

**Testosterone Quality Control Reference****Material****Size:** 1.8mL**Lot No:** 300914/59 **Exp.:** May 2020**INTENDED USE**

Weqas *Testosterone Quality Control Reference Material (QCRM)* is for in vitro diagnostic use as an assayed quality control material for testing of Testosterone. This material is **not** intended for use as a calibration standard. The assigned ID-GCMS target values are provided as a confirmation of accuracy.

**SUMMARY**

The use of quality control materials to objectively monitor the accuracy and precision of procedures is well established in clinical laboratories.

**PRODUCT DESCRIPTION**

1.8mL volume supplied in 2mL plastic tubes. The material is human serum, with an antibiotic added to prolong stability. The serum is dispensed and stored at -70°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 Control should be treated the same as patient specimens and run in accordance with the instructions accompanying the test system being used. 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**

The *Testosterone QCRM* 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 QCRM* requires storage as described in STORAGE AND STABILITY and handling as described in PROCEDURE.

**ASSIGNMENT OF VALUES**

The assigned values were derived from analyses of vials representative of the entire lot. Measurand values were obtained from the Weqas Reference Laboratory using a validated ID-GCMS 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) controls.

**UNCERTAINTY**

The targeted values within this report are quoted with an expanded uncertainty with a 95% level of confidence and a coverage factor of 2.

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Pool	ID-GCMS Target Value (nmol/L)	Expanded Uncertainty
Pool 595	4.49	0.14
Pool 631	9.68	0.31
Pool 622	15.11	0.48
Pool 620	28.93	0.92

**! 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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