

• Items

Calprotectin Low Control	CACOS-002	1 x 2 ml	↓ 2-8°C
Human origin Calprotectin in sample dilution buffer (SDBUF), sodium azide (< 0.1 %)			
Lot number:	21E23		
Expiry date:	08/2021		
Control date:	07/07/2021		
Control report number:	DGM-QAC-REP-21115		
Document prepared and signed by:	L. Ginneberge		

• Concentrations

Protein	CONTROL	
	mg/kg	
	Target	Range
Calprotectin	36.9	29.5 – 44.3

Value assigned compared to 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).

- **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 control is 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 control is 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.

• 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		This product meets the requirements of European Directive 98/79 CE concerning diagnostic medical devices in vitro
Ab	Antibody or Antiserum		Track version changes

 DiAgam Headquarters	DiAgam Belgium: Rue du Parc Industriel 40, 7822 Ghislenghien, Belgium Avenue Louis Lepoutre 70, 1050 Brussels, Belgium
-------------------------	---

Distributed by :	<p>DiAgam SA, Avenue Louis Lepoutre 70, 1050 Bruxelles, Belgium, and its authorized representatives. www.diagam.com</p> <p>Calpro AS, Arnstein Arnebergs vei 30, 1366 Lysaker, Norway, and its authorized representatives. www.calprogold.com</p>
------------------	---

All product names, registered trademarks, company names in this document remain the property of their respective owners.