

✓ **REFERENCE**

<b>Beta 2 Microglobulin Control</b>	<b>B2CON-003</b>	<b>1 x 3 ml</b>	<b>2-8°C</b>
Beta 2 Microglobulin control is a pooled human serum standardized from the reference ERM-DA470k/IFCC.			
Lot #	18111		
Expiry date	12/2019		
Control date	17/09/2018		
Quality control report #	DGM-QAC-REP-18113		
Document prepared and signed by	L Ginneberge		

✓ **SAMPLES AND REFERENCE VALUES**

See the corresponding reagents technical sheet.

✓ **COMPOSITION**

Beta 2 Microglobulin control is a pooled human serum. Stabilizers are added before lyophilisation.

✓ **PRINCIPLE OF TEST**

The human serum sample reacts upon a specific antibody for  $\beta$ 2M coated on a latex particles. In the presence of  $\beta$ 2M, the particles agglutinate. This aggregation and the turbidity induced by the formation of immune complexes is recorded at 575 nm. The turbidity measured is directly proportional to the  $\beta$ 2M sample concentration.

✓ **PRECAUTIONS**

For in vitro single diagnostic use. To be handled by entitled Personnel. Products from human source were tested and found free from HBsAg and antibodies to HCV and HIV but this material should be treated just as carefully as potentially infective.

✓ **ANALYTICAL PERFORMANCES**

See the corresponding reagents technical sheet.

✓ **PREPARATION AND REAGENTS STABILITY**

The control has to be stored in unopened vial at 2-8°C. The control is lyophilized and has to be reconstituted before use with 3 ml of distilled water; swirl gently and let stand undisturbed for 30 minutes at room temperature. Do not invert vial or mix vigorously. Gently mix contents before each use. Once proper reconstituted, it is stable for 2 weeks at 2-8°C in capped vial.

✓ **METHOD OF ANALYSIS AND CALCULATION.**

See the corresponding reagents technical sheet.

✓ **QUALITY CONTROL.**

**Accuracy and reproducibility:** Accuracy and reproducibility: analytical performances can be checked with the internal quality control serum of the laboratory.

✓ **BIBLIOGRAPHY**

Certification of proteins in the human serum. Certified Referenced Material ERM®-DA470k/IFCC. I. Zegers et al. <http://irmm.jrc.ec.europa.eu/>



B2CONFTEEN 17/09/2018 v01

<b>Beta 2 Microglobulin</b>	<b>CONTROL</b>	
	mg/l	
	<b>Target</b>	<b>Range</b>
	<b>8.7</b>	<b>7.0 – 10.4</b>

Values assigned from the reference ERM-DA470k/IFCC.