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FRIENDS OF SCIENCE IN MEDICINE (FSM) RECOMMENDATIONS FOR PATHOLOGY TESTS IN AUSTRALIA

This paper was prepared by the FSM Pathology Advisory Group which includes distinguished pathologists from Australia and New Zealand.

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Introduction

The results of pathology tests are often the basis for important decisions in healthcare. If a patient is going to make an important health-related decision on the basis of a pathology test, it is essential that the test result be accurate and reliable. If a pathology test is not consistently accurate, it is inevitable that a patient will end up making the wrong decision on the basis of an inaccurate result.

When healthcare practitioners are assessing the value of a pathology test, they consider three characteristics of the test:

- **Does the test result reflect the reality in the patient's body?** In other words, does the measurement in the test tube accurately reflect the measurement in the patient's blood (or whatever tissue is being analysed)? This characteristic of the test is called its "**analytical validity**".
- **Does the test result have a significant relationship with the disease in question?** In other words, is the measurement typically abnormal in patients with a particular disease? Can the test result be used to predict that a person is likely to develop a particular disease? This characteristic of the test is called its "**clinical validity**".
- **Does the test result provide additional information that is not already available?** In other words, does the test result enable the patient to make a health care decision that would not have been otherwise possible? If the test result simply confirms something



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that the patient already knows, then the test has not provided useful information. This characteristic of the test is called its "**clinical utility**".

It is easy to see the importance of these characteristics for a pathology test.

- If the test result does not accurately reflect a measurement in the patient's body, then the test result will be misleading. For example, there would be little point in measuring the haemoglobin concentration in blood if the test result was inaccurate.
- If the test result is accurate, but the measurement bears no relationship to the patient's risk of disease, then the result will be meaningless. For example, there would be little point in providing accurate analysis of a gene responsible for breast cancer if the disease of concern to the patient is dementia.
- If the test result is accurate and associated with the disease in question, the result will only be useful if it provides additional information. For example, if a patient is known to have a bacterial infection, a further test that simply confirms that the patient has a bacterial infection has not provided useful information.

There is a fourth characteristic of the pathology test that is important. Is the cost of the test justified by its usefulness? This is important for both governments and individuals when they decide for what tests they will pay. This characteristic is called its "**cost-effectiveness**".

The Australian Government funds many pathology tests through Medicare. These tests have usually been through a rigorous process of assessment to confirm that each test has analytical validity, clinical validity, clinical utility, and is cost-effective. These tests are listed in the Medical Benefits Schedule

(<http://www.health.gov.au/internet/mbsonline/publishing.nsf/Content/Medicare-Benefits-Schedule-MBS-1>). This list of tests is constantly changing as some tests are removed and new tests are added.

There are also tests which are considered to fulfil these criteria, but which are not funded by Medicare. These tests have not necessarily had the rigorous process of assessment required for listing of the test on the Medical Benefits Schedule, but they are deemed by medical practitioners to have the required characteristics. These tests are often funded by a State Department of Health, or the patient may pay for the test. This includes many genetic tests



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which have been introduced relatively recently and have yet to be assessed for Medicare funding. This is a rapidly changing category of pathology tests. See LabTests On line <http://www.labtestsonline.org.au/>, or the genetic testing site of RCPA <http://www.rcpamannual.edu.au/>. It is important that any health practitioner considering using such a test be aware of the test characteristics, to ensure that the patient's interests are met by having the investigation.

The tests in both the Medicare- and non- Medicare funded categories can be the basis for important decision-making by patients in consultation with their doctors. However, they can be overused or used inappropriately. To ensure that the pathology tests are provided consistently at an appropriate standard, there is a national program of accreditation for the tests, for the laboratories which provide them, and for health professionals who work in them. This national accreditation program provides assurance that these pathology tests can be relied upon when making significant medical decisions. These processes also ensure that the people ordering, performing, and using the test are accountable for their actions.

There are many tests offered to patients that do not have these required test characteristics. This is a major concern of FSM and it initiated this advisory paper after consultation with leading specialists in clinical and laboratory medicine.

- **A test that has not been provided by an accredited pathology laboratory has not been assessed for its analytical validity. In other words, the test result may not necessarily match the reality inside the patient's body.**
- **Claims are frequently made about the relationship between the test result and the risk of disease for which the evidence is flimsy or non-existent. This means that such tests may have little if any clinical validity.**
- **Such tests should not be the basis for decision-making in healthcare because they are potentially unreliable, and have little if any clinical utility. Indeed, if such a test result leads to a patient making the wrong decision for their health care, the test is harmful. The end result can be that patients end up paying for something that does them harm.**
- **Such tests bypass the chain of accountability in which healthcare professionals are responsible for the requesting, performing, and utilisation of tests.**



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- **Laboratories offering these tests should not be endorsed or ratified by the RCPA and NATA, no rebate should be available from government or private health insurance authorities, and no rebate should be given for the taking of blood for these tests.**

We recognise the importance of every member of our community taking steps to look after themselves, to reduce their own risk of disease, and to report any new symptoms promptly. Access to accurate pathology tests constitutes an important element in fostering a healthy community. But **the promotion and commercialisation of tests which lack analytical validity, clinical validity, clinical utility, and cost effectiveness are not in the interests of the individual or public health in general.**

Recommendations

- Friends of Science in Medicine (FSM) endorse the use of scientifically validated and clinically relevant pathology tests provided by nationally accredited professionals and laboratories.
- All pathology tests that attract a Medicare rebate should be scientifically validated and clinically relevant in at least some clinical settings.
- Tests that are listed in the Medicare Schedule or which have sufficient evidence to justify their use for specific clinical purposes should only be ordered by an appropriately qualified and registered health practitioner, and only if the test is clinically indicated. These tests should only be provided by accredited professionals working in accredited medical laboratories.
- **There are other tests which are offered to the public outside the context of medical testing. These tests are advertised directly to the public, may involve patients collecting their own samples, and may not require the involvement of a registered health practitioner. These tests are not publicly funded by the Australian Government (through Medicare) or by State or Territory Governments. The FSM do not consider such tests to have a sufficient evidence base or accredited testing**



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processes for them to be used for medical purposes or decision-making. Some examples of such tests are in Table 1.

- FSM respects the right of individuals to have unvalidated tests provided by unaccredited laboratories (Table 1) performed on themselves if they so wish. However, these tests cannot be regarded as “medical tests” or “pathology tests” as they do not have the analytical validity, clinical validity, or clinical utility required of a test to be used for medical purposes.
- A healthcare practitioner who orders an unvalidated test, or who bases a clinical decision on such a test, could potentially be held liable for failing to act in the best interests of a patient.
- It is recognised that, over time, a test may cease to be suitable or may become suitable for medical purposes. Nonetheless, the distinction between tests that are suitable for medical purposes and those that are not should not be blurred. It is both inaccurate and potentially dangerous for an unsubstantiated non-validated test (Table 1) to be regarded in the same light as tests that are substantiated and are provided by laboratories accredited for medical testing.
- Subject to the above, the FSM offers no opinion on the right of a provider to offer tests in Table 1 to the public if the provider acknowledges the lack of validity of these tests and the potential dangers of using these tests as a basis for medical decision-making. These cautions should be included in the test report.
- This policy should not be understood to be an endorsement by the FSM or RCPA of the appropriateness of any particular validated pathology test for a particular patient. Responsibility for such tests remains with the requesting clinician, the medical laboratory providing the test, and the accrediting and regulatory bodies governing the practice of pathologists and medical laboratories.

Relevant websites

<http://www.nhmrc.gov.au/guidelines/publications/e99>



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<http://www.nhmrc.gov.au/guidelines/publications/ps0004>

Selected tests that can be useful or abused (E.g. Genetic testing). This is a rapidly evolving area where some genetic tests performed by government accredited laboratories backed by accredited genetic counsellors may be clinically useful e.g. genes that are established to increase cancer risk or antenatal or preimplantation genetic screening for major chromosomal inherited disorders.

However, it is also possible to provide a genomic profile of individuals which will include many genetic alterations of unknown clinical significance which may cause the patient anxiety and lead to unproven and unnecessary interventions. Until much more is understood, commercially driven exploratory whole genome and exome sequencing of individuals is not appropriate.

Table 1. Non Medicare approved tests that have no proven validity and should be avoided

- ☒ Live blood analysis
- ☒ Salivary hormone tests for reproductive hormones, thyroid, cortisol, melatonin etc (except for salivary cortisol (bedtime sample) for Cushing's syndrome)
- ☒ Reflexology, Iridology and kinesiology testing
- ☒ "Vega" tests
- ☒ "Functional" pathology tests e.g. liver detoxification profile
- ☒ Clot retraction Tests
- ☒ Complete digestive stool analysis
- ☒ Hair analysis for toxins, mineral analysis (non-forensic)
- ☒ Blood type testing for blood type dieting
- ☒ Zinc taste tests
- ☒ Unvalidated cancer markers
- ☒ A variety of pseudo-diagnostic machines e.g. 'Electro Dermal Screening' devices
- ☒ Some food allergy tests not performed by NATA-approved laboratories provocation/neutralisation skin or sublingual testing for allergy. See Appendix



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Appendix: The Australasian Society of Clinical Immunology and Allergy (ASCIA) – Unorthodox Techniques for the diagnosis and treatment of Allergy, Asthma and Immune Disorders.

<http://www.allergy.org.au/health-professionals/papers/unorthodox-techniques-for-diagnosis-and-treatment>