Service Level Agreement: Nutritional Supplements

LGC will provide the following services in accordance with the terms and conditions set out in the Master Services Agreement (or Informed-Sport / Informed-Choice License Agreements) agreed by both parties.

Technical Description of Service

- Each sample is tested for the presence of the drugs listed within Appendix 1, at the Method Capability / Reporting Levels indicated (definitions provided below).
- 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.
- Acceptance criteria relating to the Informed-Sport / Informed-Choice programmes are detailed within the respective license agreements.
- The range of substances included in the testing protocol will be reviewed regularly against current knowledge and intelligence, and updated as necessary.

Reporting Level / Method Capability

The testing process will include the analysis of control samples alongside each batch of test samples, covering test substances (or representative isomers). The analytical data from the test sample(s) is compared directly with the data from the control samples.

The control samples contain drugs at the validated method capability / reporting levels for each procedure (see definitions provided below).

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.

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.

Androstenedione in milk and milk based products [2]

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. One reference (Gaiani) cites values of around 3.5 ng/ml. 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.

Samples will be reported as a screening indication if the test indicates its presence at or above the reporting level of 50ng/g specified. Results from the test sample are compared to a control sample to determine whether androstenedione is present at, above or below the specified concentration. This control sample is prepared in a representative matrix, which may vary to some extent from that of the test sample. In order to compensate for any differences between the control sample matrix and the test sample matrix a 'recovery factor' is applied.

The recovery factor is calculated during method validation and is designed to be a 'worst case scenario'. That is, it will account for matrices that vary significantly from that of the control matrix. This means that for those samples with a matrix similar to the control, the recovery factor will over compensate. Samples may therefore be reported as 'Screening Indication' at concentrations lower than the specified reporting levels.

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

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.

Reporting of Results

Results will be communicated to customers in the form of a certificate of analysis for each sample analysed.

Screening Indication

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

a) Meet the diagnostic criteria for screening and verification analysis, or
b) 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, to obtain unequivocal data that meets internationally agreed standards used within sports doping control or additional investigative analysis to support original screening findings. Contact LGC for further details or a proposal relating to additional analysis.

Trace Screening Indication (only applicable to substances with a reporting level)[#]

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, to aid customer quality control procedures, notification of the trace screening indication will be provided within accompanying communications.

[#]**Note:** Due to the known presence of androstenedione within milk and milk derived substances, trace levels of 4-androstene-3,17-dione and/or 5(6)-androstene-3,17-dione will not be notified within accompanying communications. This applies only to products containing milk and milk derived substances.

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'.

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.

Customers should be aware that the supplement screen is designed to detect trace levels of the test substances specified. If a customer suspects that a sample they wish to submit for analysis may contain one or more of the test substances, they should notify the lab when submitting the sample so that precautionary measures may be taken.

Sampling and Reporting Times

Samples should be submitted for analysis in shelf-ready, sealed packaging. 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.

Any initial screening indications will be re-tested before the final result is released. This may delay reporting of the final result.

Distribution of Results and Website Publishing

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

LGC may publish with prior written consent (i.e. a completed Website Agreement) from the customer selected information relating to the testing of supplement products on LGC's website www.lgcgroup.com. This may include, but is not limited to, customer name, nutritional supplement product details and the substances screened for.

Samples analysed as part of the Informed-Sport and/or Informed-Choice programmes will be published on the relevant website.

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.

Sample Storage and Disposal

Negative samples (including those with Trace findings) 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 +44(0)1638 724400

Appendix 1: Substances analysed by GCMS and LCMS

Substances analysed by GCMS	Method Capability*		Reporting Level*	
	Standard Test	Fats/Oils Test[3]	Standard Test	Fats/Oils Test[3]
1,4-androstadiene-3,17-dione	10 ng/g	50 ng/g	-	-
4-androstene-3,17-dione and/or 5(6)-androstene-3,17-dione[1]	-	-	10ng/g (50ng/g)[2]	50 ng/g
4-androstene-3β,17β-diol	-	-	10ng/g	50 ng/g
5α-androstane-3β,17β-diol	-	-	10ng/g	50 ng/g
5(6)-androstene-3β,17β-diol	-	-	10ng/g	50 ng/g
5α-androstane-3,17-dione	-	-	10ng/g	50 ng/g
Dehydroepiandrosterone (DHEA)	-	-	10ng/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	-	-	10ng/g	50 ng/g

* See section titled Reporting Level/Method Capability for full definition of terms.

1 These compounds are isomeric and indistinguishable from each other by this test.

2 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").

3 Method capability / reporting levels only applicable to oil based products

Substances analysed by LCMS	Method Capability*	Reporting Level*
	Standard Test	Standard Test
1(3-chlorophenyl)piperazine	100 ng/g	-
Acebutolol	100 ng/g	-
Alfentanil	100 ng/g	-
Alprenolol	100 ng/g	-
Amiphenazole	100 ng/g	-
Amphetamine	100 ng/g	-
Atenolol	100 ng/g	-
Bambuterol	100 ng/g	-
Benzoylecgonine	100 ng/g	-
Benzphetamine	100 ng/g	-

Substances analysed by LCMS	Method Capability*	Reporting Level*
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	-
Cathine (Norpseudoephedrine)	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	-
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	-
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	-

Substances analysed by LCMS	Method Capability*	Reporting Level*
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	-
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-dimethylpentylamine)	100 ng/g	-
Methylphenidate	100 ng/g	-
Methyltrienolone	100 ng/g	-
Metoprolol	100 ng/g	-
Modafinil	100 ng/g	-
Moprolol	100 ng/g	-
Nadolol	100 ng/g	-
Nadoxolol	100 ng/g	-
Nalbuphine	100 ng/g	-
Nalorphine	100 ng/g	-
Naloxone	100 ng/g	-
Naltrexone	100 ng/g	-
Nikethamide	100 ng/g	-
Oripavine	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	-

Substances analysed by LCMS	Method Capability*	Reporting Level*
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	-
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	-
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	-
Trifluoromethylphenylpiperazine	100 ng/g	-
Tripamide	100 ng/g	-
Tuaminoheptane	100 ng/g	-
Tulobuterol	100 ng/g	-
Xylomatazoline	100 ng/g	-

* See section titled Reporting Level / Method Capability for full definition of terms.