Testing Specification: Nutritional Supplements_v4

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 (Substances Analysed), at the Method Capability / Reporting Levels indicated (definitions provided in section 1.1).
- Sample preparation is by liquid and solid phase extraction techniques.
- Internal markers are added to each sample to assess the suitability of the matrix for testing and to monitor extraction efficiency.
- Positive and negative controls are analysed alongside samples to assess extraction performance.
- Analysis is conducted using both gas and liquid chromatographic techniques coupled with mass spectrometric (including high resolution) detection (GCMS, LCMS & HRAM-MS). 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.
- Where applicable Informed programme requirements are detailed within the respective Certification Agreement / 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, included within LGC's ISO17025 scope of accreditation, 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

Analytical testing methods employed utilise a combination of positive and negative control samples, which are analysed alongside test samples. Data obtained from the control samples is reviewed to ensure batch acceptance.

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 specified reporting level(1). Results from the test sample are compared to a control sample to determine whether a substance 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) As part of LGC's ongoing commitment to continual improvement and adherence to the ISO/IEC17025 quality standard, LGC is currently conducting a broad review of measurement uncertainty, specifically in relation to reporting level compounds. This program of review has been completed and implemented within LGC's UK laboratory and is under evaluation within LGC's US laboratory. Where implemented, measurement uncertainty will be included as part of the determination process for reporting level compounds.

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 (or products containing a high percentage of oil and / or fat) will be analysed at an increased method capability / reporting level for the test substances as indicated in Appendix 1.

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

A reporting level of 20ng/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 20ng/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 – Relevant Informed programme 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 territories outside of the UK 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 is 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.

Note: Where a trace finding is considered atypical of the sample matrix under investigation or relevant to production QC procedures, LGC may advise customers of such trace findings within accompanying communications (e.g. e-mail). It should be noted that such additional communications fall outside of LGC's scope of ISO/IEC17025 accreditation.

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.
- For Reporting Level compounds only; contain a test substance at a level at or exceeding the 'Reporting Level' (in respect of substances with a specified reporting level – 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 up to 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.

Occasionally, 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 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.

Samples that are certified on the Informed Sport, Informed Choice and Informed Ingredient programmes will also receive a certificate of batch compliance (CoBC) should all programme acceptance / conformance criteria be met. The CoBC is designed to be customer facing and can be provided to end users. It should be noted that certificates of batch compliance are not provided for Informed Sport 'blind' samples as these will have already been endorsed on pre-release testing

Samples analysed as part of the Informed programmes will be published on the relevant website with specific batch / product expiry dates listed. Additional information can be found within relevant Certification Agreements / 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 in-line with LGC's Quality System and is accredited to ISO17025 for a wide range of formulation types, including bars, powders, capsules (including gel capsules), gels, liquids and tablets.

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 and reference 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.

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

Substance	Method Capability* / ngg^{-1} (Method Capability: Fats/Oils Test)[4]	Reporting Level* / ng/g^{-1} (Reporting Level: Fats/Oils Test)[4]
1(3-chlorophenyl)piperazine	100	-
1,3-dimethylbutylamine (AMP Citrate)	100	-
1,4-androstadiene-3,17-dione (1,4-ADD, Boldione) [2]	20 (50)	20 (50)
1,5-dimethylhexylamine (Octodrine, Ottodrina, Vaporpac, Amidrine, 2-Amino-6-methylheptane)	100	-
17a-methylnortestosterone (Normethandrone, 4-estren-17a-methyl-17b-ol-3-one)	10	-
17-hydroxyprogesterone	100	-
19-norandrosterone	10 (50)	-
1-androstenedione (5a-androst-1-ene-3,17-dione)	100	-
1-testosterone (5a-androst-1-ene-17b-ol-3-one)	100	-
20-Norstanozolol	10	-
2-amino-5-methylhexane (1,4-dimethylpentylamine)	100	-
4,9-estradien-3,17-dione (Dienedione, Xtren)	10	-
4-androstene-3,17-dione and/or 5(6)-androstene-3,17-dione [1,3]	-	20 [3] (50)
4-androstene-3b,17b-diol	-	20 (50)
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 (50)	
4-estrene-3b,17b-diol (19-nor-4-androstene-3b,17b-diol) and/or 5(10)-estrene-3b,17b-diol (19-nor-5(10)-androstene-3b,17b-diol) [1]	10 (50)	
4-hydroxytestosterone	100	-
5(6)-androstene-3b,17b-diol	-	20 (50)
5-androstene-3b,17a-diol	-	20 (50)
5a-androstane-3,17-dione	-	20 (50)
5a-androstane-3a,17b-diol	-	20 (50)
5a-androstane-3b,17b-diol	-	20 (50)
7-ketoDHEA	500	-
α-ethylphenethylamine (1-phenyl-2-butanamine)	100	-
AC262536	100	-
Acebutolol	100	-
Acetazolamide	100	-
ACP105	100	-
Alfentanil	100	-
Alprenolol	100	-
Amiloride	500	-
Amphetamine	100	-
Anastrazole	100	-
Andarine (S-4)	100	-
Androstatriene-17b-ol-3-one (Androsta-1,4,6-trien-17b-ol-3-one, 17b-hydroxyandrosta-1,4,6-triene-3-one)	10	-

Substance	Method Capability* / ngg^{-1} (Method Capability: Fats/Oils Test)[4]	Reporting Level* / ng/g^{-1} (Reporting Level: Fats/Oils Test)[4]
Androstatriene-3,17-dione (Androsta-1,4,6-trien-3,17-dione, Androstatrienedione)	10	-
Androstenetrione (Androst-4-en-3,6,17-trione, 6-OXO)	500	-
Androsterone	-	20 (50)
Arimistane	100	-
Atenolol	100	-
β-methylphenethylamine (2-phenyl-3-propanamine)	100	-
Bambuterol	100	-
Bendroflumethiazide	100	-
Benzoylecgonine	100	-
Benzphetamine	100	-
Benzylpiperazine	100	-
Bisoprolol	100	-
Bolasterone (7a,17a-dimethyltestosterone)	10	-
Boldenone	10	-
Bumetanide	100	-
Bunitrolol	100	-
Bupranolol	100	-
Buprenorphine	100	-
Bupropion	100	-
Buthiazide	100	-
Butofinolol	100	-
Canrenone	100	-
Carazolol	100	-
Carfentanil	100	-
Carphedone (Fonturacetam, 4-phenylpiracetam)	100	-
Carteolol	100	-
Celiprolol	100	-
Chlorothiazide	100	-
Chlorphentermine	100	-
Chlorthalidone	100	-
Cimaterol	100	-
Clenbuterol	10	-
Clobenzorex	100	-
Clomifene	100	-
Clopamide	100	-
Clorprenaline	100	-
Clostebol (4-androstene-4-chloro-17b-ol-3-one, chlorotestosterone)	100	-
Cocaine	100	-
Conivaptan	100	-
Croethamide	100	-
Cropropamide	100	-

Substance	Method Capability* / ngg^{-1} (Method Capability: Fats/Oils Test)[4]	Reporting Level* / ng/g^{-1} (Reporting Level: Fats/Oils Test)[4]
Cyclopentamine	100	-
Cyclothiazide	100	-
Cyproheptadine	100	-
Danazol	100	-
Dehydroepiandrosterone (DHEA)	-	20 (50)
Dextromoramide	100	-
Diamorphine	100	-
Dienolone (estra-4,9-diene-17b-ol-3-one)	50	-
Diethylpropion (Amfepramone)	100	-
Dimethamphetamine	100	-
Dipipanone	100	-
Diprenorphine	100	-
Doxapram	100	-
Drostanolone	10 (50)	-
Ephedrine	-	100
Esmolol	100	-
Etafedrine	100	-
Etamivan	100	-
Ethacrynic acid	100	-
Exemestane	100	-
Fenbutrazate	100	-
Fencamfamine	100	-
Fenfluramine	100	-
Fenoterol	100	-
Fenozolone	100	-
Fentanyl	100	-
Fluorophenethylamine	100	-
Fluoxetine	100	-
Fluoxymesterone	100	-
Fluvoxamine	100	-
Formestane	500	-
Formoterol	100	-
Furosemide	100	-
Gestrinone	50	-
GSK2881078	100	-
GW0742 (inc Sulfone & Sulfoxide forms)	100	-
GW501516 (Cardarine inc Sulfone & Sulfoxide forms)	100	-
Heptaminol	100	-
HMMA	100	-
Hydrochlorthiazide	100	-
Hydroflumethiazide	100	-
Ibutamoren	100	

Substance	Method Capability* / ngg^{-1} (Method Capability: Fats/Oils Test)[4]	Reporting Level* / ng/g^{-1} (Reporting Level: Fats/Oils Test)[4]
Indapamide	100	-
Isometheptene	100	-
Labetolol	100	-
Letrozole	100	-
Levophacetoperane	100	-
Ligandrol (LGD-4033)	100	-
Mabuterol	100	-
MDA (Tenamfetamine)	100	-
MDEA	100	-
MDMA (ecstasy)	100	-
Mefenorex	100	-
Mefruside	100	-
Mephentermine	100	-
Methadone	100	-
Methamphetamine	100	-
Methandienone	10	-
Methandriol	10 (50)	-
Methasterone	10 (50)	-
Methenolone	10 (50)	-
Methoxyphenylpiperazine	100	-
Methyclothiazide	100	-
Methyl-1-testosterone	100	-
Methylclostebol	100	-
Methylephedrine	100	-
Methylhexanamine (1,3-dimethylamylamine, 4-methylhexan-2-amine)	100	-
Methylphenidate	100	-
Methylpseudoephedrine	100	-
Methyltestosterone	10 (50)	-
Methyltrienolone	100	-
Metolazone	100	-
Metoprolol	100	-
Mibolerone	10 (50)	-
Modafinil	100	-
Moprolol	100	-
N,α-diethylphenethylamine (2-amino-N-ethyl-1-phenylbutane, N,a-diethylbenzeneethanamine)	100	-
N,β-dimethylphenethylamine	100	-
Nadolol	100	-
Nadoxolol	100	-
Nalbuphine	100	-
Nalorphine	100	-
Naloxone	100	-

Substance	Method Capability* / ngg^{-1} (Method Capability: Fats/Oils Test)[4]	Reporting Level* / ng/g^{-1} (Reporting Level: Fats/Oils Test)[4]
Naltrexone	100	-
Nandrolone (19-nor-4-androstene-17b-hydroxy-3-one)	10 (50)	-
Nikethamide	100	-
Norclostebol	100	-
Norephedrine	100	-
Norethandrolone	100	-
Norpseudoephedrine (Cathine)	100	-
Oripavine	100	-
Ostarine (Enobosarm, MK-2866)	100	-
Oxilofrine	100	-
Oxprenolol	100	-
Oxycodone	100	-
Oxymesterone	500	-
Oxymetazoline	100	-
Pemoline	100	-
Penbutolol	100	-
Pentazocine	100	-
Pentetrazol	100	-
Pentoxyverine	100	-
Pethidine	100	-
PF06260414	100	-
Phendimetrazine	100	-
Phenmetrazine	100	-
Phentermine	100	-
Pindolol	100	-
Pirbuterol	100	-
Piretanide	100	-
Polythiazide	100	-
Practolol	100	-
Probenecid	100	-
Prolintane	100	-
Propranolol	100	-
Prostanozol	10	-
Prothipendyl	100	-
Pseudoephedrine	-	100
Quinethazone	100	-
RAD140	100	-
Relcovaptan	500	-
Ritodrine	100	-
S23	100	
Salbutamol	100	-
Salmeterol	100	-

Substance	Method Capability* / ngg^{-1} (Method Capability: Fats/Oils Test)[4]	Reporting Level* / ng/g^{-1} (Reporting Level: Fats/Oils Test)[4]
Selegiline	100	
Sibutramine	100	-
Sildenafil	500	-
Sotalol	100	-
Spironolactone	100	-
SR9009	100	-
SR9011	100	-
Stanozolol	10	-
Stenbolone	100	-
Strychnine	100	-
Tamoxifen	100	-
Terbutaline	100	-
Testolactone	100	-
Testosterone	-	20 (50)
Tetrahydrogestrinone (THG)	50	-
TFM4AS1	100	-
Tibolone (inc delta4-tibolone)	500	-
Timolol	100	-
Tolvaptan	100	-
Torasemide	100	-
Toremifene	100	-
Tramadol	100	-
Trenbolone	100	-
Trendione (estra-4,9,11-triene-3,17-dione)	100	-
Triamterene	100	-
Trichlormethiazide	100	-
Trifluoromethylphenylpiperazine	100	-
Tripamide	100	-
Tuaminoheptane	100	-
Tulobuterol	100	-
Turinabol (Dehydrochloromethyltestosterone)	100	-
Xylomatazoline	100	-

* 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 ingredients 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 (or high oil content) products