

## Pathological Anatomy Archives: the need for a paradigm shift

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### Summary

With the advent of personalized medicine, it has become increasingly clear that histological preparations stored in the archives of Pathological Anatomy Departments, from simple “residues” of a diagnostic process, have become containers of large quantities of biopathological information, useful to the patients themselves and to scientific research. For these reasons, taking inspiration from a “near disaster” recently published in *Pathologica*, we propose a different way of conceiving, managing and protecting these archives.

**Key words:** pathology archive, Biorepositories, FFPE tissues, Biobanks, Bioresources.

We read with interest the letter by Eccher et al.<sup>1</sup>; thanking these authors for the intellectual honesty with which they have informed the community of Italian and non-Italian anatomical pathologists of this near-miss disaster, we would like to take this opportunity to make the following considerations:

1. The management of Pathological Anatomy departments archives is often conceived as a marginal aspect of their overall activities to which scarce resources are assigned, dislocating them in unsuitable premises for size, location and technical characteristics (safety against natural disasters, fires, temperature and humidity). Actually, the histological preparations (slides and related paraffin inclusions) should (must) be promptly inserted into a fully traceability path, department's LIS managed, relying on the unequivocal identification of the individual samples, that must bear the stamp of the progressive number and QR code and be scanned and located in specific slide holders, even robotic, from which they can be promptly recovered in case of need (as hoped by the authors themselves in another recent article<sup>2</sup>).

2. The supposed 20-year deadline for the disposal of histological samples is somewhat ambiguous as it derives from an old circular of the Italian Ministry of Health<sup>3</sup>, which equated histological preparations to “clinical documentation”, similarly to X-ray images or the results of chemical-clinical analyses. The subsequent document of the Italian Superior Council of Health<sup>4</sup> shortened this period to 10 years, but this does not constitute a legal obligation, nor the heads of pathology departments can autonomously implement it without specific authorizations from their hospital or regional health institutions (assuming, but it is not certain, that they will eventually grant it).

In our experience we have received requests for tissues taken during autopsies in the 1960s (to resolve paternity issues in cases of contro-

Received: June 3, 2025  
Accepted: June 6, 2025

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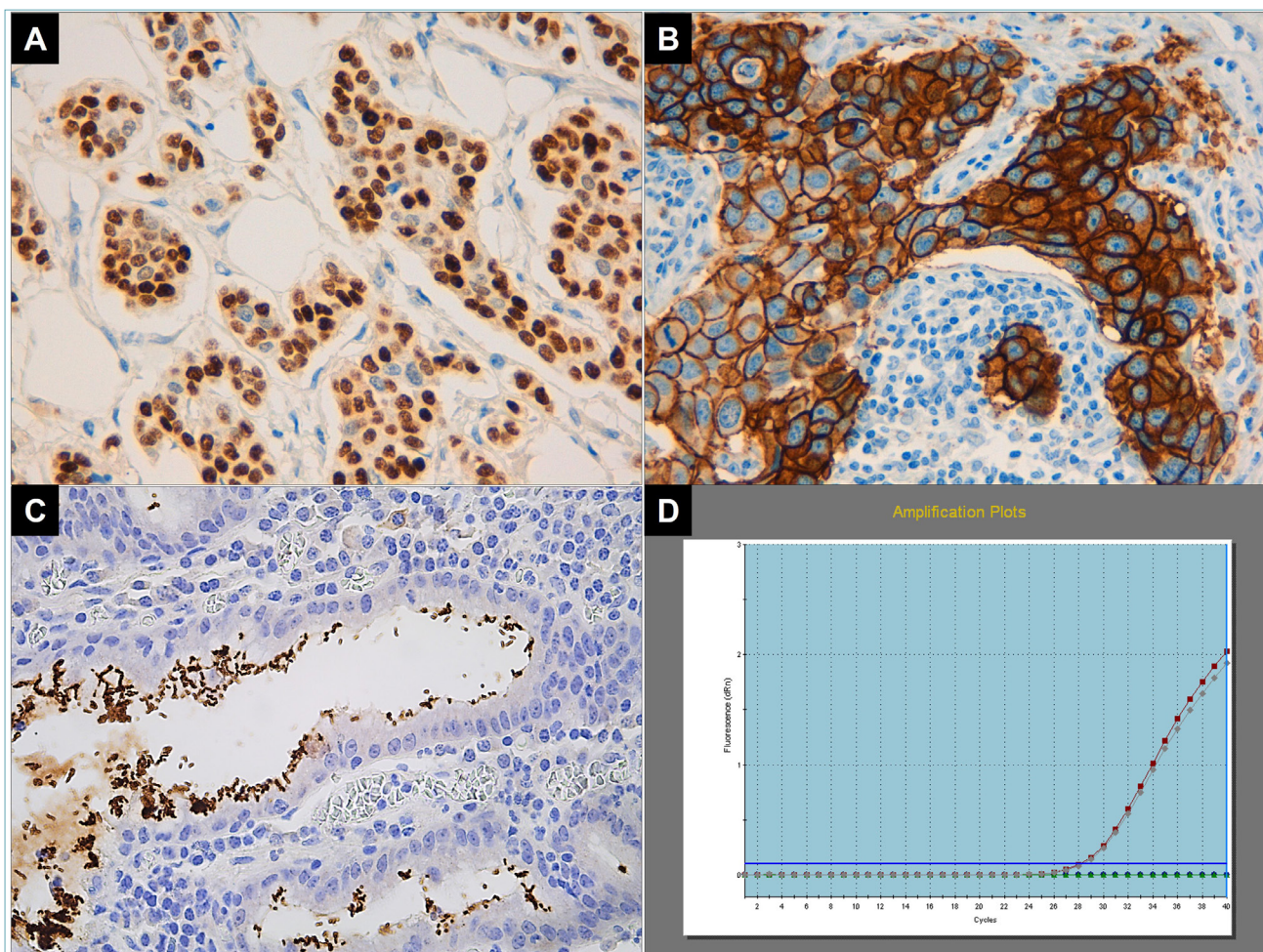
**How to cite this article:** Mandarano M, Floridi C, Pelliccia C, Sidoni A. Pathological Anatomy Archives: the need for a paradigm shift. *Pathologica* 2025;117:306-308; <https://doi.org/10.32074/1591-951X-1393>

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**Figure 1.** Intense and diffuse Progesterone Receptor (A) and HER2 (B) immunostaining in breast carcinoma samples from 1942 — samples number 358 and 386, respectively. *Helicobacter pylori* demonstrated immunohistochemically (C) in a specimen diagnosed as peptic ulcer in 1949 — sample number 5811. Moreover, the same case showed in panel B was tested for the housekeeping gene Ribosomal Protein L37a (RPL37A) — which primer probe set is contained in EndoPredict® QC Strip, that was used for determining total RNA yield through a RT-qPCR — gave a Ct value of 26.8 (D).

versal inheritance) or for neoplastic tissues examined 35 years earlier in the case of long-surviving patients (breast cancer) who needed biomarker determinations. It is quite clear that, in similar situations, it is (ethically) better to have preserved the samples than to have taken them to the incinerator.

3. Our Pathology Department still holds all the histological samples dating back to the old Institute of Pathological Anatomy and Histology of the University of Perugia (1942-2008), subsequently transferred to the new hospital site and reunited with the current series (2009 to date). Preliminary studies conducted on the oldest part of this material allowed us to demonstrate immunohistochemically the presence of hormone receptors and HER2 protein overexpression

in breast carcinomas (Fig. 1 A and B) or the presence of *Helicobacter pylori* in gastrectomies for peptic ulcer (Fig. 1 C). In a subsequent pilot study, we were able to observe a satisfactory conservation of the RNA (Fig. 1 D). These results surprised us greatly both for the objective “antiquity” of the material and for the historical storage conditions, not always optimal, and for the absolute lack of information on the pre-analytical phase of these samples, which at the time were often fixed in alcohol.

Obviously, these observations confirm that tissue samples (FFPE and slides) equipped with demographic data and essential clinical information, as well as the original histological diagnosis, represent formidable opportunities for scientific research. The great poten-

tial of these biological specimens is demonstrated, for example, by the possibility of retrospective follow-ups of 40-50 years or more for the main human cancers or by the mutational analysis of neoplasms dating back to an era in which environmental carcinogenic factors were totally different from nowadays ones, or by the chance of identifying the moment in which new etiopathogenetic factors appeared in the determinism of certain pathologies.

In conclusion, we are convinced that histological samples, on which we have formulated diagnoses, especially oncological ones, must be conceived as extremely precious materials for which we must guarantee high quality standards (with particular reference to the pre-analytical phase) and care, both in the interests of patients/owners and of scientific research. In this perspective, and always remembering that precision medicine has an inseparable relationship with tissues<sup>5</sup>, we must conceive our repositories as true biobanks<sup>6</sup>, whose heritage will become a formidable credit for our discipline as well as an interesting basis for scientific research. For all these reasons, we believe that no FFPE samples should be disposed off, but stored for indefinite periods, allocating specific budgets for this purpose, this aspect being an integral part of our mission. In case of the real impossibility of storing samples in our hospitals, these should be given to (public) research biobanks, but they should never be destroyed nor be a source of risks similar to the one described by Eccher and Colleagues.

#### CONFLICTS OF INTEREST STATEMENT

The authors declare no conflicts of interest.

#### FUNDING

No funding to declare.

#### AUTHORS' CONTRIBUTIONS

All the authors (MM, CF, CP and AS) have contributed to the conception of the present letter to the Editor, either drafting the article or revising it critically. All the authors have read and approved the submitted version of the manuscript.

#### ETHICAL CONSIDERATION

The research was conducted ethically, with all study procedures being performed in accordance with the requirements of the World Medical Association's Declaration of Helsinki.

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