

## 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 eletrónica para utilização disponível em diferentes línguas em / **BG:** електронни инструкции за употреба на различни езици на адрес./ **DA:** elektronisk brugsanvisning på forskellig 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:** különböző 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

## Calibrator Kit

B-KSCAL-CASET  
Version A1

For *In Vitro* Diagnostic Use



Manufacturer

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## INTENDED USE

The BÜHLMANN sCAL® turbo Calibrator Kit is intended for use with the BÜHLMANN sCAL® turbo Reagent Kit for the determination of serum calprotectin (MRP8/14) levels in serum samples. Each calibrator establishes a point of reference for the calibration curve that is used to calculate test results from patient samples.

For laboratory use only.

## CALIBRATOR VALUE

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

## REAGENTS SUPPLIED

Reagents	Quantity	Code	Preparation
<b>Calibrators</b> Calibrators 1-6 containing an assigned concentration of recombinant calprotectin	1 x 6 vials 1 mL/vial	B-KSCAL- CASET	Ready to use

Table 1

## REAGENT STORAGE AND STABILITY

<b>Unopened calibrators</b>
Store at 2-8 °C. Do not use kit past expiration date printed on the labels.
<b>Opened calibrators</b>
Store for up to 55 days at 2-8 °C, capped.
<b>Calibration curve stability</b>
Refer to the instrument specific application note.

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 Control Kit</b> Controls low and high	3 x 2 vials 1 mL/vial	B-KSCAL-CONSET

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 calibrators of different lots or switch caps between reagents.
- Ensure that calibrators have no bubbles prior to running the test.
- Avoid evaporation of the calibrators.

## 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.

### Establishment of the calibration curve

The BÜHLMANN sCAL® turbo Calibrator Kit is used to establish a six-point calibration curve according to the instrument manual. Calibrator values are lot-specific. A new calibration must be performed for each new calibrator and reagent lot. Otherwise, calibration should be performed every one to two months according to the instrument specific application notes. Refer to the enclosed QC-data sheet for assigned calibrator values. Contact BÜHLMANN support if calibration cannot be performed without error.

### QC controls

The calibration curve must be validated with controls, low and high, each day before running patient serum samples. Refer to the Instruction for use for BÜHLMANN sCAL® turbo Control Kit for further information.

## 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.