

BENEFITS OF USING AN ACCREDITED MEDICAL LABORATORY

Choosing an accredited laboratory provides peace of mind and an assurance of a job well done



You wouldn't drive a car that isn't roadworthy – because the risks are obvious. The same is true of services from medical laboratories – you need to make sure that your choice is safe and assured.

You need the confidence that the laboratory operates within defined procedures and to established standards. You want to know that your tests will be undertaken by a laboratory that has the right people, facilities, expertise, systems and track record to do the job right – first time and every time.

That's what laboratory accreditation is all about.

Accreditation is a means of determining the technical competence of testing, calibration and medical laboratories to perform specific types of testing, measurement and calibration. It provides formal recognition that laboratories are competent, impartial and independent, therefore providing a ready means for customers to identify and select reliable testing, measurement and calibration services that are able to meet their needs. To maintain this recognition, laboratories are re-evaluated regularly by a recognised accreditation body to ensure their continued compliance with requirements, and to check that their standard of operation is being maintained.

Laboratory accreditation is highly regarded both nationally and internationally as a reliable indicator of technical competence.

Accreditation uses criteria and procedures specifically developed to determine technical competence. Specialist technical assessors conduct a thorough evaluation of all factors in a laboratory that affect the laboratory results.

The criteria are based on the international standards called ISO 15189, which are used to evaluate medical laboratories throughout the world.

WHAT FACTORS ARE IMPORTANT WHEN CHOOSING A LABORATORY?

When selecting a testing, calibration or measurement laboratory, you need to be sure that it can supply you with accurate and reliable results that meet your requirements. The list of the test, calibration, or measurement procedures for which the laboratory is accredited is specified in a laboratory's Scope of Accreditation, which can either be provided by the laboratory upon request, or is contained within the directory of accredited laboratories produced by the accreditation body. You should check that the laboratory is accredited for the specific work that you require to be undertaken.

The technical competence of a laboratory depends on a number of factors, including:

- Qualifications, training and experience of the staff
- Correct equipment – properly calibrated and maintained
- Adequate quality assurance procedures
- Proper sampling practices
- Appropriate and valid testing procedures and methods
- Traceability of measurements to national standards
- Accurate recording and reporting procedures
- Suitable testing facilities

By being accredited, the laboratory is demonstrating that these requirements, amongst others, have been and continue to be met, thus assuring you, the client, that your laboratory's examination results are accurate and reliable.

Advantages of using an accredited laboratory
Most of the accreditation bodies have adopted ISO 15189 as the basis of accrediting medical laboratories. This has helped countries employ a uniform approach to determining laboratory competence. This uniform approach allows countries

to establish agreements among themselves, based on mutual evaluation and acceptance of each other's accreditation systems. Such international agreements, called mutual recognition arrangements (MRAs), are crucial in enabling laboratory data to be accepted between countries. This effectively reduces costs to the patients as it eliminates the need for re-testing in another laboratory.

Other benefits to the client include:

- **The knowledge that results are traceable to international standards**
- **The knowledge that tests have been carried out by competent staff** on well-maintained, regularly calibrated equipment
- **The knowledge that results are as reliable as possible**
- In the event of a dispute the **results will carry far more weight than results from a non-accredited laboratory.**

HOW DOES USING AN ACCREDITED LAB BENEFIT GOVERNMENT AND REGULATORS?

Government bodies and regulators are constantly called upon to make decisions related to:

- Protecting the health and welfare of consumers and the public
- Protecting the environment
- Developing new regulations and requirements
- Measuring compliance with regulatory and legal requirements
- Allocating resources, both technical and financial

In order to make informed decisions, they must have confidence in the data generated by laboratories carrying out testing, measurement or calibration in these fields. Using an accredited laboratory can help establish and assure this confidence.

When a laboratory is accredited by a recognised accreditation body, it has demonstrated that a prescribed level of technical competence to perform specific types of testing, measurement or calibration activities has been achieved. The result is assurance that the laboratory is capable of producing data that is accurate, traceable and reproducible – critical components in governmental decision-making.

Using an accredited laboratory benefits government and regulators by:

- Increasing confidence in data that is used to establish baselines for key analyses and decisions
- Reducing uncertainties associated with decisions that affect the protection of human health and the environment
- Increasing public confidence, because accreditation is a recognisable mark of approval
- Eliminating redundant reviews and improving the efficiency of the assessment process (which may reduce costs)

Using an accredited laboratory also increases confidence that:

- Decisions regarding multiple facilities are based on comparable data
- Costs associated with laboratory problems, including re-testing, re-sampling, and lost time are minimised
- False positives and negatives, which can directly affect compliance with regulations, are minimised

POTENTIAL HAZARDS TO ONE'S HEALTH WHEN USING NON-ACCREDITED LAB

Reporting a wrong result can have potentially devastating effects on the patient. For example, one patient could receive wrong medical or surgical treatment while another doesn't get the treatment he or she needs. Either situation can result in severe, irreversible consequences.