			1					
5 calibrators KIT	FNRGK-000	5 x 1 ml	2-8°C					
Human Ferritin in synthetic biological fluid standardized from the								

SAMPLES AND REFERENCE VALUES

See the corresponding reagents technical sheet.

COMPOSITION

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

PRINCIPLE OF TEST

The human ferritin reacts upon colloidal gold coated with a mixture of monoclonal antibodies to ferritin. In the presence of ferritin, the particles agglutinate, which induces a red shift in the visible spectrum of the colloid. This induces an increase in optical density at 600 nm, which is directly proportional to the ferritin concentration of the calibrator which can be used for the quantitative determination of ferritin in immunocolorimetry.

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.

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 $^{ extsf{T} extsf{N}}$ Immunoassay Plus Control (BIO-RAD).

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

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

BIBLIOGRAPHY

- (1) WHO International Standard Ferritin, human, recombinant NIBSC code: 94/572. http://www.nibsc.ac.uk/documents/ifu/94-572.pdf
- (2) Thorpe, S.J. et al. International collaborative study to evaluate a recombinant L ferritin preparation as an International Standard. Clin. Chem. 43:9 (1997) 1582-1587
- (3) Thorpe, S.J. et al. Automated immunoassay methods for ferritin: recovery studies to assess traceability to an international standard. Clin. Chem. Lab. Med. (2008); 46(10): 1450-7.

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ANALYTICAL PERFORMANCES

See the corresponding reagents technical sheet.

Ferritin	CAL	1	CAL	2	CAL	3	CAL	4	CAL	5
	μg/l		μg/l		μg/l		μg/l		μg/l	
	0		25		75		150		300	

Values assigned from the Ferritin international standard NIBSC 94/572.

