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The Royal College of Pathologists of Australasia (RCPA) Fact Sheets are in an easy to read format to inform the general public on the risks and benefits of pathology testing, and assist in providing an understanding of the important role pathology plays in the delivery of health care.

The Fact Sheets involved a number of stakeholders including the Consumer Health Forum of Australia; Royal Australian College of General Practitioners, Royal Australasian College of Physicians; Lab Tests Online; Pathology Associations Council; and the Department of Health and Ageing.
Who works in pathology and what do they do?

Australia’s pathology workforce consists of about 24,000 people who collect, process and report on approximately 500 million pathology tests each year. These tests play a vital role in more than 70% of medical diagnoses and inform many of the clinical decisions related to patient care. A typical pathology laboratory uses a variety of scientific methods to test and report on pathology samples, and the workforce is very diverse. Here is a snapshot of the people who work in pathology, including some points to consider.

Collection, transportation and preparation for testing

Collectors are trained to collect specimens from people’s bodies such as blood from a vein or swabs from a wound. They are usually trained by pathology laboratories through internal training programs, or they may have a qualification from a technical college. Collectors are usually the only pathology staff most patients will see.

Collectors can provide information about collection procedures such as advice on preparing for a pathology test and what to do after the test. However, they are not trained or qualified to answer questions about the medical reason a pathology test was requested, or to discuss test results. These questions should be directed to the treating practitioner who requested the pathology test.

Did you know?

Correct identification and labelling of pathology specimens is a key patient safety and quality issue in pathology.

Couriers are trained by the pathology laboratory to transport pathology specimens and deliver reports and materials, such as collection supplies, to healthcare facilities.

Laboratory assistants are trained by the pathology laboratory to perform many of the tasks that involve specimen handling. They confirm specimens are correctly identified and labelled and carry out preliminary processing steps such as dividing specimens into smaller portions for specific tests and directing them to the relevant parts of the pathology laboratory. Laboratory assistants are not generally required to have any specific post-school qualifications.
Testing, reporting of results and liaising with treating practitioners

**Pathologists** are medical graduates who have undergone additional specialist study, training and examinations in pathology. They study the cause of diseases and the ways diseases affect the body by examining changes in tissues, blood and other body fluids. Pathologists also provide expert clinical advice relating to the interpretation of pathology results to treating practitioners, such as explaining the significance of particular test results or how a disease should be managed based on test results. It takes a minimum of 13 years to become a pathologist.

**Medical scientists and laboratory technicians** perform most of the actual testing of specimens but work closely in consultation with pathologists. Medical scientists usually have a university degree in laboratory science, while some have higher qualifications such as a Masters degree or PhD. Laboratory technicians may have a qualification from a technical college, or an Associate Diploma level of training in laboratory techniques.

**Ancillary staff** play an important role in the pathology process. They provide expertise in areas such as management, secretarial support, reception duties, data entry, information technology, health informatics, human resources, accounts and stores.

**Did you know?**

There is a worldwide shortage of pathologists and medical scientists. These shortages can compromise the delivery of pathology-related services including the timeliness, quality and accuracy of diagnosis for a range of diseases. Professional organisations, such as the Royal College of Pathologists of Australasia (RCPA), are working with the government and educational institutions to ensure there will be enough properly trained professionals to provide the pathology testing needed by Australians in coming years.

Reliable information on pathology can be found at:

- The Royal College of Pathologists of Australasia (RCPA) - [www.rcpa.edu.au](http://www.rcpa.edu.au)
- ePathWay (the RCPA's online magazine for consumers) - [http://epathway.rcpa.edu.au](http://epathway.rcpa.edu.au)
- The Pathology Associations Council (PAC) - [www.pathology.med.pro](http://www.pathology.med.pro)
- Lab Tests Online - [www.labtestsonline.org.au](http://www.labtestsonline.org.au)
Why do I need a **pathology** test?

More than 11 million Australians have at least one pathology test a year for a variety of reasons. Here is a snapshot of those reasons, including some points to consider.

**Pathology tests can assist a medical diagnosis**

Pathology tests are associated with more than 70% of all diagnoses and almost all cancer diagnoses. They can:

- provide information to confirm or exclude the presence of particular diseases, such as a wound swab to confirm or rule out a bacterial infection
- provide a final diagnosis such as an assessment of a biopsy to check if a mole or lesion is a skin cancer.

**Pathology tests can assist disease/condition monitoring and management**

Approximately 20% of pathology tests are requested to monitor and manage the progress of a disease or condition, and provide information about how it is likely to progress (prognosis). An example is using blood tests to monitor the progress of kidney disease. Pathology tests can also:

- help monitor the effectiveness of treatment for a disease or condition such as assessing the average amount of glucose in the blood over a few months to monitor diabetic control

**Pathology tests don’t give a simple ‘yes’ or ‘no’ answer about the future risk of a disease. Pathology test results must be assessed along with other factors such as age, environment or gender.**

- help prevent an infectious disease spreading to others in the family or wider community such as testing pregnant women for rubella (German measles) to prevent serious birth defects or miscarriage.

**Pathology tests can assist treatment monitoring and preparation**

Approximately 13% of pathology tests are requested to monitor treatments such as drug therapy. Pathology tests can also determine how well a treatment is working by:

- determining the response to a therapeutic drug treatment such as warfarin therapy to “thin the blood”
• confirming the treatment is working, or if the dose for drug treatment needs adjustment, such as using a thyroid function test to check if thyroxine replacement therapy is effective.

Pathology tests can also help prepare a person for treatment by:

• assisting pre-treatment preparations such as cross matching blood prior to having a blood transfusion following an accident or surgery
• excluding the possibility of an adverse event such as testing for certain antibodies to prevent a blood transfusion reaction
• monitoring the progress of a disease or condition with and without treatment.

Pathology tests can be used to screen for particular diseases

Screening is an organised and systematic public health strategy to reduce the incidence of death and illness from particular diseases. For example, Pap smears are used to screen women for cervical cancer as part of the National Cervical Screening Program.

Another type of screening is ‘opportunistic’ which happens when a treating practitioner decides that a person may have an increased risk of developing a particular disease. For example, a person with a family history of diabetes may have their blood glucose levels checked when they consult their treating practitioner for another reason.

Pathology tests can be used for health checks

Pathology tests can provide information about some aspects of a person’s health at that point in time. They can also assist in the early detection of diseases which avoids delayed diagnosis and the possibility of advanced forms of the disease. For example, a person with high blood pressure may have a pathology test to assess their risk factors for heart disease.

Pathology tests can help classify the future risk of disease

Classifying the future risk of disease is often useful for implementing early intervention or prevention strategies. Pathology tests can help this process by:

• documenting a baseline measurement for future reference such as a lipid (blood fat) profile to record cholesterol levels
• predicting if a disease has a high risk of developing such as monitoring the risk of diabetes in people who are overweight or obese
• providing an indication about the risk of developing a particular inherited disease or condition,

Screening tests are not 100% accurate because they are designed to provide early information about a disease. A positive result simply means additional review and testing may be required, while a negative result is reassuring, but does not guarantee the condition will not present itself in the future.

Pathology tests for employment health checks

Some employers may request drug screens to detect or exclude the presence of abused and/or illegal drugs before they offer employment.

Pathology tests for insurance

Pathology tests for insurance purposes are not compulsory, but the insurer may decide not to provide insurance without them.
Possible outcomes of any pathology test

There is always the possibility of a healthy person testing positive for a disease or condition they don’t have (“false positive”), or a person testing negative for a disease or condition they do have (“false negative”). This is why pathology test results should be interpreted by the requesting practitioner who will take other factors into account, such as age, gender, environment, medications, family history and other medical conditions, when considering a diagnosis or interpreting an unexpected test result.

The insurance industry in Australia has agreed not to require an applicant or insured person to have a genetic test as part of a policy application. (Refer to fact sheet - What should I know about genetic testing.)

Did you know?

Reliable information on pathology can be found at:

- The Royal College of Pathologists of Australasia (RCPA) - [www.rcpa.edu.au](http://www.rcpa.edu.au)
- ePathWay (the RCPA’s online magazine for consumers) - [http://epathway.rcpa.edu.au](http://epathway.rcpa.edu.au)
- The Pathology Associations Council (PAC) - [www.pathology.med.pro](http://www.pathology.med.pro)
- Lab Tests Online - [www.labtestsonline.org.au](http://www.labtestsonline.org.au)
Consent - What you need to know

Pathology is a ‘referred’ service which means the treating practitioner who requests the pathology test is usually responsible for obtaining their patient’s informed cooperation and consent. The level of consent required generally relates to the type of procedure being performed or the type of information being acquired. Here is a snapshot of consent related to pathology, including some points to consider.

Implied consent
Implied consent occurs when a person freely cooperates in a process without discussion or formal consent. An example is a person rolling up their sleeve and extending their arm to have a blood test.

Verbal consent
Verbal consent occurs when a person freely states their consent to a procedure. An example is a woman verbally agreeing to have a Pap smear in a treating practitioner’s office.

Written consent
Written consent occurs when a person freely signs a consent form confirming the procedure and its associated risks have been explained, and they have understood this information. It is usually required for invasive medical procedures, such as a biopsy or surgery to remove a cancerous growth, or for genetic and Human Immunodeficiency Virus (HIV) testing and other lifelong conditions.

Financial consent
Financial consent occurs when the costs for a treatment or procedure, including likely out-of-pocket expenses, are explained before the procedure or pathology tests begin. However, the final account for pathology services may not be known before the pathology tests commence. This is because under Federal Legislation, accounts for services cannot be issued until after all of the pathology tests are completed. (Refer to fact sheet - How are pathology test fees calculated?)

The Private Health Insurance Ombudsman produces a brochure about medical fees.

Consent involving children

Consent involving children is a complex issue. While very young children need the consent of a parent or guardian, the age they are able to formally consent to their own treatment varies according to different State and Territory laws. However this is a grey area. For example, if a treating practitioner assesses that a young teen is sufficiently mature to understand the nature and consequences of a medical procedure, such as a pathology test for a sexually transmitted infection (STI), then it may be possible to validly consent to this treatment. This complex area is further explained in a fact sheet by The Medical Insurance Group at http://www.miga.com.au/riskresources/library/10RRAR05.pdf

Can I refuse to have a pathology test?

Yes. A person can refuse to have a pathology test at any time, although the consequences of this decision should be discussed with the treating practitioner who requested the pathology test.

Tests authorised by statute

These are medical treatments or interventions identified in law such as requirements to have a blood test for alcohol following a traffic accident, or compulsory drug screening. Refusal to consent to these tests may constitute an offence.

Consent related to Cancer Registries

Pathology laboratories are required by law to send details of all incidences of cancer to their State or Territory Cancer Registry.

Consent related to notifiable diseases

Pathology laboratories in each State and Territory have a list of notifiable diseases, such as measles, that must be reported to their local health authority.
Consent related to clinical trials, research and biobanks

Written consent is required for participation in clinical trials, medical research and biobanks (facilities which store human biological samples, called biospecimens, for use in research). Patients can change their mind and decide not to participate in any of these situations, even after the consent form is signed.

Waiver of consent may apply to allow biospecimens from existing collections to be used in research with scientific merit that have been approved by a human research ethics committee. The biospecimens usually have any identifying personal information removed when this occurs.

Did you know?

While patients have the right to withdraw from a clinical or research trial or biobank at any time, it may sometimes not be possible to withdraw if the specimen or information has already been used for analysis, or if all personal identifying information has already been removed.

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
Where can I have a pathology test?

Pathology tests can be performed at the place of collection and/or transported to a pathology laboratory, which should be accredited, for processing. Here is a snapshot of places to have a pathology test, including some points to consider.

What is an accredited pathology laboratory?

The National Association of Testing Authorities (NATA) and the Royal College of Pathologists of Australasia (RCPA) jointly perform an accreditation assessment of pathology laboratories seeking approval as an Approved Pathology Laboratory. Accreditation is performed against quality standards defined by the National Pathology Accreditation Advisory Council (NPAAC) which is a ministerially-appointed expert body that develops and maintains the standards for accreditation of pathology laboratories.

How do you know if a pathology laboratory is accredited?

Look for the NATA/RCPA logos or endorsement certificates, or ask the laboratory staff if they have NATA/RCPA accreditation. Patients can also refer to the NATA website www.nata.com.au which lists all Medical Testing laboratories currently accredited in Australia.

Approved Pathology Collection Centres (APCCs)

APCCs are the facilities to which patients take their pathology request form to have their pathology specimen or sample collected for testing in the pathology laboratory. They are linked to accredited pathology laboratories and are subject to ongoing monitoring processes to ensure the quality of pathology collection services.

Medical consulting rooms

Treating practitioners routinely collect pathology specimens, such as Pap smears or wound swabs, as part of their consultation. Most pathology tests collected by treating practitioners are sent to an accredited pathology laboratory for testing.

Consumers may perform some simple pathology tests themselves using kits approved for sale in Australia by the Therapeutic Goods Administration (TGA). Even though these test systems are relatively simple and reliable, problems may occur such as incorrectly interpreting a result from a home glucose-monitoring kit or pregnancy test kit.
Hospitals

Hospitals require a large amount of pathology testing to support their diagnosis and treatment activities. This includes tests on pathology samples collected during operations, such as the diagnosis and staging of cancers. Pathology laboratories that service hospitals must comply with those institutions’ accreditation systems, and with NATA/RCPA pathology laboratory accreditation.

At Home

Collecting pathology samples at home may be required due to illness or immobility, or due to a test requirement such as a 24hr urine collection. If a treating practitioner requests the test, and the sample is sent to an accredited pathology laboratory, then it will be tested within an accredited framework.

A pathology collector can collect the sample during a home visit, or patients may need to collect their own sample for some tests. Because most patients do not have any training in pathology collection procedures, common problems that may occur with self-collected samples include:

- the sample might be identified incorrectly such as writing the wrong type of specimen on the label
- the sample might be collected incorrectly such as using a poor technique to collect a mid-stream urine specimen
- the sample might be stored incorrectly such as a urine specimen not being placed in the refrigerator
- the patient might not carry out necessary follow-up actions such as returning the collected sample to the pathology laboratory within a suitable timeframe to prevent it deteriorating.

Patients should be aware of these potential issues when they collect their own sample.

Non-accredited settings

Testing offered by complementary health care professionals, some pharmacies or non-accredited pathology laboratories usually operate outside of an accredited framework which may have implications for the quality of the test results. Some of the risks associated with these tests may include:

- that there may be no evidence that the tests offered are appropriate or relevant
- the tests may be performed and interpreted by staff without appropriate laboratory qualifications, training or experience
- the tests may have a high risk for false-positive (testing positive for a disease or condition that isn’t present) and false-negative (testing negative for a disease or condition that is present) results which create unnecessary stress or false reassurance for the patient
- the test results may require follow-up testing to confirm their accuracy
- the tests may be expensive and are not eligible for a Medicare rebate which means the patient will probably be responsible for the full cost of the tests.

A list of all Medical Testing laboratories currently accredited in Australia can be found on the NATA website (www.nata.com.au).
Can I choose which pathology laboratory I go to?

Yes. From 1 July 2010 legislative changes enabled patients to choose which pathology laboratory they go to, unless the request form is directed to a particular pathology laboratory for the reasons listed below.

Why should I go to a particular pathology laboratory?

There are a number of reasons why a treating practitioner may request pathology tests from a particular pathology laboratory. These include:

- the treating practitioner may be familiar with the particular reporting style of a pathology laboratory, and/or have specialised infrastructure and procedures in place to enhance communication of information and test results to the requesting practitioner. If a patient takes their request to a different pathology laboratory then these benefits may be lost
- chronic conditions may require regular monitoring with pathology tests, and the results may be more difficult to track over time if the tests are not performed using the same method, equipment and reporting style of one pathology laboratory
- not all pathology laboratories perform all tests, so the treating practitioner may direct a patient to a particular pathology laboratory that performs the relevant range of tests they have requested
- treating practitioners have a legal obligation to act upon the results of pathology they request. They may encounter difficulties following-up test results if they don’t know which pathology laboratory performed the pathology tests
- the pathology laboratory may have difficulty communicating urgent results outside normal business hours if the requesting practitioner is not a regular requester and their after hours contact details are not known to the pathology laboratory. This can lead to the involvement of emergency services to deliver the test results.

Can I order my own pathology test?

Ordering pathology tests is a complex process and interpreting the results requires medical training. Pathology laboratories are also under no obligation to perform a pathology test without a treating practitioner involved in the process. Even if they do agree to perform the test, Medicare benefits will not be payable and the patient will be responsible for the full cost of the pathology tests.

Did you know?

The decision about which pathology laboratory to attend should be made in consultation with the treating practitioner (see below).

Did you know?

A doctor may rent premises to a pathology laboratory for collection services, but is prohibited from receiving payments for referring patients to a particular pathology provider. Furthermore, according to the RCPA’s position statement, treating practitioners should disclose to patients any commercial links or financial interests they may have in products or services they recommend or provide, including pathology testing services.

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
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.

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.

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

Did you know?

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

**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.
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.

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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.

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

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.

Did you know?

True negatives

’Normal’ level for a healthy person

False negatives

False positives

True positives

Healthy people

People with disease

Possible outcomes of any pathology test

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.
Pathology

What should I know about pathology test results?

Pathology test results influence about 70% of healthcare decisions and patients have the right to know what tests have been requested, and to have their results explained to them. Here is a snapshot of different elements of the pathology test results process, including some points to consider.

Interpreting pathology test results

The treating practitioner is the most appropriate and qualified person to explain and discuss pathology test results. This is because tests represent just one of the many factors that are considered in reaching a diagnosis and planning treatment. Other factors may include:

- age and gender
- current condition and physical findings
- medical, family and social history
- medications
- other diagnostic procedures
- occupation
- ethnicity
- diet.

Can I talk directly to a pathologist about my pathology test results?

While there is no formal restriction on directly contacting a pathologist, the most appropriate person to discuss pathology test results is the treating practitioner. This is because pathology test results must be interpreted in the context of other factors which may not be known to the pathologist, such as complete information to interpret the test result including history and physical examination.

Can I have a copy of my pathology test results?

Yes. Patients are legally entitled to a copy of their pathology test results although the treating practitioner is in the best position to understand and interpret the test results and its potential impact for their patient. If patients would like a copy of their test results, they should be requested from the treating practitioner at the time of consultation, or directly from the relevant pathology laboratory.

Each pathology laboratory will have their own protocol on how to release pathology test results to patients, and they may inform the treating practitioner of this request. This is because reading their own pathology test results may be distressing or potentially confusing for some people. Pathology test results are also reported using technical medical language and may be difficult for most patients to interpret or understand.

A 'normal' pathology test result for one person might be an 'abnormal' result for another. Resources to explore this concept further include a series of brochures produced by the Royal College of Pathologists of Australasia (RCPA) (www.rcpa.edu.au/Publications/Educational/dayinlife.html) and Lab Tests Online (www.labtestsonline.org.au).
Who else can access my pathology test results?

Pathology laboratories are bound by privacy laws regarding the use and release of personal information. This means pathology test results can only be released to health practitioners directly involved in the person’s care. Other potentially interested parties, including family members, cannot access pathology test results without the consent of the person who had the pathology test.

There are circumstances where pathology laboratories are required to release pathology test results to a third party such as:

- when they are required by law to send results of newly diagnosed cancers to Cancer Registries in each State or Territory, or report notifiable diseases, such as measles, to the relevant health authority.

How long will it take to get my pathology test results?

Pathology test ‘turnaround times’ depend on the circumstances and type of pathology test requested. For example, an urgent blood test result may only take minutes to generate. The same test for a non-urgent case may be processed on the next routine run of that particular test, or even the next day. Other pathology tests might take days to complete, such as growing bacteria on a culture plate, or weeks to months if they are sent to a specialist reference laboratory or overseas.

How are pathology test results delivered?

Most pathology test results are transmitted electronically, although some are still delivered to treating practitioners by phone, fax or paper. Treating practitioners can download results from secure Internet sites or access results online using a unique password and login.

Can I get a second opinion?

Yes. While patients cannot directly request a second opinion from the pathology laboratory, they can ask their treating practitioner to arrange one. This may involve collecting another sample, or a second pathology laboratory may be able to process the same sample.

Did you know?

Even when arrangements have been made for patients to receive a written copy of their pathology test results, the laboratory will not release them verbally over the phone due to the difficulty of positively identifying the caller.

Useful resources on health information can also be found through the Office of the Australian Information Commissioner (www.privacy.gov.au).

Did you know?

While patients have a right to request a copy of their results, medical records (including pathology test results) are the property of the treating practitioner. Accessing medical records could require formal requests for access to information via mechanisms such as Freedom of Information Requests (only for public patient records), or in accordance with Privacy Principles such as those published by the RCPA. (http://www.rcpa.edu.au/Publications/PolicyManualPublic/Guidelines.htm and click on Privacy Principles).
Can I have my pathology specimen back?

Yes. Although the original pathology specimen belongs to the person who had the test, it becomes the property of the pathology laboratory once it has been processed or analysed. Pathology laboratories must retain all specimens for a mandatory time specified by law, which varies according to the type of specimen or pathology test, and can be anything from a few days to 20 years. After this time the specimen is destroyed for reasons of privacy, and to avoid infection risks, unless the patient has requested its return. The pathology laboratory may charge a fee to return the specimen because it requires special handling and processing procedures.

**Point of Care Testing (PoCT)**

Point of Care Testing occurs when pathology tests are performed on a testing device at the actual point of care, with results used immediately for patient care. It is particularly suited for critically ill patients in intensive care and emergency units, and in rural and remote communities where pathology laboratory access may be restricted by factors such as geographical distance. For example, PoCT enables pathology test results to be available before a person leaves the treating practitioner’s room to travel home - which can be hundreds of kilometres away.

**Did you know?**

Patients can contact their referring practitioner or the pathology laboratory to get an indication of when their pathology test results will be available.

**Did you know?**

Point of Care tests are often more expensive than the same pathology test sent to a pathology laboratory for analysis, and the costs are not usually subsidised by Medicare.

**Did you know?**

Second opinions may be helpful for a complex diagnosis, or for a significant diagnosis that has serious consequences for the person or their family.

Reliable information on pathology can be found at:

- The Royal College of Pathologists of Australasia (RCPA) - [www.rcpa.edu.au](http://www.rcpa.edu.au)
- ePathWay (the RCPA’s online magazine for consumers) - [http://epathway.rcpa.edu.au](http://epathway.rcpa.edu.au)
- The Pathology Associations Council (PAC) - [www.pathology.med.pro](http://www.pathology.med.pro)
- Lab Tests Online - [www.labtestsonline.org.au](http://www.labtestsonline.org.au)
How are pathology test fees calculated?

Medicare refund payments, which are also known as ‘rebates’, cover most or all of the financial costs of pathology tests for patients. While rebates apply to many pathology tests, patients should not assume this is always the case. Some pathology tests do not qualify for a rebate under any circumstances, while others only qualify if certain criteria are met. The following information may clarify how pathology fees are calculated.

What does Medicare cover?

The Australian Government funds certain pathology services on a fee-for-service arrangement through the Medicare Benefits Scheme. This scheme includes a list of Medicare services subsidised by the Australian Government called the Medicare Benefits Schedule (MBS). Only tests listed on the MBS are eligible for a rebate if certain conditions are met. These include:

- a treating practitioner who is registered with Medicare requests the pathology test
- there is a medical reason for the pathology test
- the pathology sample is sent to a Medicare approved pathology laboratory (Refer to fact sheet - How safe is the pathology testing process?)
- the pathology test has been supervised and quality assured according to Medicare accreditation rules.

For example, if a treating practitioner requests a pathology test that is covered by Medicare to investigate chest pain, and it is sent to a Medicare approved pathology laboratory, that test qualifies for a rebate. If the treating practitioner requests this same pathology test, but for insurance purposes, it does not qualify for a rebate, even though it has been sent to a Medicare approved pathology laboratory.

There are also situations where the frequency of a particular pathology test is limited. For example, a person with established diabetes can only have four of the tests known as ‘Haemoglobin A1c’ rebated by Medicare in every 12 month period, from the date of the first test, to monitor their disease. If they have further Haemoglobin A1c tests within this time frame they must pay the full test fee.

Some pathology tests don’t qualify for a rebate at all and the patient must pay the full test fee. This applies to several scenarios, such as pathology tests associated with elective cosmetic surgery or insurance testing, and a number of genetic tests.

Non-Medicare funded pathology is mostly purchased or funded by government authorities other than Medicare such as workers’ compensation authorities, public hospitals or the Department of Veterans’ Affairs.
What is direct billing?
Direct billing (also called bulk billing) occurs when pathologists accept the Medicare rebate as full payment for their service and there are no out-of-pocket expenses for the patient. Only tests listed on the MBS can be direct billed.

Did you know?
About 85% of all pathology services are direct billed which is the highest rate of any medical specialty.

What are out-of-pocket expenses?
Out-of-pocket medical expenses occur if the pathology laboratory chooses not to direct bill and charges a fee greater than the Medicare rebate. In this instance, the out-of-pocket expense is the difference between the fee the pathology laboratory charges, and the Medicare benefit and private health insurance benefit paid to the patient.

Not all pathology laboratories charge the same fee for the same pathology tests. They are able to set their own fee-for-service according to a range of factors such as operating and staffing costs or according to company policies.

Hospital pathology test fees
When a person is in hospital, the category of their admission determines who pays the pathology account. Public hospital patients are funded through the State public hospital system with no direct cost to them. Private hospital patients are privately billed and they, along with Medicare and their private health fund, are responsible for paying the pathology account. Private health funds often have billing arrangements with particular pathology laboratories for no-gap fees, although not all pathology tests may qualify for a rebate.

How do I find out how much my pathology tests will cost?
To obtain information about the cost of a pathology test, patients can:
- ask their treating practitioner about how the requested pathology tests are being billed
- contact the pathology laboratory for an indication of the approximate cost and out-of-pocket expenses for their requested pathology tests
- contact their private health fund and ask about their pathology billing arrangements
- contact Medicare by calling their 24 hour patient line on 132 011 or go to their website – www.medicareaustralia.gov.au - to find out about Medicare rebates for tests
- contact the relevant hospital and ask about their pathology billing arrangements.

What happens if I don’t pay my pathology account?
While most pathology accounts are direct billed, pathology laboratories will send an account when:
- the test/s are not covered by Medicare
- the pathology laboratory does not direct bill for the full cost of the pathology test.
Patients have a right to be informed by the treating practitioner or pathology collector if there is an out-of-pocket expense before the test. Most pathology laboratories also produce brochures or have information pages on their website about their fees.

If accounts are sent to individuals or organisations and they refuse to pay without an explanation, then debt recovery action may be initiated. If the account causes financial distress, patients can contact the accounts staff at the pathology laboratory to discuss payment options.

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
What should I know about genetic testing?

Genetic testing has benefits and risks that are different from those associated with other pathology tests. This is due to the predictive nature of certain genetic tests and the shared nature and ownership of genetic information. While there are also different reasons to have genetic tests, such as paternity testing and research, this fact sheet focuses on medical genetic tests which impact on health-related decisions.

The benefits of genetic testing

Genetic tests may:
- clarify an uncertain situation such as confirming a diagnosis
- provide peace of mind if fears of a genetic disposition to a disease prove unfounded
- predict a genetic predisposition to a particular disease. This enables health prevention and screening strategies to be put into place to reduce the risk, severity or impact of the disease.

The risks of genetic testing

The purpose of the genetic test in a specific situation determines the level of medical, psychological, social and ethical risk. This is because a genetic test can be used for multiple purposes with different levels of associated risk. For example, one genetic test may be used to screen a population for at-risk individuals of a particular disease, confirm a diagnosis, predict the risk of developing a particular disease or predict the risk of having a child affected with a genetic disorder.

Did you know?

It can be important to share genetic information with relatives, but an Australian study has shown that some relatives do not necessarily want to know this information. (http://jmg.bmj.com/content/43/8/665.full)

The general risks associated with genetic testing include:
- genetic test results can be distressing and may cause psychological harm if they identify a risk of developing a disease; especially if there is no known prevention, treatment or cure
- people can learn distressing information about inherited diseases or disorders involving other family members. This raises issues such as: ‘Should I tell the family?’ Other family members may not want to know this information and it may interfere with family relationships
- genetic tests results can change existing social obligations within families
- genetic information may lead to difficulties obtaining some forms...
Will I need genetic counselling?

The treating practitioner requesting the test can provide genetic counselling and advice about the genetic condition, or they may recommend referral to a specialist genetic counsellor. The extent of genetic counselling required depends on the level of uncertainty regarding the medical implications of the genetic test result, the potential implications for the patient and the further implications for their family.

Who can request a genetic test?

- treating practitioners can request genetic tests for their patients.
- patients can request genetic tests directly from some private pathology laboratories. This is called Direct-to-Consumer (DTC) genetic testing. (Refer to fact sheet - What should I know about Direct-to-Consumer genetic testing?)

Consent for genetic tests

Before a person consents to a genetic test, their referring practitioner should provide information that helps them clearly understand the risks, benefits, limitations and implications of the test. They should also be given clear information about how long genetic samples and personal data are stored including what happens to these if the pathology laboratory ceases operation. They should also receive information about how results of important genetic tests that may have familial implications can be communicated to others in the family over a time period that may exceed a human lifetime.

Who performs genetic tests?

- specialist genetic testing laboratories in the public hospital system (the usual route for complex testing)
- pathology laboratories in the public and private sectors who perform genetic tests for a few common disorders
- Direct-to-Consumer (DTC) laboratories that advertise directly to patients through public media such as the Internet and magazines.

Did you know?

Genetic counsellors in Australia are tertiary trained health professionals with specialist training in genetics and counselling.

Did you know?

Genetic tests don’t predict what will happen; they only give an idea of what might happen and therefore don’t determine the medical outcome. For example, a genetic predisposition to heart disease does not necessarily mean a person will develop the disease, only that they might develop it. There are other non-genetic factors that influence the outcome such as lifestyle, environment, chance or age.

of life, travel or disability insurance or affect family planning decisions

• genetic information can also lead to discrimination in personal, social or work-related matters, even though these outcomes should not occur.
Pathology laboratory accreditation

The National Association of Testing Laboratories (NATA) and the Royal College of Pathologists of Australasia (RCPA) jointly accredit medical laboratories in Australia. Accreditation is only required if a pathology laboratory seeks a Medicare rebate for certain pathology services. This means that genetic tests could be performed in a pathology laboratory that has not been accredited for that scope of testing.

NATA/RCPA accredits very few medical laboratories outside Australia so assessing the quality standards of some DTC laboratories can be difficult. It is especially risky if the pathology laboratories are located in countries with minimal patient protection laws.

Interpreting genetic test results

Genetic test results should be interpreted by an experienced treating practitioner in the context of other health factors such as family history, environmental characteristics, other health conditions and current medications. The results can be challenging to interpret due to factors such as:

- a positive test result doesn’t necessarily translate to a confirmed medical diagnosis, but might only indicate an increased risk of developing a disease or condition
- a negative test result doesn’t mean there is no risk of disease. For example, a person may have the same risk of developing the disease as the general population, or carry a genetic alteration that has not yet been identified but increases their risk of that disease
- the same test result can have different implications for different people based on factors such as their age, sex and environment.

Confidentiality of genetic test results

Genetic information is not provided to other health professionals, family members or third parties such as employers or insurance companies without the consent of the patient. However, pathology laboratories are required to send a copy of all test results to the requesting practitioner. Additionally, if the test has been referred from one pathology laboratory to another for testing, then the testing laboratory is required to send a copy of the report to the requesting laboratory.

Did you know?

Pathology laboratories may refer some services to overseas laboratories to access rare or obscure genetic tests.

Most genetic tests are offered free of charge to patients if they access them through a genetics service. Lists of these services are freely available through the Centre for Genetics Education – www.genetics.edu.au.

A treating practitioner may be authorised under Federal privacy legislation to release information directly to at-risk relatives about a familial disorder. This is only allowed in exceptional circumstances. For further information go to: http://www.privacy.gov.au/index.php?option=com_content&view=article&id=960&Itemid=2147

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Did you know?
Potential misuse of genetic information

Genetic test results, and their implications, may be misunderstood and misused by those who have access to them if they are not interpreted accurately. There is also the risk of intentional interference with test samples in certain situations such as during family law proceedings.

Will I have to pay for my genetic test?

Patients should ask their treating practitioner, or the pathology laboratory performing the genetic test, about the financial costs involved before they attend to have their test. This is because some genetic tests are provided free-of-charge through public hospitals, and a select few are funded by Medicare, while many genetic tests are offered privately, but only via a fee-for-service arrangement.

Genetic testing and the insurance industry

Under Australian law, applications for life and disability insurance are usually required to disclose any known health or genetic information about themselves or genetic relatives. Insurance companies and employers traditionally obtained this information by asking questions about the health and causes of death of close genetic relatives.

However, the insurance industry in Australia has agreed not to require an applicant or insured person to have a genetic test as part of a policy application. If they already have information about a genetic relative, they don’t extract that information and insert it into the person’s file.

In Australia, private health insurers cannot charge a higher premium based on a person’s medical history, including their genetic test results.

The fact sheet has been developed by the Royal College of Pathologists of Australasia (RCPA) and the Human Genetics Society of Australasia (HGSA).

Did you know?

There is a risk that a person might not have a genetic test, or seek genetic counselling, in case the test results jeopardise access to life insurance at the expense of potentially lifesaving medical interventions.

Reliable information on pathology can be found at:

- The Royal College of Pathologists of Australasia (RCPA) - www.rcpa.edu.au
- The Human Genetics Society of Australasia (HGSA) - www.hgsa.org.au
- Centre for Genetics Education - www.genetics.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
What should I know about Direct-to-Consumer genetic testing?

Direct-to-Consumer (DTC) genetic testing refers to tests directly requested from a laboratory by a consumer without requiring a referral from a treating practitioner. The consumer deals directly with the laboratory including collecting the sample and sending it to the laboratory, receiving the results and paying for the test. DTC genetic tests are usually marketed directly to consumers through public media such as the Internet and magazines.

How do DTC genetic tests differ from other types of genetic tests?

Recreational genetics: Some genetic testing carries no risk of impact on health or wellbeing. For example, “recreational” genetics may involve testing the type of earwax one has, while “genealogy” or “ancestry” genetics may involve determining which country a person’s original ancestors came from. DTC can be very convenient for this type of genetic testing.

Paternity testing and forensic genetics: Genetic testing can be used to establish the identity of people, and to test if two people are related to each other. This type of testing is highly regulated by the courts and involves testing in accredited pathology laboratories. (Refer to fact sheet - How safe is the pathology testing process?)

Community genetics: Community genetics offers testing directly to the consumer, but only as part of a full healthcare program involving accredited pathology laboratories and registered health practitioners. Community genetics is often relevant to consumers from particular geographic origins and community groups, and can be used to screen for risk of particular inherited disorders such as “Tay-Sachs disease” which is a serious disorder affecting young children.

Medical genetics: Genetic testing is increasingly used to diagnose a range of diseases including inherited disorders and some cancers. This type of testing is only carried out as part of a medical consultation, and the treating practitioner will use an accredited laboratory to test the sample and provide the pathology report.

Did you know?

Some DTC laboratories offer tests for medical genetics, but label the results with a disclaimer that it is “for informational purposes only”. Using these DTC services greatly increases the risks to consumers as they are left without the support of a health practitioner to advise them about which genetic test results are relevant to their particular individual health circumstances, and which genetic test results may require medical follow-up or treatment.
Do DTC genetic tests put me in charge of my own health decisions?

Consumers are encouraged to take greater care and responsibility for their own health, actively participate in their health care decisions and adopt a healthy lifestyle. The rapid advances in genetic testing have meant consumers can now purchase low-cost DTC investigations which might appear to fulfil this ‘healthy living’ independent philosophy, but is not always the case.

Are DTC genetic test results reliable?

The National Association of Testing Authorities (NATA) and the Royal College of Pathologists of Australasia (RCPA) jointly perform an accreditation assessment of pathology laboratories in Australia. Accreditation is not compulsory for DTC testing. In fact, anybody can offer DTC genetic testing, regardless of qualification or experience, because they are usually offered outside of the regulatory and accreditation framework that applies to most other pathology tests.

The quality of the genetic test result can be assured if an accredited laboratory tests the sample. The consumer should therefore ensure that testing offered by a DTC service is only performed in an accredited pathology laboratory. They can do this by looking for the NATA/RCPA logos or endorsement certificates that should be clearly displayed in accredited pathology laboratories, or by asking the pathology laboratory staff if they have NATA/RCPA accreditation.

Similarly, accurately interpreting the test result requires an appropriately trained expert health practitioner to review the results.

There is also the risk of testing benefits being overstated. For example, some DTC services claim genetic tests can predict “skin health” or “nutritional health”, even though there may be limited evidence about the accuracy or usefulness of such tests.

Interpreting genetic test results

Interpreting genetic test results is not an easy task - even the experts can find it challenging! The results must be interpreted within the context of a person’s medical and family history because other factors, such as obesity or smoking, may pose a greater threat to a person’s health than their genetic risk profile.

There are also psychological risks involved if a person receives adverse genetic test results without appropriate genetic counselling, as well as the potential for consumers to be falsely reassured or alarmed if their genetic test results are not properly interpreted by an experienced health practitioner.

While a genetic test result can confirm if a particular genetic variation is present or not, this result does not necessarily provide a precise estimate of the risk or severity of disease associated with that gene. This is because a single genetic variation is only one of many factors, such as lifestyle, age and changes in other genes, which determine future health. The context of the test usually determines the medical significance of
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.

Health practitioners assist consumers with decisions that are appropriate for their personal situation, and can arrange access to the relevant expertise required to follow through with that decision, such as genetic counselling. They can also discuss the ethical and social issues raised by the specific genetic test/s being considered. These benefits are lost with DTC genetic tests if they are performed without this expert interpretation and counselling.

Did you know?

Genetic tests should only be carried out once the consumer has been given sufficient and relevant information about the risks, benefits, limitations and implications of the test, and then freely given their consent.

Consumers should ensure they do not unintentionally consent to the release of their genetic information for secondary purposes, such as research, or for their information to be sold to a third party such as a pharmaceutical company. They can ensure this does not happen by reading the consent form thoroughly, or by asking these specific questions if they have the opportunity.

Pathology laboratories should also take reasonable steps to ensure the specimen received for testing is actually from the person identified as the specimen provider. This is difficult to monitor in some DTC testing because the consumer is usually never sighted by the DTC laboratory staff and may inadvertently accept specimens that are submitted under false names or identities, leading to serious threats to people’s privacy.

This fact sheet has been developed by the Royal College of Pathologists of Australasia (RCPA) and the Human Genetics Society of Australasia (HGSA).

For further information on DTC Genetic testing the following document may be useful:

Reliable information on pathology can be found at:

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

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- www.hgsa.org.au

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