



# Nutritional supplement and ingredient testing services

Through the acquisition of HFL Sport Science, LGC has a world-class sports anti-doping laboratory that has pioneered a sports supplement and ingredient testing service for reputable manufacturers.

All testing is performed using methods accredited to the international ISO 17025 standard (audited by UKAS, the United Kingdom Accreditation Service), providing trusted results.

## Detection levels

The nutritional supplement screen can be used to analyse both final products and raw materials for the presence of banned substances at exceptionally low detection levels. Steroid contaminants can be detected at levels of 10 ng/g (10ppb) whilst stimulants and other contaminants can be detected at levels of 100 ng/g (100ppb), or lower. The formulation types suited to this screen include powders, liquids, gels, capsules, bars and tablets.

## Turnaround time and reporting

Sample analysis typically takes 7-10 working days following receipt at the laboratory. Results are reported to the customer via a Certificate of Analysis





### Quality assurance

The nutritional supplement screen assists supplement manufacturers and suppliers with process and quality control procedures. LGC has been partnering with supplement companies for more than 10 years, and has analysed more than 40,000 products to date.

The screen is used to test supplements or ingredients for a broad range of substances that are prohibited by sports regulatory authorities, helping to ensure that the products are not inadvertently contaminated with such substances. Ultimately the screen aims to reassure athletes that supplements that are made to good quality standards and that are tested for banned substances are safer to use.



### Secure nutritional supplement storage

LGC offers a secure, independent long-term storage facility for nutritional supplement products. This service is ideal for companies who wish to have 'A' and 'B' sample analyses performed, a procedure routinely used in sports regulatory testing.

The 'A' sample is tested upon arrival at the LGC laboratory and will be disposed of once the analysis has been completed.

The sealed 'B' sample is checked upon arrival at LGC to ensure that all seals are intact. This sample is transferred into secure storage for the shelf life, rounded up to the nearest full year.

The secure storage option is particularly useful for the following:

- It enables subsequent testing of a supplement to be performed in cases where allegations against a product are made – the 'B' sample may be retrieved from secure storage at the request of the customer for any further work they would like to have carried out
- It enables progressive product testing – the WADA list of prohibited drugs in sport is updated annually and new drugs may be added or removed from the list. The detection levels required for the prohibited substances may also be subject to change. The nutritional supplement screen is therefore continually evolving to keep abreast of these changes. Any supplement held in secure storage may be retested at any time at the request of the customer against the most up-to-date version of the supplement screen

All samples in secure storage are fully traceable on our LIMS (Laboratory Information Management System) and samples may be retrieved from storage at any time at the written request of the customer.

### Sports supplements and cGMP

cGMP refers to the current Good Manufacturing Practice regulations promulgated by the US Food and Drug Administration under the authority of the Federal Food, Drug, and Cosmetic Act. These regulations, which have the force of law, require that manufacturers and packagers of drugs, blood, medical devices, and some food, take steps to ensure that their products are safe, pure, and effective. cGMP regulations require a quality approach to manufacturing, enabling companies to minimise or eliminate instances of contamination, mix ups, and errors. This in turn, protects the consumer from purchasing a product which is not effective or may even be dangerous. Failure of firms to comply with cGMP regulations can result in very serious consequences including recall, seizure, fines and potentially jail for Directors.

cGMP regulations address issues including recordkeeping, personnel qualifications, sanitation, cleanliness, equipment verification, process validation, and complaint handling. However, most cGMP requirements are general and open-ended, allowing each manufacturer to decide individually how to best implement the necessary controls. This provides much flexibility, but also requires that the manufacturer interprets the requirements in a manner which makes sense for each individual business.

### The regulation of supplements

Currently, in the US the FDA regulates dietary supplements under a different set of regulations than those covering "conventional" foods and drug products (prescription and Over-the-Counter). Under the Dietary Supplement Health and Education Act of 1994 (DSHEA), the dietary supplement manufacturer is responsible for ensuring that a dietary supplement is safe before it is marketed.

The FDA is responsible for taking action against any unsafe dietary supplement product after it reaches the market. The manufacturers do not need to register their products with the FDA nor get FDA approval before producing or selling dietary supplements. Manufacturers must make sure that product label information is truthful and not misleading.

### Frequently asked questions

#### Is cGMP an effective way of assuring that the product is free from contamination with banned substances?

Whilst the requirements of cGMP will undoubtedly provide a degree of confidence in the integrity of the manufacturing process, it does not specifically address the particular issue of potential contamination of sports supplements by low concentrations of WADA prohibited substances. cGMP will essentially focus on issues of safety, requiring quality control testing for contaminants at levels typically 1000-10000 times higher than concentrations that might trigger a positive WADA test in urine.

It is possible, therefore, that products manufactured in a cGMP certified facility can still be contaminated with trace levels of WADA prohibited substances simply because cGMP requirements do not include high sensitivity (part per billion concentration) screening for trace contaminants that are relevant to sport.

For the best reassurance, athletes should look for products that are manufactured to cGMP standards and that are tested for the presence of WADA prohibited substances using an ISO 17025 accredited test.

#### ISO 17025 Quality - what does it mean to the supplement manufacturing industry?

LGC is committed to the highest standards of quality, compliance and service in all aspects of its work. We produce trusted, dependable results day in, day out.

Laboratory screening of Sports Supplements should always be carried out using an ISO 17025 test that is specifically accredited for supplement analysis (nothing else is relevant!)

## The main objectives of ISO 17025 are to:

- Assure the customer that the testing is exactly in line with their requirements
- Deliver a quality service time and time again
- Assure the customer that they are dealing with a high integrity service provider, which works to the highest professional standard

## An ISO 17025 accredited screen indicates that:

- The screen has been assessed against international standards, and has been shown to be robust and capable of meeting the detection levels advertised on a routine basis
- The screen has been developed and validated for all the formulation types advertised
- Alongside every batch of samples tested a number of strict control measures are carried out in order to ensure the screen is working as it should be every single day

All of these measures at LGC are subject to external audit on an annual basis, as well as internal audits throughout the year

## Key questions to ask when considering a testing programme for supplements:

- a) Is the screen accredited to ISO 17025, specifically for supplement analysis?
- b) What range of substances is tested for?
- c) At what detection limits?
- d) What is the turnaround time for analysis?
- e) What expertise/experience exists in steroid analysis/testing for drugs in sport?
- f) Can the lab assist in the associated marketing of such testing?
- g) Does the lab assist in educating people about supplement testing?
- h) What is the cost of entering a testing programme?
- i) What is the cost of testing each sample?

Above all, LGC is a partner, working across the sports authorities and industry to offer athletes an informed choice about supplements.

## Website directories

Informed-Sport and Informed-Choice offers a sports nutrition web listing service for supplement manufacturers who have their products tested by LGC.

To read the listings please visit [www.informed-sport.com](http://www.informed-sport.com) or [informed-choice.org](http://informed-choice.org).



All supplement products that have been tested at LGC can be included in the directory, which is updated on a regular basis. It contains:

- Contact details of the manufacturer/ supplier
- Product name and batch identification
- Batch expiry date
- Details of the screening analysis
- Information on secure storage of the product

This independent supplement listing enables consumers to make a more informed choice about the products they are taking.

**In December 2010 LGC acquired HFL Sport Science. All services offered by HFL now form part of the LGC Group.**



For further information on how LGC can assist with sport supplement testing, please email: [info@informed-sport.com](mailto:info@informed-sport.com) or call +44(0)1638 720500.

