Calprotectin in the assessment of rheumatoid arthritis

Turbidimetric immunoassay → **Detection of inflammation** → **Assess disease activity**

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Calprotectin in rheumatoid arthritis (RA)

Calprotectin, a biomarker for neutrophil activation, has been shown to have clinical diagnostic and prognostic value in rheumatoid arthritis (RA), including the potential to monitor treatment response. During inflammation, neutrophils migrate to the inflammatory site and secrete large amounts of calprotectin which act as a soluble proinflammatory mediator[1].

Calprotectin is released locally at inflammation sites, including inflamed synovium, and enters the systemic circulation where it can be measured. Since calprotectin is released predominantly from locally activated leukocytes at the sites of joint inflammation, it directly reflects joint inflammatory activity[2].

Calprotectin will provide valuable information for assessment of disease activity, treatment response and relapse in RA

The ability to assess disease activity and relapse in RA

Since the concentration of calprotectin reflects the degree of inflammation, it can provide valuable assesment of disease activity, treatment response and relapse. Circulating calprotectin is elevated in active disease and decreases after effective treatment and has been shown to be a more sensitive biomarker of disease activity in RA than conventionally used acute-phase proteins[3]. Calprotectin can be more effective than erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) to gauge disease activity, as it has been demonstrated that more than 40 % of RA patients have normal ESR or CRP[4-6]. In these patients, calprotectin can potentially be a useful inflammatory marker.

Calprotectin may also be used to more accurately predict relapse in patients in remission or with low disease activity receiving biological drugs, which potentially would guide therapeutic decisions towards safer and more cost-effective treatment strategies[7].

Assessment of disease activity whilst using TNF-alpha, IL-1 and IL-6 and other bDMARDs

RA patients are often treated with a wide range of medication. It is important to realise that some medication which moderates TNF-alpha, interleukin IL-1 or IL-6 might, in addition to a reduction of the cytokine levels, also directly lower levels of proteins downstream in the pro-inflammatory cascade, such as CRP. Calprotectin can therefore represent a useful biomarker when for example CRP is normal or difficult to interpret, such as in patients treated with therapies that suppress IL-6[8] . Calprotectin, however, is not influenced by these medications, and will only reflect the leucocyte activation during inflammation[9].

Calprotectin has also been seen to have the highest agreement with ultrasound synovitis and anticipated treatment response. Hence, it could be considered as a marker for assessing inflammation and responsiveness in patients with RA on bDMARD (biological disease-modifying antirheumatic drug) treatment[10]. Moreover, calprotectin may more accurately segregate the disease activity in RA patients receiving TNF-alpha treatment than other acute phase reactants, even in patients with low inflammatory activity[11].

Why the Gentian Calprotectin GCAL® Immunoassay?

GCAL® is a novel Particle-Enhanced Turbidimetric Immunoassay (PETIA) that can be applied on a wide range of automated clinical chemistry analysers. The assay is rapidly performed in only 10 minutes.

The GCAL® immunoassay is developed and manufactured by Gentian. GCAL® is CE-marked.

Performed in 10 minutes

Turbidimetric test

Faster throughput

Can be applied on most automated platforms

Process time normally less than 10 minutes

Avian antibodies

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References: 1. Ometto et al. (2017), Experimental Biology and Medicine; 242: 859–873 **2.** Johne B et al. (1997) Mol Pathol. 1997; 50(3):113-23 **3.** Andrés et al. Arthritis Res Ther. 2011;13:R122 **4.** Pincus T, Sokka T (2009) Rheum Dis Clin N Am 35(4):731–734 **5.** Sokka T, Pincus T (2009) J Rheumatol 36(7):1387–1390 **6.** Pincus et al. (2014) Clin Exp Rheumatol 32(5 Suppl 85):S-23-28 **7.** Inciarte-Mundo et al. (2018)Arthritis research and therapy 20:275 **8.** Jarlborg et al. (2020) Arthritis Research & Therapy 22:105 **9.** Berner Hammer et al. (2007) Ann Rheum Dis 2007; 66:1093-1097 **10.** Nordal et al. Arthritis Research & Therapy (2017) 19:3 **11.** Inciarte-Mundo et al. Arthritis Research & Therapy (2016) 18:160 **12.** Blirup Jensen et al. Clin Chem Lab Med, 2008:46(10):1470-1479

GCAL® - Gentian Calprotectin Immunoassay Performance	
Sample type	Li-Heparin plasma, Serum
Assay type	PETIA
Format	Liquid reagents, ready to use
Precision (sample >1 mg/L)*	Total CV 4.0 %
LoQ*	0.3 mg/L
Security zone*	Up to 95 mg/L
Measuring range*	0.4 - 20 mg/L
Calibration stability*	4 weeks

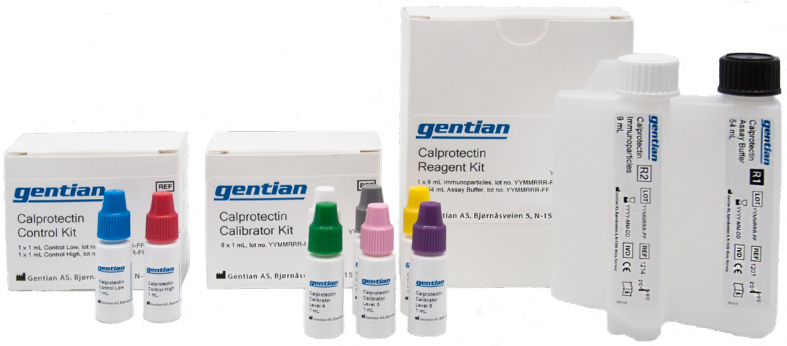
Instrument dependent results achieved on Architect c4000 during validation.

Calibrator standardisation

The calibrator for GCAL®, the Gentian Calprotectin Immunoassay, is available as a 6-point pre-diluted calibrator kit. The calibrator is established according to section 5.6 in ISO 17511:2003. The calibrator is traceable via a published value transfer protocol[12] to a highly pure recombinant calprotectin solution with assigned value by total protein determination by UV280 and known extinction coefficient.

Product range

Product no.	Product	Content
1201	Gentian Calprotectin Reagent Kit	R1 54 mL + R2 9 mL
1202	Gentian Calprotectin Reagent Kit S	R1 30 mL + R2 5 mL
1219	Gentian Calprotectin Control Kit	2 x 1 mL
1251	Gentian Calprotectin Calibrator Kit	6 x 1 mL



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