



Retinol Binding Protein Calibrators KIT

✓ REFERENCE

5 calibrators KIT	RBREK-000	5 x 1 ml	2-8°C
Human biological fluid containing Retinol Binding Protein standardized with reference to the secondary preparation of RBP, sodium azide (< 1g/l)			
Lot #	20C19		
Expiry date	09/2021		
Control date	17/04/2020		
Quality control report #	DGM-QAC-REP-20050		
Document prepared and signed by	L. Ginneberge		

✓ SAMPLES AND REFERENCE VALUES

See the corresponding reagents technical sheet.

✓ COMPOSITION

RBP calibrators are human biological fluids containing human RBP at fixed values and sodium azide (<1g/l) as preservative.

✓ PRINCIPLE OF TEST

The human RBP react upon a specific antibody for corresponding protein and the turbidity induced by the formation of immune complexes is recorded at appropriate wavelength. The turbidity measured is directly proportional to the RBP concentration of the calibrators which can be used for the quantitative determination of RBP in immunoturbidimetry.

✓ 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 (avoid pipetting and decantation).

✓ 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 control (RBCOS-002, RBCON-002, RBCOX-002). In case of analytical performances modification, calibrate the method again and contact the manufacturer if modifications are subsisting.

✓ 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



RBREKFTEN 02/06/2020 v00

	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*
Retinol Binding Protein	7,50	0,38	15,00	0,75	30,33	1,52	63,10	3,16	119,3	5,97

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



DiAgam Avenue Louis Lepoutre 70 – 1050 BRUSSELS Belgium

mail@diagam.com

Tel: +32 (0) 68 55 14 82 / Fax: +32 (0) 68 56 89 40