Beta 2 Microglobulin calibrators KIT

✓ ***REFERENCE***

5 calibrators KIT	B2REK-000	5 x 1 ml	2-8 °C
Beta 2 Microglobulin in synthetic biological fluid standardized from the international standard ERM-DA470/IFCC[1], sodium azide (< 1g/l)			
Batch number :		**22E19**	
Expiry date :		**10/2023**	
Control date :		**19/05/22**	
Quality control report :		DGM-QAC-REP-**22120**	
Document prepared and signed by :		**L.Ginneberge**	

✓ ***SAMPLES AND REFERENCE VALUES***
See the corresponding reagents technical sheet.

✓ ***COMPOSITION***
Beta 2 Microglobulin calibrators are synthetic biological fluids containing human Beta 2 Microglobulin at fixed value diluted in buffer containing stabilizers and sodium azide (<1g/l) as preservative.

✓ ***PRINCIPLE OF TEST***
The human serum sample reacts upon a specific antibody for β2M coated on a latex particles. In the presence of β2M, the particles agglutinate. This aggregation and the turbidity induced by the formation of immune complexes. The turbidity measured is directly proportional to the β2M 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 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 calibrators are ready for use; once opened, they are stable until expiry date if stored stoppered in appropriate temperature conditions and without any contamination.

✓ ***METHOD OF ANALYSIS AND CALCULATION***
See the corresponding reagents technical sheet

QUALITY CONTROL
Accuracy and reproducibility: Analytical performances can be checked with the internal quality control serum of the laboratory.

Calibration: Calibration curve and stability of calibration curve can be validated with the DiAgam calibration controls (B2COS-003, B2CON-003, B2COX-001).

Calibrate when the quality control results are outside acceptable range (contact the manufacturer if the deviations subsist), when the reagent lot number changes or when government regulations require.

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

CE

B2REK 22E19 IFU EN v02 31/05/22

	CAL 1		CAL 2		CAL 3		CAL 4		CAL 5	
	mg/l		mg/l		mg/l		mg/l		mg/l	
	certified val.	*U**	certified val.	*U**	certified val.	*U**	certified val.	*U**	certified val.	*U**
Beta 2 Microglobulin	**1.5**	***0.08***	**5.0**	***0.25***	**10.0**	***0.50***	**50.0**	***2.50***	**80.0**	***4.00***

U : The certified uncertainty is the half-width of the 95% confidence interval of the mean.*
Values assigned from the reference ERM-DA470k/IFCC.

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Symbols

The following symbols may appear on the packaging and labelling :

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

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