Retinol Binding Protein calibrators kit

✓ ***REFERENCE***

5 calibrators KIT	RBREK-000	5 x 1 ml	2-8 °C
Human origin Retinol Binding Protein in synthetic biological fluid standardised with reference to the secondary preparation of RBP, sodium azide (<1g / l)			
Batch number :		**22H22**	
Expiry date :		**01/2024**	
Control date :		**05/09/22**	
Quality control report :		DGM-QAC-REP-**22220**	
Document prepared and signed by :		**Do Bach Mai**	

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

✓ ***COMPOSITION***
RBP control is synthetic biological fluids containing human-derived RBP in known concentrations and diluted in HEPES pH 7.4 buffer containing stabilisers and sodium azide at <1g/l as a preservative.

✓ ***PRINCIPLE OF TEST***
The retinol-binding protein contained in the sample to assay reacts specifically with anti-human retinol-binding protein antiserum and the turbidity induced by the formation of the antigen-antibody immune complex is measured at 340 nm and 700 nm. The measured turbidity is proportional to the retinol-binding protein concentration contained in the sample.

✓ ***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 control is ready for use; once opened, they are stable until the expiry date provided, they are kept at the marked temperature in a closed bottle to avoid any contamination.

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

✓ ***QUALITY CONTROL***
Exactitude et reproductibilité : Analytical performance can be verified using the internal control serum in labs or with the LiquichekTM (BIORAD) control sera (see dosages obtained with DiAgam reagents and stated on the sheet accompanying these controls).

✓ ***BIBLIOGRAPHY***

1. Tietz Textbook of Clinical chemistry and molecular Diagnostics, fourth edition, edited by Carl A. Burtis, Edward R. Ashwood, David E. Bruns, 2006
2. Use of Anticoagulants in Diagnostic Laboratory Investigations & Stability of blood, plasma and serum samples. Publication WHO/DIL/LAB/99.1 Rev. 2. Jan. 2002.
3. Clinical guide to laboratory tests, second edition, edited by Norbert W. Tietz, 1990
4. CLSI. Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard-Sixth Edition. CLSI document H3-A6 (ISBN 1-56238-650-6). CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA; 2007.
5. NCCLS. Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens; Approved Standard-Fifth Edition. NCCLS document H4-A5 [ISBN 1-56238-538-0]. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2004.

CE

RBREK 22H22 IFU EN v01 06/09/22

	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**
RBP	**8,87**	*0,44*	**17,73**	*0,89*	**36,48**	*1,82*	**75,17**	*3,76*	**151,27**	*7,56*

U: The certified uncertainty is the half-width of the 95% confidence interval of the mean.*
Value assigned compared to the secondary preparation of RBP.

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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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