



# Tapasztalatok DiaGam reagensekkel

**Dancsokné Kovács Judit,  
Szent Lázár Megyei Kórház, Salgótarján**

# CRP „XL” Wide Range



- immunturbidimetria 340nm
- 0,8-300 mg/l
- Norm.< 8 mg/l
- használatra kész
- 2x60 ml,1x15 ml
- 310 mérés/doboz,
- Saját kalibrátor

# KALIBRÁCIÓ

## C Reactive Protein (CRP) Calibrators KIT

✓ REFERENCE.

5 calibrators KIT	CPREK-000	5 x 1 ml	2-8°C
Human CRP in synthetic biological fluid standardised from the reference CRM 470, sodium azide (< 1g/l)			
Lot #	04H17		
Expiry date	08/2005		
Control date	19/08/04		
Quality control report #	DGM-QAC-REP-04260		
Document prepared and signed by	Anne-Sophie Roos		

✓ SAMPLES AND REFERENCE VALUES.

See the corresponding reagents technical sheet.

✓ COMPOSITION.

CRP calibrators are synthetic biological fluids containing human CRP at fixed value diluted in HEPES pH 7.4 buffer containing stabilisers and sodium azide (<1g/l) as preservative.

✓ PRINCIPLE OF TEST.

The human CRP reacts upon a specific antibody for human CRP and the turbidity induced by the formation of immune complexes is recorded at 340 nm. The turbidity measured is directly proportional to the CRP concentration of the calibrators which can be used for the quantitative determination of CRP 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.

CRP	CAL	1	CAL	2	CAL	3	CAL	4	CAL	5
	mg/l		mg/l		mg/l		mg/l		mg/l	
	6.25		25.00		50.00		100.00		200.00	

Values assigned from the reference CRM 470 (Reference preparation for the human serum proteins certified conjointly by the College of the American Pathologists, the Communal office of Reference and the International Federation of Clinical Chemistry (IFCC).

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 or with the Liquichek™ (BIO-RAD) Control sera (see the values range obtained with DIAGAM reagents and indicated on the accompanying BIO-RAD sheet).

Calibration: calibration curve and stability of calibration curve can be validated with the DIAGAM calibration control (CPCON-002).

In case of analytical performances modification, calibrate the method again and contact the manufacturer if modifications are subsisting.

✓ BIBLIOGRAPHY.

Johnson, A.M.: A new international preparation for proteins in human serum, Arch. Pathol. Lab. Med. 117 (1993) 29-31.

 CPREKFTE 09/09/2004



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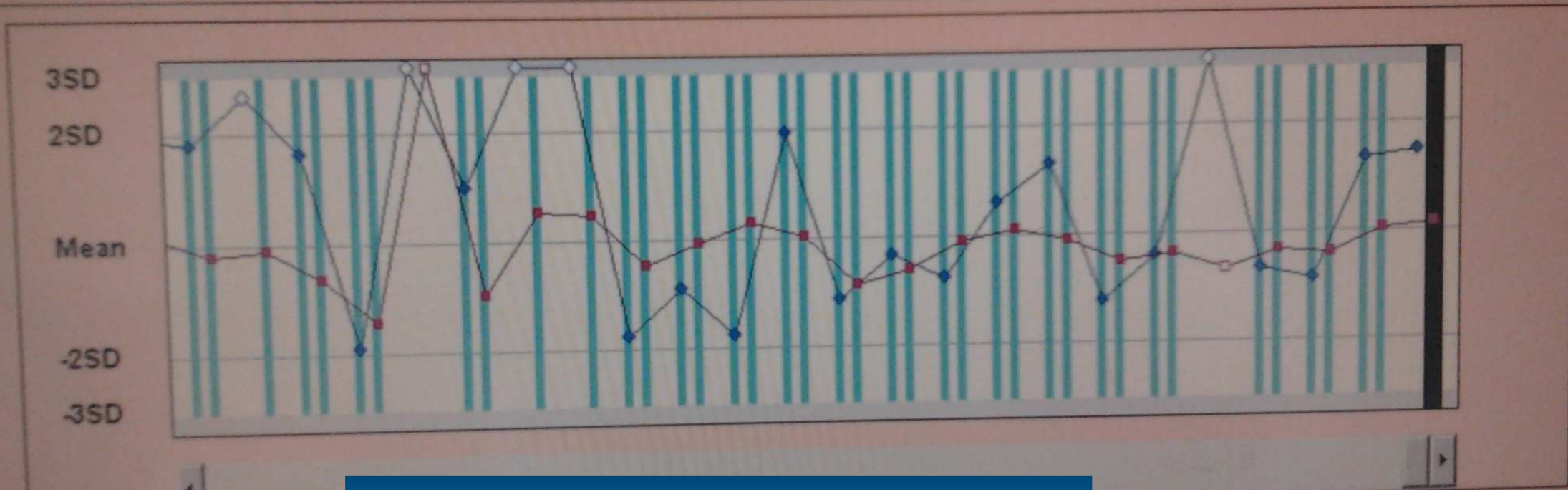
Tel: +32 (0) 68 55 14 82 / Fax: +32 (0) 68 56 89 40  
Tel : +33(0)3.20.42.85.17/ Fax : +33 (0) 3 20 54 22

# Individual QC Chart

Test: CRP-D  
Module: P1

Legend: ■ Comment, □ Excluded, ■ Comment and Excluded

Plot	Control	S. Type	Lot No.	Data	Unit	Date	Time	N	Mean	SD	CV(%)
(1)	◆ pcc1	Ser/PI	158562		mg/L						
(2)	■ pcc2	Ser/PI	158562	40.68	mg/L	11/11/16	08:13	1	40.680		
(3)	● CRP PN	Ser/PI	156547		mg/L						



n=21	n=21
Átlag=6,53 mg/l	Átlag=39,4 mg/l
SD=0,29	SD=0,77
CV%=4,47	CV%=1,97

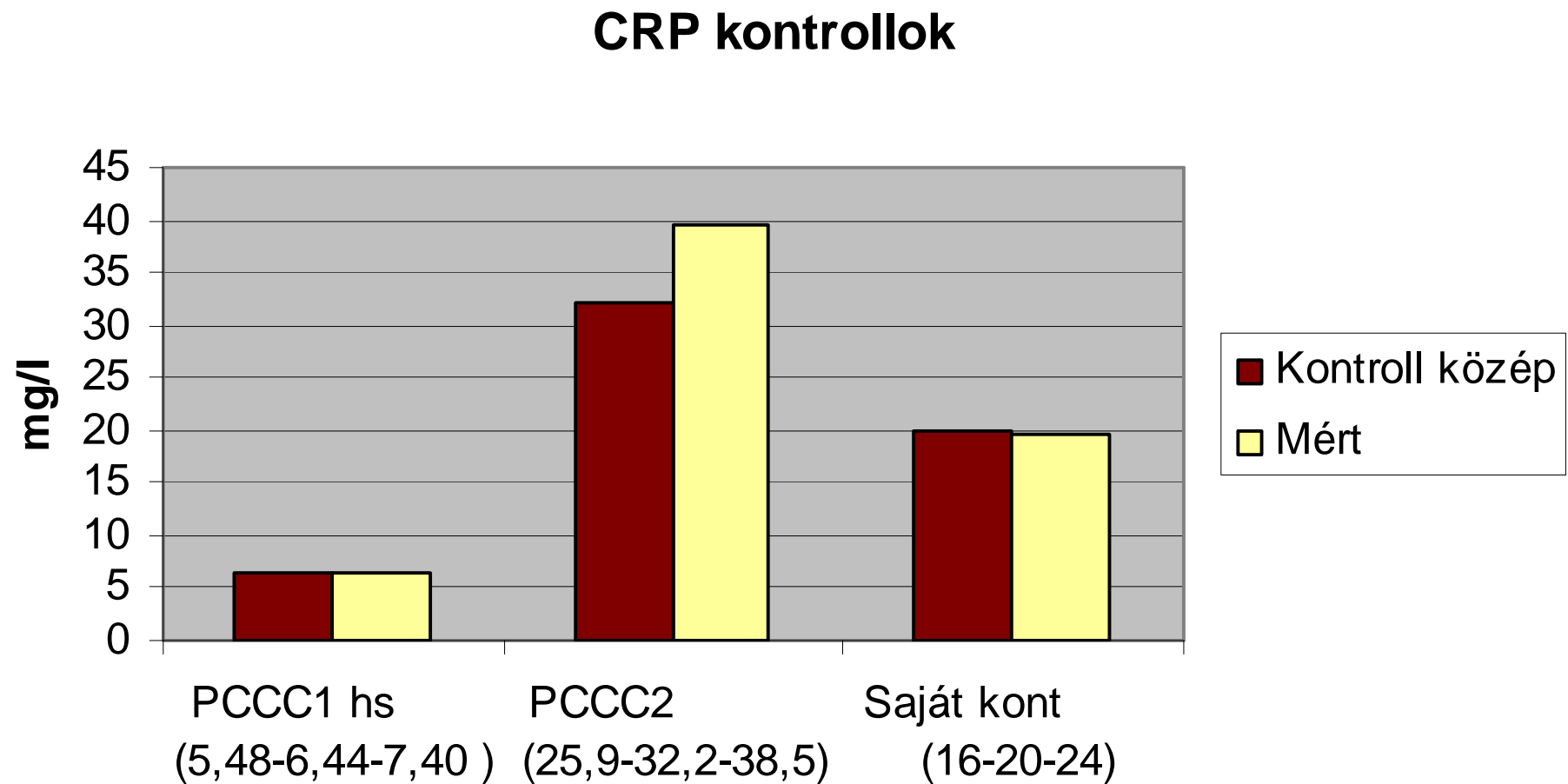
Close

? Help

Select the test

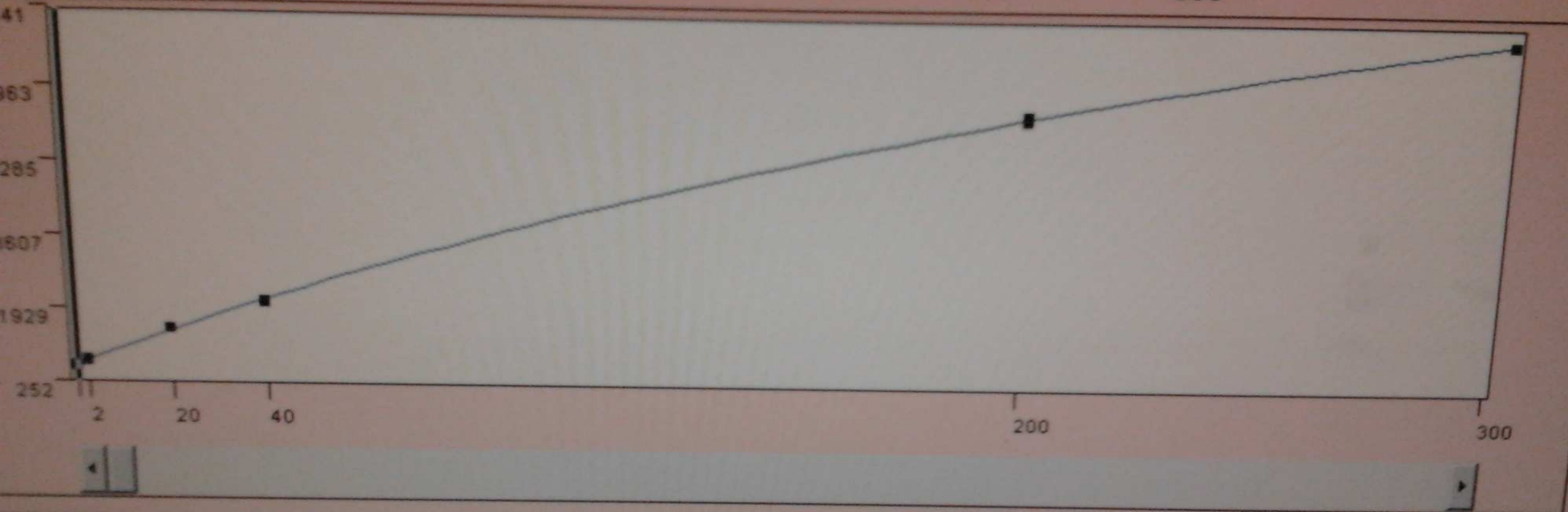


# CRP kontrollok



### Working Information

Module	Calibration Type	Scale	Abs. 1	Abs. 2	Update Factor
P1	Logit-Log 4P	Automatic	635	633	



S1 Abs.	K	A	B
19706	-1.903E+4	2.207E+1	1.000E+0

Scale

Reagent

Close

?  
Help

Touch the screen, click the mouse, press the space bar or <Enter>.

?  
Help

## ANALYTICAL PERFORMANCES

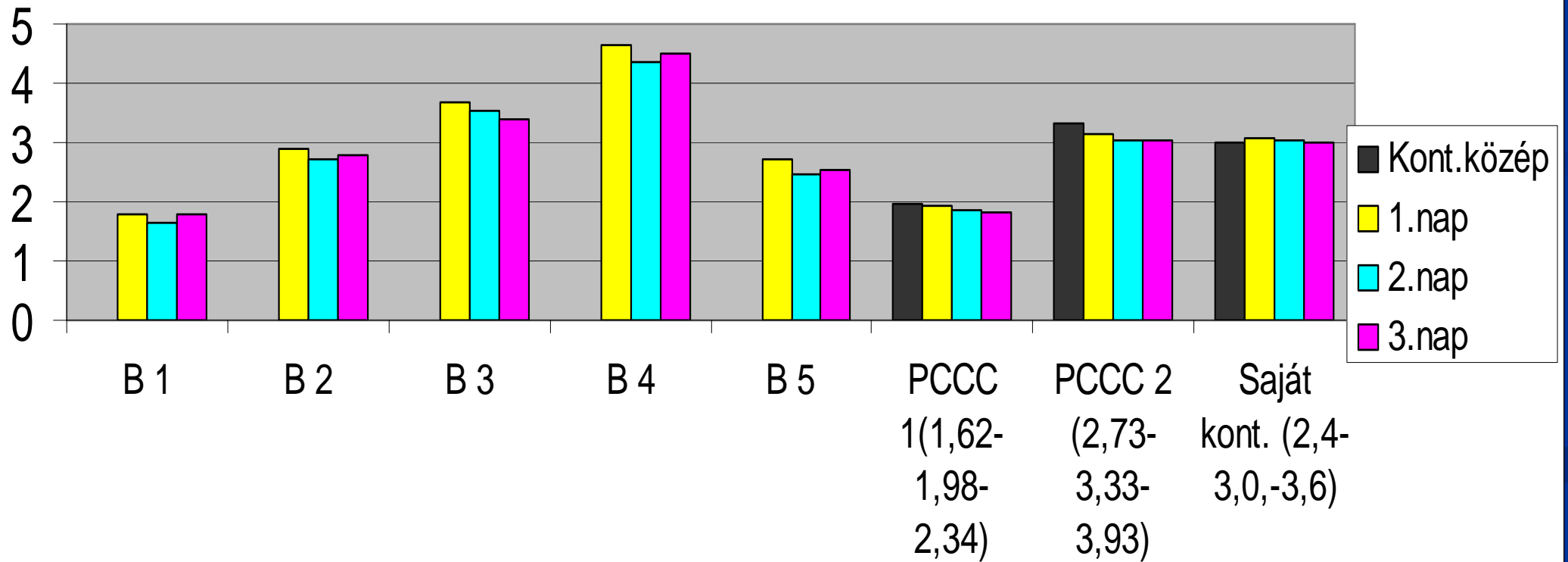
specificity		single precipitation arc in presence of total human serum in immunodiffusion or electrophoresis
repeatability n=10		< 2.5%
reproducibility n=10		< 4.0%
detection limit		0.55 mg/l
hook effect		> 2750 mg/l
analytical range		0.80 mg/l to 300 mg/l
calibration stability		depending on the equipment > 4 weeks on analyser
<b>interference :</b>		
triglycerides		< 10% or 2 DS until 22.6 mmole/l
hemoglobin		< 10% or 2 DS until 120 $\mu$ mole/l
bilirubin		< 10% or 2 DS until 375 $\mu$ mole/l
heparin		< 10% or 2 DS until 0.5 g/l
sodium fluoride		< 10% or 2 DS until 4 g/l
EDTA		< 10% or 2 DS until 5 g/l
sodium citrate		< 10% or 2 DS until 5 g/l

TRANSZFERRIN	FERRITIN	RF
High Calibrator	Cal .Kit	High Calibrator
Norm:		
Újszülött:1,3-2,75g/l	Újszülött:25-200ug/l	< 20 kIU/l
3hó-16év:2,03-3,6	1-5hó: 50-600	
Felnőtt: 2,00-4,00	6hó-15év: 7-140	
	Ffi.: 20-240	
	Nő: 10-120	
Mérési tartomány:		
0,06-8,00 g/l	5-1000 ug/l	1,2-120 kIU/l



# TRANSZFERRIN

## TRANSZFERRIN



A serene winter landscape featuring a calm river that perfectly reflects the surrounding scene. The banks are lined with trees heavily laden with snow, their intricate branches mirrored in the still water. In the distance, a range of mountains with snow-dusted peaks rises against a clear, bright blue sky. The overall atmosphere is peaceful and crisp.

**Köszönöm a figyelmet!**