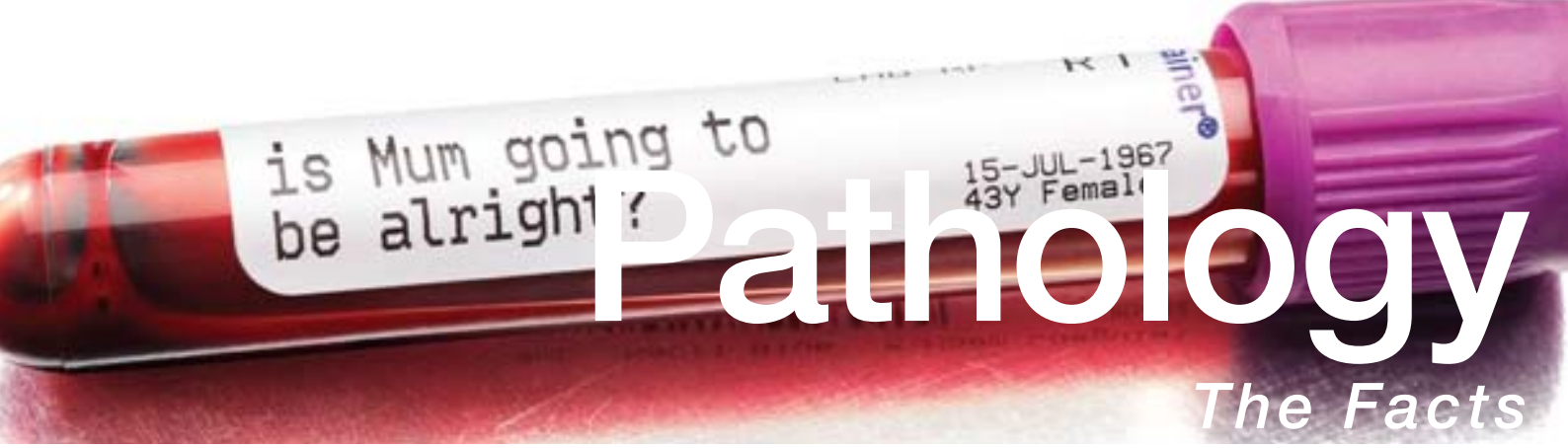


Pathology
The Facts

How safe is the **pathology** testing process?

Australia's pathology laboratories process about 500 million pathology tests each year. Here is a snapshot of that process, including some questions to consider.

Did you know?

Pathologists may need to review up to 90 slides under a microscope to diagnose one case of cancer.

Does anyone regulate the safety and quality of pathology laboratories?

Accreditation is performed against standards developed and maintained by the National Pathology Accreditation Advisory Council (NPAAC), which is a ministerially-appointed expert Council that provides advice to the Australian Government and State and Territory Ministers on matters relating to the accreditation of pathology laboratories. NPAAC plays a key role in ensuring the quality of Australian pathology services. The National Association of Testing Authorities (NATA), which is an independent assessing body, and the Royal College of Pathologists of Australasia (RCPA) jointly perform an accreditation assessment of pathology laboratories seeking approval as an Approved Pathology Laboratory.

This accreditation process is compulsory for tests funded through Medicare and ensures Medicare benefits are only paid for pathology services performed to a high standard of accuracy. Potential risks to patients are also addressed by these standards.

How do I know if a pathology laboratory is accredited?

Look for the NATA/RCPA logos or endorsement certificates that should be clearly displayed in collection centres or pathology laboratories, or ask the pathology laboratory staff if they have NATA/RCPA certification. Patients can also refer to the NATA website www.nata.com.au which lists all Medical Testing laboratories currently accredited in Australia.

NATA

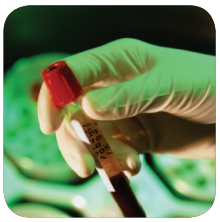
RCPA
The Royal College of Pathologists of Australasia

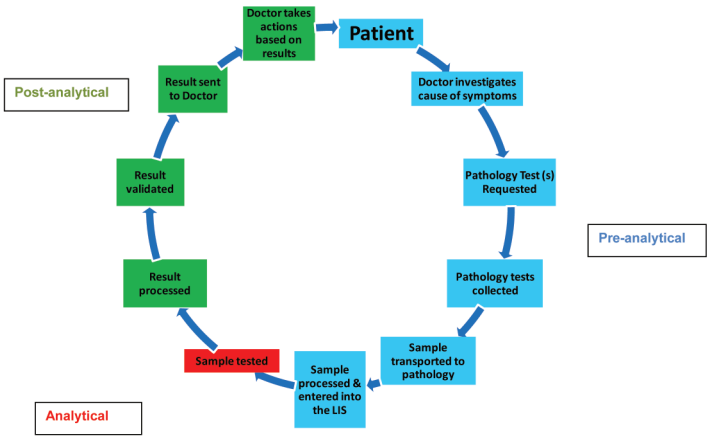
How safe is pathology testing? Are there any risks?

The request-test-report cycle represents the pathology testing process and can be divided into three main stages:

1. The pre-analytical stage covers all aspects of the process before the sample is tested
2. The analytical stage is the actual testing of the sample





3. The post-analytical stage covers the steps after the sample is analysed.

Are there any risks?

The highest risk in the pathology process is when a person presents to have their sample collected. If the person is not identified correctly, or the pathology sample and/or request form do not have the correct information about the correct person, the results may be attributed to another person or treatment may be delayed or missed. For example, a person can be transfused with the wrong blood type if they are not correctly identified.

More than 97% of all pathology specimens are analysed without incident. About 2% of pathology specimens have a minor issue that may require clarification and delay the result. Less than 1% of pathology specimens have a problem that prevents the result being issued safely, or requires collecting another sample.

Other important but rare risks include:

- the sample may be degraded by being transported incorrectly. The risk to a person is usually minimal and might involve collecting another sample
- the actual testing of the sample may not be performed accurately in the analytical stage. This risk is monitored and controlled by quality assurance processes required by all accredited pathology laboratories
- reports issued in the post-analytical stage may contain incorrect results that need to be withdrawn and the report re-issued.

Are all pathology specimens analysed by machines?

Some areas of pathology are highly automated and involve placing multiple specimens, such as tubes of blood, into sophisticated machines called analysers. These highly automated instruments can analyse the specimens quickly with minimal human assistance, although highly skilled staff are still required to ensure the equipment is operating effectively and producing the correct results.

Other areas of pathology are very labour intensive and cannot be automated. For example, tissue samples or slides viewed under a microscope must be manually prepared and individually assessed by pathology staff.

Did you know?

Even though pathologists are involved in the majority of medical episodes, there are very few reported cases of negligence involving pathologists.

What are reference intervals?

Reference intervals (or “ranges”), provided by the pathology laboratory in their report, are required to guide treating practitioners when they interpret a pathology test result. They may be specified by age and gender, and may take other characteristics into account such as a pre-existing medical condition. The most widely used reference intervals reflect the values of 95% of a ‘healthy’ population.

Did you know?

Pathology laboratories are leaders in the medical profession in monitoring and reducing rates of errors and adverse incidents. All pathology laboratories must participate in quality assurance programs that test their performance as part of their accreditation requirements. They must also actively investigate any actual or potential errors and demonstrate corrective actions in their procedures to prevent similar errors from occurring again.

What are false positive and false negative results?

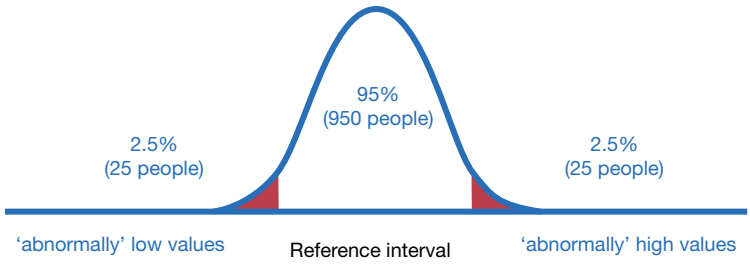
False positive results occur when a person tests positive for a disease or condition they don't have. False negative results occur when a person tests negative for a disease or condition they do have. These occur because reference intervals are only a guide which means some healthy people will have results outside of this range, and some people will have results within this range, even when they are ill.

Are all pathology laboratories the same?

While all accredited pathology laboratories are required to meet the same quality standards, not every pathology laboratory is the same. Some have particular areas of expertise while others are located in particular locations, such as near a hospital or in a rural area, and their services reflect their patients' needs. Patients, and their treating practitioners, should be comfortable with the capabilities, location, services offered and fees charged by their chosen pathology laboratory.

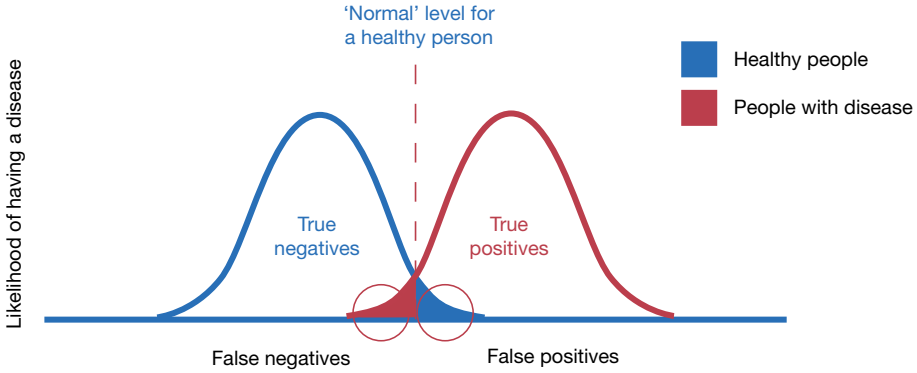
Did you know?

Patients can help pathology laboratory staff minimise the possibility of an error by checking self-collected samples are labelled with the correct information.






Possible outcomes of any pathology test



There are some healthy people who test positive for a disease (false positive) and some people with a disease who test negative (false negative)

Did you know?

Since 95% of healthy people fall inside the set reference interval, the other 5% of healthy people will have a result outside of this range and have a pathology test result that is apparently 'abnormal'. This means that even perfectly healthy people can have a result outside of the reference interval which highlights the importance of interpreting pathology test results against other factors such as age, symptoms and past medical history.

Reliable information on pathology can be found at:

The Royal College of Pathologists of Australasia (RCPA) **- www.rcpa.edu.au**

ePathWay (the RCPA's online magazine for consumers) **- http://epathway.rcpa.edu.au**

The RCPA Manual **- http://rcpamanual.edu.au**

The Pathology Associations Council (PAC) **- www.pathology.med.pro**

Lab Tests Online **- www.labtestsonline.org.au**

The RCPA wishes to acknowledge the Australian Government Department of Health and Ageing for funding the production of Benefits and Risks for Consumers of Pathology Testing

RCPA
The Royal College of Pathologists of Australasia