Calprotectin Calibrators Kit

Items

Calprotectin Calibrators kit	CAREK-000	6 x 1 ml	2-8°C
Human native Calprotectin standardised with internal reference method, sodium azide (< 1g/l)			
Lot number:		21E22	
Expiry date:		08/2021	
Control date:		07/07/2021	
Control report number:		DGM-QAC-REP-21114	
Document prepared and signed by:		L. Ginneberge	

Concentrations

Proteins	CAL 1		CAL 2		CAL 3		CAL 4		CAL 5		CAL 6	
	mg/kg		mg/kg		mg/kg		mg/kg		mg/kg		mg/kg	
	Certified val.	U*	Certified val.	U*	Certified val.	U*	Certified val.	U*	Certified val.	U*	Certified val.	U*
Calprotectin	0.0	0.00	34.1	1.71	79.0	3.95	184.7	9.24	421.6	21.08	850.7	42.54

U* : The certified uncertainty is the half-width of the 95 % confidence interval of the mean.
Values assigned from an internal reference method.

Composition

Calprotectin control is made of human native Calprotectin derived from blood products. Native Calprotectin is diluted in sample dilution buffer (SDBUF) with < 0.1% sodium azide as a preservative.

Principle of the method

The gold particles in colloidal form are stabilized using monoclonal antibodies directed specifically against human calprotectin. The reaction of these conjugates with human calprotectin, present in a biological sample, causes the specific agglutination of the gold particles. This agglutination, directly proportional to the concentration of the calprotectin in the sample, is read at 546 nm and 600 nm.

Precautions for use

For single in vitro use; must be handled by authorised personnel under the responsibility of a biologist. Human-derived products have been screened for anti-HIV 1 and 2 antibodies, anti-HCV antibodies and HBsAg but should be handled as potentially infectious.

Products containing sodium azide should be handled with care: avoid ingestion and contact with skin or mucous membranes. Sodium azide becomes explosive on contact with heavy metals such as copper or lead.

Analytical performance

Refer to the relevant reagent data sheets (reference: CACOL-B00 or CACOL-B00/XXX, CACOL-H00 or CACOL-H00/XXX, CACOL-L00 or CACOL-L00/XXX).

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• Sample and reference values

Refer to the relevant reagent data sheets (reference: CACOL-B00 or CACOL-B00/XXX, CACOL-H00 or CACOL-H00/XXX, CACOL-L00 or CACOL-L00/XXX).

• Preparation and stability

The calibrators are ready for use. Once opened, it is stable until its expiry date. To be stored at 2-8°C in a closed bottle to avoid any contamination. The calibrators are shipped at 2-8°C.

• Analytical procedure and concentration calculations

Refer to the relevant reagent data sheets (reference: CACOL-B00 or CACOL-B00/XXX, CACOL-H00 or CACOL-H00/XXX, CACOL-L00 or CACOL-L00/XXX).

• Quality control

Accuracy and reproducibility

Analytical performance can be verified using the internal control in laboratory.

Calibration

Calibration curve and stability of calibration curve must be validated with the DiAgam calibration controls (CACOS-002, CACON-002 and CACOX-002).

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

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• Key to symbols

The following symbols may appear on the packaging and the label:

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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