Service Level Agreement: Nutritional Supplements

HFL Sport Science 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 extracted and tested using GCMS or LCMS for the presence of substances detailed within Appendix 1, at the method capabilities / reporting levels specified.

Technical Notes

Sample Analysis

- Each sample is tested for the presence of the drugs listed within appendix 1, at the Method Capability / Reporting levels indicated
- Sample preparation is by liquid-liquid and solid phase extraction techniques.
- Internal marker(s) are added to each sample to assess suitability of matrix for testing
- Analysis is conducted using gas chromatography with mass spectrometric detection (GCMS) and liquid chromatography with mass spectrometric detection (LCMS).
- Testing is accredited to the ISO17025 standard for the following formulation types: bar, powder, capsule, gel, liquid and tablet.
- A Laboratory Information Management System (LIMS) is used to record sample details and analysis findings.
- Products will be accepted for testing on the understanding that if any of the quality control measurements used to establish extraction efficiency fail, the sample will be reported as “sample unsuitable for analysis” for the specific compounds which have failed the analysis procedure. Information relating to any failed analysis will be recorded on the certificate of analysis. Such samples will be charged at the normal rate.
- 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. 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.
- 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 HFL for further details or a proposal relating to additional analysis.

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Reporting Level / Method Capability

The testing process will include the analysis of control samples alongside each batch of test samples, covering all 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 compounds 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.

  - The range of substances included in the testing protocol will be reviewed regularly against current knowledge and intelligence, and updated as necessary.

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 with a high content of 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

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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

Reporting of Results

Customers will be notified if samples contain any test substance at a level that would constitute a screening indication. 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 compounds with a specified reporting limit – detailed within appendix 1.)

Trace Screening Indication (samples with a specified reporting limit)[#] – Where a test substance is found to be below a specified reporting level, however, all other diagnostic and verification criteria has been met, the sample will be reported as a 'trace screening indication'.

[#]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 reported on the certificate of analysis. This applies only to products containing milk and milk derived substances.

Samples where the above criteria are not met, and control samples have validated the extraction process will be reported as "None Were Found".

All results will be confidential between HFL 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.

HFL 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 HFL's website www.hfl.co.uk. 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.

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.

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

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contain one or more of the test substances, they should notify the lab when submitting the sample so that any precautionary measures may be taken.

Typical sample turnaround for negative results is 6 working days from receipt of the sample at the laboratory. Notification of receipt of samples at the laboratory is part of the standard service.

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

Quality

Testing is carried out within HFL's Quality System and is accredited to the UKAS ISO17025 standard.

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.

HFL 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.

Definitions:

- The **"Sample"**: is the representative portion taken by HFL of the sample of material provided to HFL by the Customer pursuant to the provision of the Services.

- "**Test Criteria**": mean the services to be supplied to the Customer by HFL as outlined in this Agreement.

- "**Sports Regulatory Body**" / "**Sporting Authority**": shall mean any organisation that has a responsibility for regulating sport.

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Appendix 1: Substances analysed by GCMS and LCMS

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

Substances analysed by LCMS	Method Capability*	Reporting Level*
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	-
Benzylpiperazine	100 ng/g	-
Bisoprolol	100 ng/g	-
Bumetanide	100 ng/g	-

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Substances analysed by LCMS	Method Capability*	Reporting Level*
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	-
Fluoxetine	100 ng/g	-
Fluvoxamine	100 ng/g	-
Formoterol	100 ng/g	-

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Substances analysed by LCMS	Method Capability*	Reporting Level*
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	-
Phenmetrazine	100 ng/g	-
Phentermine	100 ng/g	-
Pindolol	100 ng/g	-

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Substances analysed by LCMS	Method Capability*	Reporting Level*
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.

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