

Testosterone Targeted Calibrators**Size:** 1.0 mL**Lot No:** 092014**Expiry:** SEP-2022**INTENDED USE**

Weqas *Testosterone Targeted Calibrators* are intended for use with Tandem Mass Spectrometry. These calibrators are for in vitro diagnostic use as an assayed quality control material for testing of in-house prepared testosterone calibrators. This material may also be of use as a calibration standard. The assigned ID-LCMS/MS target values are provided as a confirmation of accuracy.

SUMMARY

The use of accurate calibrators is well established in clinical laboratories. For routine chemistry analysers, the calibrators are generally supplied by the manufacturer. With the use of Tandem Mass Spectrometers in the area of steroid analysis, separate calibrators are required. In order to meet the requirements of the IVD Directive and ISO15189, traceability of analysis should be provided. Through the use of a certified reference material in the preparation of these calibrators and value assignment by a JCTLM listed Reference Measurement Laboratory, with ISO15195 accreditation, the traceability chain is maintained.

PRODUCT DESCRIPTION

1.0 mL volume supplied in 2 mL plastic tubes. The base material is double charcoal stripped human serum, with lipids subsequently removed using Cab-o-sil M5. The serum is dispensed and stored at ~-80 °C until dispatch.

STORAGE AND STABILITY

The material is stable until the expiration date on the vial label when stored unopened at -20 °C. The material must be used immediately following thawing and must not be subjected to freeze thaw cycles.

PROCEDURE

The material should be treated the same as calibrators and run in accordance with the instructions accompanying the test system being used. Allow to equilibrate to room temperature before use. Gently mix the contents of each vial before sampling to ensure homogeneity. Always use a clean pipette to withdraw liquid to avoid contamination. Always wear gloves to avoid contamination.

Although every effort is made to ensure that the material is free from any known infectious agent, the samples should be handled as for clinical specimens.

LIMITATIONS OF PROCEDURE

Testosterone Targeted Calibrators should not be used past the expiration date on the vial label. If there is evidence of microbial contamination or excessive turbidity in the product, discard the vial. The *Testosterone Targeted Calibrators* require storage as described in STORAGE AND STABILITY and handling as described in PROCEDURE.

ASSIGNMENT OF VALUES

The assigned values were derived from measurements of vials representative of the entire lot. Measurand values were obtained from the Weqas Reference Laboratory using a validated ID-LCMS/MS method. The testosterone target values presented within this report are traceable to SI units via the use of M914b (primary standard) and internally prepared QC material (primary reference material - M914b spiked charcoal stripped serum). The targeted values within this report

are quoted with an expanded uncertainty with a 95% level of confidence and a coverage factor of 2.

Testosterone Targeted Calibrators

Sample ID	Target Value (nmol/L)	Expanded Uncertainty
Level 0	0	-
Level 1	0.52	0.014
Level 2	1.03	0.028
Level 3	3.04	0.084
Level 4	8.09	0.222
Level 5	15.05	0.413
Level 6	25.25	0.693
Level 7	40.07	1.100

! CAUTION !

Human source material. Treat as potentially infectious.

Each unit of serum used in the manufacture of this product has been tested by CE marked IVD methods and found to be non-reactive for the presence of HbsAg and antibody to HIV-1/2, HCV and HIV-1 Ag. While these methods are highly accurate, they do not guarantee that all infected units will be detected. Because no known test method can offer complete assurance that the hepatitis B virus, hepatitis C virus, human immunodeficiency virus (HIV) or other infectious agents are absent, all products containing human source material should be considered potentially infectious and handled with the same precautions used with patient specimens.

DISPOSAL

Dispose of as potentially hazardous and biologically contaminated material using the normal practice within your laboratory for clinical samples.

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