

## Fact Sheet

### Requirements for the retention of laboratory records and diagnostic material (Ninth Edition 2022)

## Retention period for deceased donor samples

**This fact sheet provides guidance on the retention period for deceased donor samples used in subsequent retrospective surveillance.**

### Issue

The National Pathology Accreditation Advisory Council's (NPAAC) *Requirements for the retention of laboratory records and diagnostic material* (the Retention standard) sets the requirements for pathology laboratories to retain laboratory records and materials, including specimens. For example, Table 2 of the Retention standard outlines the minimum retention times for anatomical pathology.

Retaining specimens has two primary purposes:

1. to ensure there is a physical audit trail in case the integrity or identification of the specimen needs to be established
2. to allow additional testing on the original specimen, if required.

Access to retained deceased donor samples is crucial for retrospective testing, when a recipient has a post-transplant complication that is potentially donor derived, such as an infection or malignancy.

In Australia, there are approximately 450 deceased organ donors annually.<sup>1</sup> As part of routine donor screening and workup, blood and other tissue / fluid samples are collected and sent for diagnostic testing. Most samples are sent to accredited Australian pathology laboratories.

Currently timeframes for the retention of samples in Australia varies. Internationally, best practice retention timeframes are a minimum of 10 years.<sup>2,3</sup> Standardising practice in Australia can improve transplant recipient follow up, care and outcomes.

## NPAAC RECOMMENDATION

**That laboratories retain deceased donor samples for a minimum of 10 years.**

In making this recommendation, NPAAC have given consideration to:

- Ensuring compliance with international best practice
- Implementing national consistency
- The compliance impact on laboratories, noting the small number of deceased donors and samples requiring storage should not place an unreasonable or onerous impost on laboratories.

## References

1. Commonwealth of Australia. Australian Donation and Transplantation Activity Report 2022. Canberra, Australia: Australian Organ and Tissue Donation and Transplantation Authority; 2022.
2. Jones JM, Kracalik I, Levi ME, et al. Assessing Solid Organ Donors and Monitoring Transplant Recipients for Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Infection — U.S. Public Health Service Guideline, 2020. MMWR Recomm Rep 2020;69(No. RR-4):1–16.
3. EDQM/European Committee on Organ Transplantation. Guide to the quality and safety of organs for transplantation, 7th edition. Strasbourg, France: Council of Europe, 2018.

## Learn more about NPAAC and the pathology standards

Please visit: [safetyandquality.gov.au](https://safetyandquality.gov.au)

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