

## Pathology Laboratory Archive at the University and Hospital Trust of Modena/ UNIMORE: “Disaster Recovery” frame by frame

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### Summary

The archive of any Pathology laboratory contains thousand of formalin-fixed and paraffin-embedded (FFPE) blocks and, as a result, serious space and management issues are created. Different authorities (with some variability) indicated that 10 years from the diagnosis is a congruous time before the disposal of stored tissues. Therefore, making room is not only a choice, but a necessity. Nowadays specific operating procedures exist, fully managed by human personnel. However, despite guidelines and recommendations, some accidents can occur: such events are often without any consequence but sometimes may cause serious damage for patients. In this paper we report an unwanted event that occurred in our archive in June 2024 during the collection of FFPE blocks from the year 2004 for elimination, which could have had dramatic consequences. We then highlight that innovation and automation of Pathology archives are the key of the custody of patient samples.

**Key words:** pathology archive, standardized operating procedures, archive automation, digital storage

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The pathology archive of any large hospital contains tens of thousands of formalin-fixed and paraffin-embedded (FFPE) blocks, with their number constantly increasing worldwide <sup>1</sup>. As a result, serious space and management issues arise. In fact, the pathology laboratory archive is probably one of the most neglected aspects of hospital planning and activities; it is usually located in the basement and primarily consists of FFPE blocks and glass slides, which are filed manually in consecutive order. With the ever-increasing demands for retrieval based on patient requests or scientific studies, many laboratories are now struggling to find solutions and adequate space both inside and outside their hospitals <sup>2</sup>. Furthermore, proper maintenance of archives in pathology laboratories is crucial in the molecular era, especially for specimens retrieved years after the original diagnosis. Adhering to storage recommendations is mandatory when considering the current retention policy recommendations of major national and international pathology associations/societies, as well as local and national governance guidelines <sup>3</sup>. For FFPE blocks, controlled temperature (<27°C) and humidity (>30% and <70%) are recommended, along with control systems to prevent parasite infestation. For glass slides, systems that guarantee safety,

traceability, and preservation suitable for possible review are recommended. The detrimental impact of improper preservation of FFPE tissue material, particularly concerning temperature and humidity, may compromise the quality of nucleic acids and protein antigens. Although there is variability in the minimum retention periods set by different authorities, and acknowledging the necessity of establishing a minimum duration for the conservation obligation, a 10-year term is adopted to adequately protect patients with regards to diagnostic needs<sup>3,4</sup>. Recent data reveal that in Italy, 300,000 lawsuits against doctors and healthcare facilities are pending, while claims for compensation for biological damage amount to 35,000 each year. Legal departments estimate that, on average, around 15% of these cases are related to archiving and handling issues of pathology samples<sup>5</sup>. Loss of FFPE blocks can have dramatic consequences for patient care, including potential delays in treatment decisions or the need for repeat procedures, resulting in diminished trust in the entire institution from referring physicians, patients, and the broader healthcare community. Pathology laboratories are equipped with standard operating procedures for the management of samples, from the acceptance phase to the archiving phase. Establishing and maintaining robust quality assurance programs minimizes the risk of errors, misplacements, or sample loss. Implemented risk management strategies, such as thorough documentation, incident reporting, and carrying appropriate liability insurance coverage, mitigate potential legal costs. Healthcare professionals should be familiar with the different types of errors to better understand the adverse events that may arise. Indeed, human error – stemming from lapses in judgment or a lack of prudent care by individuals – is generally seen as a significant contributor to reliability and safety issues. Common types of errors in archiving include the absence of standard operating procedures, equipment failures, and communication breakdowns. By identifying deficiencies, failures, and risk factors that lead to adverse events, corrective measures can be developed to prevent similar errors. Standardized operating procedures, archive automation, and digital storage can be key to revolutionizing pathology archives and should provide a more efficient and secure method to ensure complete traceability, preservation, integrity, and quality of samples.

In order to highlight this emergent issue, we report an undesirable event that occurred in the FFPE archive of the University and Hospital Trust of Modena in June 2024. According to internal standard procedures, FFPE blocks are eliminated after 20 years of storage. The event involved mistakenly collecting blocks from 2024 instead of 2004 for disposal. Fortunately, the error was corrected. The staff began to collect the FFPE blocks from 2004 for elimination (Fig. 1). Due to remarkable

similarities between the years (2004 and 2024) and a random proximity of the archived blocks, they accidentally continued with the year 2024. Several drawers were disposed of before realizing the error (Fig. 2). As a result, 80,000 FFPE blocks from the two years (2004-2024) were mixed (Fig. 3). An urgent meeting was held to evaluate the consequences and decide on the best operational action to take. To rectify the error, five laboratory technicians and one laboratory archivist were required (Fig. 4). All mixed FFPE blocks were manually



**Figure 1.** Staff during the procedure of elimination of FFPE blocks from 2004.



**Figure 2.** FFPE blocks belonging to 2004 and 2024 inadvertently mixed during the disposal process.



**Figure 3.** Bins containing mixed 2004 and 2024 FFPE blocks that had to be manually controlled to avoid inappropriate disposal of the most recent ones.

checked by technicians and the archivist, who were removed from their usual activities for a total of 216 hours of working time. All FFPE blocks from 2024 were recovered and resent for filing in consecutive order. Although major and irreversible consequences for patients' health

were avoided, this human error did result in some damage. While this “recovery” was deemed successful as not a single block was lost, potential delays in routine laboratory workflow (sampling assistance, slide cutting, immunohistochemistry settings) or archive management (consultation requests from patients, molecular analyses requested by clinicians) could have occurred. This event underscores the need for training and compliance with standard quality procedures, even if human error is not always predictable or manageable. Several possible solutions have been proposed to address the archive quandary, including centralization or the use of externally outsourced repositories supported by public-private collaborations<sup>5,6</sup>. Nevertheless, in the modern era of precision medicine, automation – defined as the use of devices designed to supplement or replace human effort in a process – plays a central role in archiving as well. Automation in pathology has demonstrated immense potential for enhancing the accuracy, efficiency, and overall quality of patient care. Automating archives significantly reduces the likelihood of human errors while also shortening procedural times, thereby ensuring the reliability and accuracy of outcomes.

#### CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

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#### ETHICAL CONSIDERATION

None.

#### AUTHORS CONTRIBUTION

Please add

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**Figure 3.** Technicians and laboratory archivist manually controlling each FFPE block to retrieve those from 2024 that were inappropriately discarded.