

✓ **REFERENCE**



Beta-2-microglobulin control	B2CON-003	1 x 3 ml	2-8 °C
Beta 2 Microglobulin control is a pooled human serum standardized from the reference ERM-DA470k/IFCC.			
Batch number :	21F24		
Expiry date :	05/2024		
Control date :	12/08/21		
Control report number :	DGM-QAC-REP-21205		
Document prepared and signed by :	L.Ginneberge		

may react with lead or copper plumbing to form highly explosive metal azides.

✓ **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 properly 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/>

✓ **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 β 2M coated on a latex particles. In the presence of β 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 β 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. Products containing sodium azide have to be handled with care ; avoid ingestion and contact with skin and mucous membranes. Sodium azide









B2CON 21F24 IFU EN v02 27/08/21


	CONTROL	
	mg/l	
	Target	Range
Beta-2-microglobulin	7.9	6.3 – 9.4

Values assigned from the reference ERM-DA470k/IFCC.

Symbols

The following symbols may appear on the packaging and labelling :

LOT	<i>Batch code</i>	BUF	<i>Buffer</i>
	<i>Use by</i>	CAL	<i>Calibrator</i>
	<i>Manufacturer</i>	H	<i>High</i>
IVD	<i>In Vitro Diagnostics Medical Device</i>	M	<i>Medium</i>
	<i>Temperature limitation (store at)</i>	L	<i>Low</i>
REF	<i>Catalogue number</i>	4 LEV	<i>4 levels</i>
	<i>Consult instructions for use</i>	5 LEV	<i>5 levels</i>
REAG	<i>Reagent</i>	6 LEV	<i>6 levels</i>
KIT	<i>Kit</i>	CONTROL	<i>Control</i>
CONT	<i>Contents</i>		<i>This product meets the requirements of European Directive 98/79 CE concerning diagnostic medical devices in vitro</i>
Ab	<i>Antibody or Antiserum</i>		<i>Track version changes</i>

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