Testing Specification: Nutritional Supplements_v1

LGC will provide the following services in accordance with the terms and conditions set out in the Proposal, Agreement or other contractual document agreed by both parties.

1 Technical Description of Service

- Each sample is tested for the presence of the compounds listed within Appendix 1, at the Method Capability / Reporting Levels indicated (definitions provided in section 1.1).
- Sample preparation is by liquid and solid phase extraction techniques.
- Internal marker(s) are added to each sample to assess suitability of matrix for testing.
- Positive and negative controls are analysed alongside samples to assess extraction efficiency.
- Analysis is conducted using gas chromatography with mass spectrometric detection (GCMS) and liquid chromatography with mass spectrometric detection (LCMS).
- A Laboratory Information Management System (LIMS) is used to record sample details and analysis findings.
- The test results are qualitative and only apply to the sub-sample of the batch that is received at the laboratory for testing. However, the tests applied to the sub-sample are highly sensitive and, assuming batch homogeneity, the results obtained are intended to provide an assessment of potential batch contamination as a whole. It is the responsibility of the customer to ensure batch homogeneity and to ensure that the sub-sample submitted to the laboratory for testing is representative of the production batch under investigation.
- Informed-Sport / Informed-Choice programme requirements are detailed within the respective License Agreement / Terms and Conditions.
- The range of substances included in the testing protocol will be reviewed regularly against current knowledge and intelligence, and updated as necessary.
- In addition to the core compounds listed in Appendix 1, LGC may, as part of its 'banned substance surveillance programmes', conduct testing for the presence of additional compounds prohibited in sport (typically in response to the latest intelligence from anti-doping agencies and the supplements industry). If a suspicious screening finding is observed as a result of this analysis the customer will be advised. Screening findings for these additional compounds will be reported outside the scope of ISO17025 accreditation (this being highlighted within customer communications).

1.1 Testing Procedure

The testing process will include the analysis of positive and negative control samples alongside each batch of test samples.The analytical data from the test sample(s) is compared directly with the data from the control samples.

The positive control samples contain the test substances (or representative isomers) at the validated method capability / reporting levels for each procedure (see definitions provided below).

1.1.a Method Capability:

Method capability levels for each substance (where appropriate) are specified within Appendix 1. Samples will be reported as a screening indication for a particular substance if screening tests and verification analysis meets established acceptance criteria. The method capability level represents a level at which the substances can be successfully detected within a wide variety of matrices. It should be noted that within certain matrices, levels lower than those specified may be reported as a screening indication if all acceptance criteria are met.

1.1.b Reporting Level:

Reporting levels for each substance (where appropriate) are specified within Appendix 1. Samples will be reported as a screening indication for a particular substance if the test indicates its presence at or above the reporting level specified. Results from the test sample are compared to a control sample to determine whether a drug is present at, above or below the specified concentration.

PLEASE NOTE: Reporting levels do not apply to swab samples. Any screening indication observed within a swab sample will be based on the reporting criteria of method capability (as detailed within section 1.1a)

1.2 Androstenedione in milk and milk based products

Androstenedione is known to be naturally present in milk and milk derived products. The concentrations found in milk are variable, but typically in the low ng/ml (low ppb) region[1]. For this reason, a reporting level of 50ng/g for 4-androstene-3,17-dione and/or 5(6)-androstene-3,17-dione is employed for products that contain milk or milk-derived substances.

Reference:
[1]R Gaiani et al. Androstenedione and testosterone concentrations in plasma and milk of the cow throughout pregnancy. J. Reprod. Fert. 1984, 70: 55-59

1.3 Oil based products (e.g. fish / plant oil)

Oil based products will be analysed at an increased method capability / reporting level for the test substances analysed by GCMS, as indicated in Appendix 1.

1.4 1,-4-androstadiene-3,17-dione in supplements containing botanical ingredients.

A reporting level of 10ng/g is applied to supplements containing botanical or botanical derived ingredients (noting the potential biotransformation of plant sterols into 1,4-androstadiene-3,17-dione). For samples with no botanical components a method capability level of 10ng/g applies.

2 Receipt of Samples

Samples should be received with a Sample Submission Form (fully completed) detailing the following:

- The name of the product/s submitted for analysis.
- Sample/s batch numbers and expiry dates.
- Testing programme - Informed-Sport / Informed-Choice or Custom.
- Customer account details (including where appropriate specific details of parties responsible for the submission of samples and payment of testing fees)

Failure to provide full information will result in the sample being placed in quarantine until appropriate details can be obtained. Such omissions of information may delay commencement of analysis.

NOTE: Customers should be aware that the supplement screen is designed to detect trace levels of the test substances specified (in the part per billion (ppb) region). If a customer suspects that a sample they wish to submit for analysis may contain one or more of the test substances listed (or any other prohibited substance), they should notify the lab when submitting the sample so that precautionary measures may be taken.

PLEASE NOTE FOR SAMPLE SUBMISSIONS INTO UK ONLY: Samples containing animal derived ingredients (e.g Whey protein, collagen etc.) which are submitted from a non-EU territory must be accompanied by appropriate shipping documentation. Failure to complete the necessary paperwork may result in the shipment being stopped at customs, delayed, destroyed or returned to sender. Please contact LGC Fordham for the additional documentation if required.

A sample receipt will be issued for all samples submitted for analysis. This document will detail all individual samples and corresponding product information (production batch numbers etc). It should be noted that it is the responsibility of the customer to check the details provided within the sample receipt and notify the laboratory of any discrepancies / required changes within 48 hours of receipt.

Any requests for changes following the reporting of results may incur an administration charge.

Where a discrepancy is noted between product details specified on submission paperwork and the product container, details from the container will be used and the customer will be advised.

Where a sample is found to be deficient (i.e. product integrity has been compromised) the sample will be placed in quarantine and the customer will be contacted.

3 Reporting of Results

Results will be communicated to customers in the form of a certificate of analysis for each sample analysed. A summary of the potential outcomes are defined below.

3.1 Negative Samples

Where no screening indications are observed, and all quality control measurements have passed criteria, samples will be reported on the certificate as 'None Were Found'.

3.2 Trace Screening Indication (only applicable to substances with a reporting level – see Appendix 1)

Where a test substance is found to be below a specified reporting level, the sample will be reported as 'None Were Found' on the certificate of analysis. However, for the compounds ephedrine and / or pseudoephedrine and 1,4-androstadiene-3,17-dione notification of the trace screening indication will be provided within accompanying communications to aid customer quality control procedures.

LGC may also advise customers of other potentially atypical trace findings.

3.3 Screening Indication

Where screening procedures indicate the presence of one or more of the specified compounds, samples will be reported as 'screening indications' for the compound(s) indicated. Samples will only be reported as 'screening indications' if they:

- Meet the diagnostic criteria for screening and verification analysis, or
- Contain a test substance at a level at or exceeding the 'Reporting Level' (in respect of substances with a specified reporting limit – detailed within Appendix 1.)

Samples reported as a 'screening indication' may require further investigation. This may include additional analysis aimed at isolating the source of the screening finding (e.g analysis of additional products / raw material etc.) or additional analyses to substantiate the initial screening finding (e.g. in instances where the analytical result my be subject to external challenge by a third party).

Please contact LGC for further details or a proposal relating to additional investigative analysis.

3.4 Sample Unsuitable for Analysis

Where any quality control measurements used to establish extraction efficiency do not pass criteria, the sample will be reported as 'sample unsuitable for analysis' for the specific substances which have failed the analysis procedure. Since analytical testing has been carried out to establish this result, the standard testing fee will be applied.

4 Sampling and Reporting Times

Samples should be submitted for analysis in sealed packaging and where possible final commercial packs. (Note: it is a requirement of the Informed-Sport testing programme that all products are submitted in final commercial packaging, unless agreed in writing). A minimum of 30 g of solid or 30 mL of liquid is required. Customers are responsible for ensuring that the samples submitted for testing are representative of the production batch.

Typical sample turnaround for negative results is 7-10 working days from receipt of the sample at the laboratory (12-15 working days for oil based products). Notification of receipt of samples at the laboratory is part of the standard service.

Occaisionaly, based on the performance of quality control markers used to evaluate extraction efficiency, a sample may require additional testing to return a negative result. In such instances there may be a delay in the reporting of a negative result, exceeding the typical turnaround time of 7-10 working days.

Any initial screening indications (with the exception of swab samples) will be re-tested before the final result is released. This may also delay reporting of the final result.

5 Distribution of Results and Website Publishing

All results will be confidential between LGC and the customer. Results will be reported on a certificate of analysis to a contact name and address designated by the customer. Disclosure of results to a third party will require written authorisation from the customer or a legally recognised request.

Customers are not permitted to publish copies of the certificates of analysis in any digital format / marketing material, e.g publishing on websites or social media etc, unless prior written approval has been provided by LGC.

Samples analysed as part of the Informed-Sport and / or Informed-Choice programmes will be published on the relevant website with specific batch / product expiry dates listed. Additional information can be found within relevant Licence Agreements / Terms and Conditions.

Any requests for additional certificates of analysis after the original release may incur an administrative charge.

6 Quality

Testing is carried out within LGC's Quality System and is accredited to the ISO17025 standard for the following formulation types: bar, powder, capsule, gel, liquid and tablet.

Additional formulations / matrices may also be analysed, however it should be noted that these matrices may not fall under the laboratories scope of ISO17025 accreditation. Where this is the case the customer will be advised in writing andreference to ISO accreditation will be removed from certificates of analysis.

It should be noted that swab samples are not included under LGC's current scope of ISO17025 accreditation.

7 Sample Storage and Disposal

Negative samples (including those with Trace findings) and samples found to be unsuitable for analysis will be disposed after they are reported. Samples where the screening test indicates the presence of a substance (reported as "Screening Indication") will be disposed 14 days after reporting, unless a different arrangement is agreed in writing.

LGC may retain with prior written consent (i.e. a completed Secure Storage Service Agreement) from the customer a second portion ('B' sample) of the test sample ('A' sample) in its secure storage facility, for a length of time agreed with the customer. There will be an additional charge for this service – information is available upon request.

For further information please call us on:
UK, Europe and Rest of the World: +44(0)1638 720500
US, Canada and the Americas: +1-859-721-0181

Appendix 1: Substances analysed by GCMS and LCMS#

Substances analysed by GCMS	Method Capability*		Reporting Level*	
	Standard Test	Fats/Oils Test[4]	Standard Test	Fats/Oils Test[4]
1,4-androstadiene-3,17-dione	10 ng/g	50 ng/g	10 ng/g[2]	50 ng/g[2]
4-androstene-3,17-dione and/or 5(6)-androstene-3,17-dione[1]	-	-	20 ng/g (50 ng/g)[3]	50 ng/g
4-androstene-3β,17β-diol	-	-	20 ng/g	50 ng/g
5α-androstane-3β,17β-diol	-	-	20 ng/g	50 ng/g
5(6)-androstene-3β,17β-diol	-	-	20 ng/g	50 ng/g
5α-androstane-3,17-dione	-	-	20 ng/g	50 ng/g
Dehydroepiandrosterone (DHEA)	-	-	20 ng/g	50 ng/g
4-estrene-3,17-dione(19-nor-4-androstene-3,17-dione) and/or 5(10)-estrene-3,17-dione (19-nor-5(10)-androstene-3,17-dione) and/or 5(6)-estrene-3,17-dione (19-nor-5(6)-androstene-3,17-dione) [1]	10 ng/g	50 ng/g	-	-
4-estrene-3β,17β-diol (19-nor-4-androstene-3β,17β-diol) and/or 5(10)-estrene-3β,17β-diol (19-nor-5(10)-androstene-3β,17β-diol) [1]	10 ng/g	50 ng/g	-	-
Nandrolone (19-nor-4-androstene-17β-hydroxy-3-one)	10 ng/g	50 ng/g	-	-
Testosterone	-	-	20 ng/g	50 ng/g

* See section 1.1 for full definitions of terms.

1 These compounds are isomeric and indistinguishable from each other by this test.
2 Reporting level applies to supplements containing botanical ingrediants only.
3 Reporting level of 50ng/g applicable to products containing milk or milk derived substances (see additional note relating to "Androstenedione in milk and milk based products").
4 Method capability / reporting levels only applicable to oil based products

Substances analysed by LCMS	Method Capability*	Reporting Level*
1(3-chlorophenyl)piperazine	100 ng/g	-
1,3-dimethylbutylamine	100 ng/g	-
20-Norstanozolol	10 ng/g	-
7-ketoDHEA	500 ng/g	-
α-ethylphenethylamine	100 ng/g	-
Acebutolol	100 ng/g	-
Alfentanil	100 ng/g	-
Alprenolol	100 ng/g	-
Amiloride	500 ng/g	-
Amiphenazole	100 ng/g	-

Substances analysed by LCMS	Method Capability*	Reporting Level*
Amphetamine	100 ng/g	-
Atenolol	100 ng/g	-
β-methylphenethylamine	100 ng/g	-
Bambuterol	100 ng/g	-
Benzoylecgonine	100 ng/g	-
Benzphetamine	100 ng/g	-
Benzylpiperazine	100 ng/g	-
Bisoprolol	100 ng/g	-
Bumetanide	100 ng/g	-
Bunitrolol	100 ng/g	-
Bupranolol	100 ng/g	-
Buprenorphine	100 ng/g	-
Bupropion	100 ng/g	-
Butofinolol	100 ng/g	-
Canrenone	100 ng/g	-
Carazolol	100 ng/g	-
Carfentanil	100 ng/g	-
Carphedone	100 ng/g	-
Carteolol	100 ng/g	-
Celiprolol	100 ng/g	-
Chlorphentermine	100 ng/g	-
Cimaterol	100 ng/g	-
Clenbuterol	10 ng/g	-
Clomifene	100 ng/g	-
Clopamide	100 ng/g	-
Clobenzorex	100 ng/g	-
Clorprenaline	100 ng/g	-
Cocaine	100 ng/g	-
Croethamide	100 ng/g	-
Cyclopentamine	100 ng/g	-
Cyproheptadine	100 ng/g	-
Dextromoramide	100 ng/g	-
Diamorphine	100 ng/g	-
Diethylpropion	100 ng/g	-
Dimethamphetamine	100 ng/g	-
Dipipanone	100 ng/g	-
Diprenorphine	100 ng/g	-
Doxapram	100 ng/g	-
Ephedrine / Pseudoephedrine	-	100 ng/g
Esmolol	100 ng/g	-
Etafedrine	100 ng/g	-

Substances analysed by LCMS	Method Capability*	Reporting Level*
Etamivan	100 ng/g	-
Fenbutrazate	100 ng/g	-
Fencamfamine	100 ng/g	-
Fenfluramine	100 ng/g	-
Fenoterol	100 ng/g	-
Fenozolone	100 ng/g	-
Fentanyl	100 ng/g	-
Fluorophenethylamine	100 ng/g	-
Fluoxetine	100 ng/g	-
Fluvoxamine	100 ng/g	-
Formoterol	100 ng/g	-
Gestrinone	10 ng/g	-
Heptaminol	100 ng/g	-
HMMA	100 ng/g	-
Indapamide	100 ng/g	-
Isometheptene	100 ng/g	-
Labetolol	100 ng/g	-
Levophacetoperane	100 ng/g	-
Mabuterol	100 ng/g	-
MDEA	100 ng/g	-
MDA	100 ng/g	-
MDMA (ecstasy)	100 ng/g	-
Mefenorex	100 ng/g	-
Mefruside	100 ng/g	-
Mephentermine	100 ng/g	-
Methadone	100 ng/g	-
Methamphetamine	100 ng/g	-
Methoxyphenylpiperazine	100 ng/g	-
Methylephedrine	100 ng/g	-
Methylhexanamine (1,3-dimethylamylamine)	100 ng/g	-
Methylphenidate	100 ng/g	-
Methylpseudoephedrine	100 ng/g	-
Methyltrienolone	100 ng/g	-
Metoprolol	100 ng/g	-
Modafinil	100 ng/g	-
Moprolol	100 ng/g	-
N,α-diethylphenethylamine	100 ng/g	-
N,β-dimethylphenethylamine	100 ng/g	-
Nadolol	100 ng/g	-
Nadoxolol	100 ng/g	-
Nalbuphine	100 ng/g	-

Substances analysed by LCMS	Method Capability*	Reporting Level*
Nalorphine	100 ng/g	-
Naloxone	100 ng/g	-
Naltrexone	100 ng/g	-
Nikethamide	100 ng/g	-
Norephedrine	100 ng/g	-
Norpseudoephedrine (Cathine)	100 ng/g	-
Oripavine	100 ng/g	-
Oxilofrine	100 ng/g	-
Oxprenolol	100 ng/g	-
Oxycodone	100 ng/g	-
Oxymetazoline	100 ng/g	-
Pemoline	100 ng/g	-
Penbutolol	100 ng/g	-
Pentazocine	100 ng/g	-
Pentoxyverine	100 ng/g	-
Pethidine	100 ng/g	-
Phendimetrazine	100 ng/g	-
Phenmetrazine	100 ng/g	-
Phentermine	100 ng/g	-
Pindolol	100 ng/g	-
Pirbuterol	100 ng/g	-
Piretanide	100 ng/g	-
Polythiazide	100 ng/g	-
Practolol	100 ng/g	-
Probenecid	100 ng/g	-
Prolintane	100 ng/g	-
Propranolol	100 ng/g	-
Prostanozol	10 ng/g	-
Prothipendyl	100 ng/g	-
Quinethazone	100 ng/g	-
Ritodrine	100 ng/g	-
Salbutamol	100 ng/g	-
Salmeterol	100 ng/g	-
Selegiline	100 ng/g	-
Sibutramine	100 ng/g	-
Sildenafil	100 ng/g	-
Sotalol	100 ng/g	-
Spironolactone	100 ng/g	-
Stanozolol	10 ng/g	-
Strychnine	100 ng/g	-
Tamoxifen	100 ng/g	-

Substances analysed by LCMS	Method Capability*	Reporting Level*
Terbutaline	100 ng/g	-
Tetrahydrogestrinone (THG)	10 ng/g	-
Timolol	100 ng/g	-
Torasemide	100 ng/g	-
Toremifene	100 ng/g	-
Trenbolone	100 ng/g	-
Triamterene	100 ng/g	-
Trifluoromethylphenylpiperazine	100 ng/g	-
Tripamide	100 ng/g	-
Tuaminoheptane	100 ng/g	-
Tulobuterol	100 ng/g	-
Xylomatazoline	100 ng/g	-

* See section 1.1 for full definitions of terms.