



ASIAN AND PACIFIC FEDERATION OF CLINICAL BIOCHEMISTRY

**MASS SPECTROMETRY  
HARMONISATION  
WORKING GROUP  
(MSHWG)**

**Serum Testosterone  
Project**

## **DEFINITION OF THE PROJECT**

This project is to harmonise the measurement of serum testosterone concentrations in clinical samples using liquid chromatography isotope-dilution tandem mass spectrometry (LCTMS) methods.

## **GOALS**

1. To provide detailed information on the different serum testosterone LCTMS methods used in Asian Pacific clinical biochemistry laboratories.
2. To harmonise the serum testosterone results through the use of a set of common secondary serum calibrators that have been validated by a reference method.
3. To harmonise reference intervals for serum testosterone of different sexes and age groups in the Asian Pacific region.

## **STRATEGIES**

1. Formation of the Project Working Group
  - 1.1. Executives of the Asian Pacific Federation of Clinical Biochemistry (APFCB) Mass Spectrometry Harmonisation Working Group (MSHWG) will invite individual members to the Serum Testosterone Project Group.
  - 1.2. MSHWG Executives will identify mass spectrometry experts working in the clinical biochemistry laboratories from the Asian Pacific region, preferably one to two members from one country/region, to the Project Group.

1.3. Project Group members are responsible to communicate the progress of the project to the APFCB member societies to which their laboratories reside.

2. Recruitment of participating laboratories

2.1. Project Group members will identify clinical biochemistry laboratories of their own country/region where LCTMS methods are used for routine measurement of serum testosterone.

2.2. The Project Group will send the project proposals to these laboratories and invite them to participate.

2.3. Each participating laboratory will be assigned with a code number and only the Project Group members will have access to the code number.

2.4. The Project Group will not impose any subscription fee from the participating laboratories. However, the laboratories are required to subscribe to the RCPA QAP Endocrine Program in which serum testosterone is one of the analytes to be evaluated. Each participating laboratory is responsible for the cost of RCPA QAP subscription.

3. Documentation of serum testosterone LCTMS methods of participating laboratories

3.1. Upon registration, each participating laboratory is required to submit detailed information of their LCTMS serum testosterone method to the Project Group for documentation.

3.2. Detailed information required includes:

3.2.1. Source and concentrations of calibrators

3.2.2. Sample processing

3.2.3. LC instrument model and inlet parameters

3.2.4. MS instrument model and tandem MS parameters

3.2.5. Limit of quantitation

3.2.6. Linearity

3.2.7. Precision performance

3.2.8. Source and concentrations of internal quality control samples

3.2.9. Reference intervals on patient reports

#### 4. Initial assessment of performance – STAGE I

4.1. Accuracy, between-batch precision and linearity performance will be evaluated via the RCPA QAP Endocrine program over a 6-month period.

4.2. If required a request will be made to the RCPA QAP to create a LCTMS user group for data analysis.

4.3. The Project Group will provide a detailed analysis report to the participating laboratories at the end of the first cycle.

#### 5. Harmonisation of accuracy performance – STAGE II

5.1. Prior to the start of the second cycle of RCPA Endocrine EQA program, a set of common secondary serum calibrators will be sent to each participating laboratory.

5.2. This set of serum calibrators are lyophilized human serum samples with different testosterone concentrations that have been validated by a

reputable laboratory using reference gas chromatography isotope dilution mass spectrometry method.

5.3. Each participating laboratory will report serum testosterone EQA results to the RCPA QAP Endocrine program using this set of calibrators.

5.4. Accuracy, between-batch precision and linearity performance will be evaluated via the subsequent RCPA QAP Endocrine program cycle.

5.5. The Project Group will compare the performance of these parameters using data obtained from the 2 cycles.

5.6. Supply of the calibrators will be for another 2 cycles of RCPA QAP Endocrine program.

6. Harmonisation of reference intervals – STAGE III

6.1. Each participating laboratory will recruit healthy volunteers as reference individuals from her country/region according to an agreed protocol to be discussed later.

6.2. Serum testosterone concentrations of these reference samples will be measured using the set of common calibrators when the RCPA QAP Endocrine performance is in control.

6.3. Project Group will collate and analyse reference values contributed by all the participating laboratories.

6.4. Project Group will source the supply of validated serum testosterone calibrators for the participating laboratories so that these harmonised reference intervals can be implemented for routine service.

## TIME LINE

<b>ACTIVITIES</b>	<b>DATES</b>
Proposed MSHWG terms of reference and the Serum Testosterone Project documentation submitted to APFCB Scientific Committee	August 2010
Approval of MSHWG and Serum Testosterone Project	October 2010
Formation of Serum Testosterone Project Group	October 2010
Recruiting participating laboratories	October – December 2010
Documentation of LCTMS methods	October – December 2010
Initial assessment of performance	January – June 2011
Harmonisation of accuracy performance	July – December 2011
Harmonisation of reference intervals	January – December 2012