

BÜHLMANN sCAL[®] turbo

Immuno turbidimetric serum CALPROTECTIN Assay

New Serum
Calprotectin Assay



Serum Calprotectin results within 10 minutes

- Adaptable on clinical chemistry analyzers
- Validated analyzer applications
- Random access, fast Turn-Around-Time

Serum Calprotectin, a promising marker

- Stratification and monitoring in RA
- Differentiation sJIA from other forms of JIA
- Differentiate sJIA from other causes of FUO

High correlation to established ELISA method

- CE marked product
- Standardized based on recombinant Calprotectin
- Pre-analytical recommendations

RA: Rheumatoid Arthritis

JIA: Juvenile Idiopathic Arthritis

sJIA: systemic Juvenile Idiopathic Arthritis

FUO: Fever of unknown Origin

Serum Calprotectin results within 10 minutes

BÜHLMANN sCAL® turbo immunoassay is the flexible solution to be applied on most clinical chemistry analyzers. The turbidimetric technology is a milestone in serum calprotectin quantification and allows very rapid and flexible random-access use. Automation supports high throughput application in the routine laboratory. The sCAL turbo assay reduces the hands-on time dramatically and allows reporting serum calprotectin results from human samples within shortest time.

The turbidimetric assay is the ideal solution for a serum biomarker like calprotectin. The offered measuring range covers the clinically relevant concentrations and allows automated re-run for extreme high-level concentrations without high dose hook effect up to >90 µg/mL. High precision and reproducibility is given with the method.

Application notes available

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|---------------------------|------------------|
| Roche cobas® c501 | Abbott Alinity |
| Roche cobas® c303 | Mindray BS-480 |
| Beckman Coulter AU series | Biosystems BA200 |

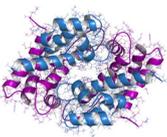
For further applications please contact support@buhlmannlabs.ch

PRODUCT DESCRIPTION

| | |
|------------------|--|
| Method | Particle-enhanced turbidimetric immunoassay (PETIA) |
| Sample Type | Serum |
| Kit Format | 2 reagents, good for ~100 tests (platform dependent) |
| Reagent on board | Stable for 90 days |
| Calibration | Stable for at least 30 days (platform dependent) |
| Measuring range | 0.30-15 µg/mL (extended range up to 225 µg/mL) |
| Sample volume | ~2-3 µL |
| Application | R1:R2 ratio = 3:1, analysis: kinetic |
| Time to result | ~10 min |

Pre-Analytics: Serum Calprotectin is stable for 15 days at room temperature. Serum separated within 6 hours after blood drawing shows most promising discrimination between normal donors and patients with active auto-inflammatory diseases.

Analyzers mentioned are registered trademarks held by the corresponding manufactures.

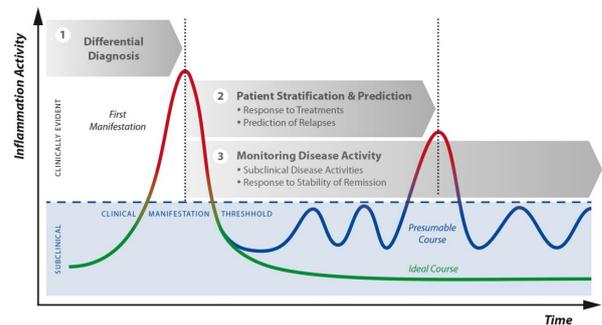


CALPROTECTIN, a so-called alarmin with important pro-inflammatory properties. It is part of the innate immune response and is expressed by granulocytes, monocytes, and macrophages after their activation via-pathogen-associated molecular patterns (PAMPs) or damage-associated molecular patterns (DAMPs).

Calprotectin is a DAMP itself being a ligand of TLR4, a major pattern recognition receptor. TLR4 transduces the signal after interacting with PAMPs and DAMPs. Calprotectin is the most abundant alarm signal during infections, arthritis, allergies, autoimmune diseases and inflammatory bowel, pulmonary, or cardiovascular diseases.

Serum Calprotectin is a powerful tool to detect the inflammatory status of a patient whether it is a classical autoimmune mediated Rheumatoid Arthritis or a rare auto-inflammatory disease like systemic juvenile arthritis (sJIA) or Still's disease (AOSD).

Detection of elevated levels support differential diagnosis but moreover calprotectin has been shown to help for stratification and disease prediction to ensure the optimal therapy for the patients.



During the course of the disease, monitoring the inflammatory activity in patients is important. Serum calprotectin has the ability to detect subclinical disease activity and allows to determine the stability of the remission.

Calprotectin in Rheumatoid Arthritis ¹⁾

CALPROTECTIN is the most up-regulated protein in RA synovial tissue and synovial fluid.

CALPROTECTIN levels are higher in the serum of RA patients compared with healthy subjects

CALPROTECTIN serum levels correlate with disease activity and are associated with markers of more severe RA in many studies.

CALPROTECTIN serum levels perform even better compared to CRP and ESR.

CALPROTECTIN has shown to correlate better with all clinical indices, such as activity (DAS28) score and simplified disease activity Index (SDAI).

CALPROTECTIN serum levels decrease in response to treatment with both conventional and biologic disease modifying anti-rheumatic drugs.

CALPROTECTIN serum levels have shown a prompt and more marked response to inflammatory changes compared with classic inflammatory indices, thus representing a sensitive biomarker for assessing treatment response

CALPROTECTIN has been independently associated with ultrasonography assessment scores, particularly in large joints

CALPROTECTIN is associated with synovitis at the ultrasonography assessment in RA and psoriatic arthritis (PSA) patients in remission.

Calprotectin for diagnosis of systemic Juvenile Idiopathic Arthritis

sJIA is an aggressive autoinflammatory disease, typically characterized by spiking quotidian fever, transient rash and arthritis, mimicking clinical signs of severe infection. Characteristic signs of active arthritis often develop in the later course of the disease. sJIA is mainly diagnosed by exclusion of other diseases and needs to be considered in children with fever of unknown origin (FUO).

Pro-inflammatory calprotectin is produced by phagocytes during activation of the innate immune system and is highly elevated in sJIA. The high stability and availability of calprotectin measurement makes the marker to an important tool to differentiate from other causes of FUO and accelerates the diagnosis for quick intervention.

¹⁾ Ometto et al. Exp Biol Med, 2017



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BÜHLMANN sCAL® turbo Ordering Codes:

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|--------------------------|--|
| Kit | KK-SCAL |
| Reagent Kit (~100 tests) | B-KSCAL-RSET R1 24 mL, R2 7.3 mL; Ready to use |
| Calibrator Kit | B-KSCAL-CASET 6 calibrators, 1 mL each; Ready to use |
| Control Kit | B-KSCAL-CONSET Low/high 3 x 1 mL each; Ready to use |

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