

---

## INCIDENT REPORTING IN EU MEMBER STATES

If any serious incident in relation to this device has occurred, please report without delay to the manufacturer and competent authority of your Member State.

---

## SHIPPING DAMAGE

Please notify your distributor, if this product was received damaged.

---

## REACH

None of the materials and reagents in the kit require a Material Safety Data Sheet (MSDS) according to CLP-Regulation (EC) No 1272/2008 and directive EC 1907/2006 (REACH).

---

## SYMBOLS

BÜHLMANN use symbols and signs listed and described in ISO 15223-

1. In addition the following symbols and signs are used:



**EN:** electronic instruction for use available in different languages at:/ **DE:** elektronische Gebrauchsanweisung in verschiedenen Sprachen verfügbar unter:/ **FR:** un mode d'emploi électronique disponible en différentes langues à l'adresse:/ **IT:** istruzioni elettroniche per l'uso disponibili in diverse lingue su:/ **ES:** instrucciones de uso electrónicas disponibles en diferentes idiomas en:/ **PT:** instrução electrónica para utilização disponível em diferentes línguas em:/ **BG:** електронни инструкции за употреба на различни езици на адрес:/ **DA:** elektronisk brugsanvisning på forskellige sprog på:/ **ET:** elektrooniline kasutusjuhend, mis on saadaval erinevates keeltes aadressil:/ **EL:** ηλεκτρονικές οδηγίες χρήσης διαθέσιμες σε διάφορες γλώσσες στη διεύθυνση:/ **LV:** dažādās valodās pieejama elektroniska lietošanas instrukcija:/ **LT:** elektroninės naudojimo instrukcijos įvairiomis kalbomis:/ **NO:** elektronisk instruksjon for bruk tilgjengelig på forskjellige språk på:/ **PL:** elektroniczna instrukcja obsługi dostępna w różnych językach na stronie:/ **RO:** instrucțiuni electronice de utilizare disponibile în diferite limbi la adresa:/ **SV:** elektronisk bruksanvisning på olika språk på följande adress:/ **SK:** elektronický návod na použitie dostupný v rôznych jazykoch na:/ **CS:** elektronický návod k použití dostupný v různých jazycích na adrese:/ **HU:** külfönböző nyelveken elérhető elektronikus használati utasítás a következő címen:/ **SR:** elektronsko uputstvo za upotrebu dostupno na različitim jezicima na:

[www.buhmannlabs.ch/support/downloads/](http://www.buhmannlabs.ch/support/downloads/)



# BÜHLMANN sCAL® turbo

Serum calprotectin turbidimetric assay

## Control Kit

B-KSCAL-CONSET

Version A1

For *In Vitro* Diagnostic Use



Manufacturer

**BÜHLMANN Laboratories AG**

Baselstrasse 55

4124 Schönenbuch

Switzerland

Tel.: +41 61 487 1212

Fax: +41 61 487 1234

info@buhmannlabs.ch



[www.buhmannlabs.ch/support/downloads/](http://www.buhmannlabs.ch/support/downloads/)

---

## INTENDED USE

The BÜHLMANN sCAL® turbo Control Kit is intended for use with the BÜHLMANN sCAL® turbo Reagent Kit, for quality control, in the determination of serum calprotectin (MRP8/14) levels in serum sample.

For laboratory use only.

## CONTROL VALUE

Control values are assigned according to a value transfer protocol (Ref. 1-2) and are indicated in the enclosed QC-data sheet. The control material comprises recombinant calprotectin and is standardized against an internal reference material.

## REAGENTS SUPPLIED

Reagents	Quantity	Code	Preparation
<b>Controls Low / High</b> Controls containing an assigned concentration of recombinant calprotectin	3 x 2 vials 1 mL/vial	B-KSCAL- CONSET	Ready to use

Table 1

## REAGENT STORAGE AND STABILITY

Unopened controls
Store at 2-8 °C. Do not use kit past expiration date printed on the labels.
Opened controls
Store for up to 55 days at 2-8 °C, capped.

Table 2

## MATERIALS REQUIRED BUT NOT PROVIDED

Reagents	Quantity	Code
<b>BÜHLMANN sCAL® turbo Reagent Kit</b> Reaction Buffer (R1) Immunoparticles (R2)	1 vial/24 mL 1 vial/7.3 mL	B-KSCAL-RSET
<b>BÜHLMANN sCAL® turbo Calibrator Kit</b> Calibrators 1-6 for establishment of six-point calibration curve	1 x 6 vials 1 mL/vial	B-KSCAL-CASET

Table 3

## WARNINGS AND PRECAUTIONS

- This test is for *in vitro* diagnostic use only.
- It is recommended that the test be handled by qualified personnel, in accordance with Good Laboratory Practice (GLP).
- Before measuring please equilibrate reagents, controls, calibrators and samples for 30 min at room temperature before starting analysis.
- Do not mix controls of different lots or switch caps between reagents.
- Ensure that controls have no bubbles prior to running the test.
- Avoid evaporation of the controls.

## ASSAY PROCEDURE

### Application notes/ assay installation

The assay procedure for the BÜHLMANN sCAL® turbo has been established on several clinical chemistry analyzers. Validated application notes describing installation and analysis on specific instruments are available from BÜHLMANN upon request.

### QC controls

The BÜHLMANN sCAL® turbo Control Kit must be assayed each day before running patient serum sample. This is to validate the calibration curve established with the BÜHLMANN sCAL® turbo Calibrator Kit. The controls have assigned, lot-specific value ranges indicated on the QC-data sheet enclosed. The control measurements must be within the indicated value ranges to obtain valid results for patient serum.

If the control values are not valid, repeat measurement with fresh controls. If control values remain invalid, recalibrate the instrument. If valid control values cannot be reproduced, after performing the steps described above, contact BÜHLMANN support.

## REFERENCES

1. Blirup-Jensen et al.: Clin Chem Lab Med 2001; 39, 1110-22.
2. Blirup-Jensen et al.: Clin Chem Lab Med 2008; 46, 1470-9.