is encouraged to supplement the information in this document with continuing education courses on microwave device safety and use.

To ensure the success of microwave-accelerated procedures in the histopathology laboratory, this document provides:

- general definitions of common microwave terminology;
- detailed discussion of safety issues particular to microwave heating of samples;
- guidelines to identify potential sources of variability; and
- a “hands-on” troubleshooting guide to improve microwave-accelerated procedures.

2 Introduction

Microwave-accelerated sample preparation of biological specimens is a field that continues to grow rapidly as evidenced by the number of innovative articles written each year. The reason for this increase in the microwave literature is simple. Microwave-accelerated procedures are useful in almost every step of sample preparation for microscopy. Microwave procedures speed up reaction processes and save time. Even more important, microwave procedures improve the retention of soluble antigens and often preserve antigen immunoreactivity better than conventional fixation methods.1,2 In short, microwave-accelerated techniques can be used to improve the efficiency of a variety of histopathology laboratory procedures, such as fixation, decalcification, processing of specimens for paraffin wax or resin embedding, and staining. Hundreds of laboratory procedures using microwave devices for histopathology have been published.1,3-5 A brief list of these procedures is provided in Table 1.

Table 1. Application of Microwave-Accelerated Methods in Histopathology (see Sections 4.3 through 4.6 for Safety Precautions)1,3-5

<table>
<thead>
<tr>
<th>Examples of Microwave-Accelerated Methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fixation of human and animal specimens</td>
</tr>
<tr>
<td>Fixation of marine specimens</td>
</tr>
<tr>
<td>Fixation of plant specimens</td>
</tr>
<tr>
<td>Fixation of insect specimens</td>
</tr>
</tbody>
</table>
Three types of microwave devices are being used in a histopathology laboratory setting: 1) microwave instruments specifically designed and certified as medical devices; 2) commercial grade microwave devices converted for laboratory/clinical use; and 3) consumer household microwave units modified for laboratory/clinical use. Laboratory microwave devices are designed with exhaust fans and safety features to protect the operator, sensors to protect the instrument, and sophisticated temperature monitoring and intricate electronics that allow improved quality control of the specimen. Household microwave units are designed for food preparation, and they are not certified for laboratory use unless they meet the requirements outlined in Section 4.

All three types of microwave devices have a large chamber in which samples are heated. Large-chamber microwave devices are often described in the microwave literature as “large-cavity” or “multimodal devices.” For the purposes of this document, we will use the term “large-cavity microwave devices.”

Several features have been added to microwave devices to reduce heating damage to biological specimens and microwave equipment (see Table 2). Manufacturers of laboratory microwave equipment have improved temperature control by adding temperature probes with feedback systems for process automation, specialized power supplies for generation of microwave power, controllable magnetron duty cycles, and variable power output. Highly specialized microwave devices have platforms with very high rotational speed, vacuum and pressure cycling, and hybrid equipment combining ultrasound and microwave irradiation.

Table 2. Use of Large-Cavity Microwave Devices With Basic or Advanced Features

<table>
<thead>
<tr>
<th>Histopathology Laboratory Procedure</th>
<th>Large-Cavity Microwave Devices with Basic Functions</th>
<th>Large-Cavity Microwave Devices with Advanced Functions</th>
<th>Rationale for Equipment Choice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drying Slides</td>
<td>X</td>
<td></td>
<td>Minimal control necessary</td>
</tr>
<tr>
<td>Melting Agar</td>
<td>X</td>
<td></td>
<td>Minimal control necessary</td>
</tr>
<tr>
<td>Enzyme/Antigen Retrieval</td>
<td>X</td>
<td></td>
<td>Minimal control necessary</td>
</tr>
<tr>
<td>Staining (nontoxic reagents)</td>
<td>X</td>
<td>X</td>
<td>Minimal control necessary</td>
</tr>
<tr>
<td>Staining (toxic reagents)</td>
<td></td>
<td></td>
<td>Exhaust fume safety</td>
</tr>
<tr>
<td>Tissue Processing</td>
<td>X</td>
<td>X</td>
<td>Precise temperature control/exhaust fume safety</td>
</tr>
<tr>
<td>In situ Hybridization</td>
<td>X</td>
<td></td>
<td>Precise temperature control</td>
</tr>
<tr>
<td>Decalcification</td>
<td>X</td>
<td></td>
<td>Process control, safety</td>
</tr>
<tr>
<td>Fixation</td>
<td>X</td>
<td></td>
<td>Exhaust fume safety</td>
</tr>
<tr>
<td>Resin Embedding</td>
<td>X</td>
<td></td>
<td>Exhaust fume safety</td>
</tr>
</tbody>
</table>

To date, there are no regulations or benchmarks specifically for microwave devices in the clinical laboratory. There are, however, many regulations regarding electrical safety and general laboratory equipment safety that include microwave devices (see Section 4 for more details). In addition, the potential to overheat and damage diagnostic biological specimens in microwave procedures is great (e.g., tissue shrinkage, denatured connective tissue, pyknotic nuclei). The need for guidelines and quality assurance for microwave procedures is well recognized.

3 Definitions

This section provides a brief list of the most common terms and definitions to facilitate reading the microwave literature. A detailed report of terminology related to microwave safety has been published.

Accuracy (of measurement) – Closeness of the agreement between the result of a measurement and a true value of the measurand (VIM93).

Anode – A positively charged conductor by which electrons leave an electrical device.
Related CLSI/NCCLS Publications*

GP17-A2  Clinical Laboratory Safety; Approved Guideline—Second Edition (2004). This document contains general guidelines for implementing a high-quality laboratory safety program, which are provided in a framework that is adaptable within any laboratory.

MM4-A  Quality Assurance for Immunocytochemistry; Approved Guideline (1999). This document provides recommendations for the performance of immunocytochemical assays on cytologic and surgical pathology specimens. It is intended to promote a better understanding of the requirements, capabilities, and limitations of these diagnostic methods; to improve their intra- and interlaboratory reproducibility; and to improve their positive and negative predictive values in the diagnosis of disease.

* Proposed- and tentative-level documents are being advanced through the Clinical and Laboratory Standards Institute consensus process; therefore, readers should refer to the most recent editions.

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