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.

SYMBOLS

BÜHLMANN use symbols and signs listed and described in ISO 15223-1.
For definition of symbols see the symbol glossary at:
www.buhlmannlabs.ch/support/downloads/
In addition the following symbols and signs are used:

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

www.buhlmannlabs.ch/support/downloads/

US Distribution
BUHLMANN Diagnostics Corp
Amherst, NH 03031, USA
Tel: (844)300-979
info@buhlmannlabs.com

CE 0123

BÜHLMANN

BÜHLMANN ACE kinetic

Angiotensin Converting Enzyme

Control Kit

B-ACK-CONSET
Version A2

For *In Vitro* Diagnostic Use

Rx Only

CLIA Complexity: Moderate

Manufacturer
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Tel.: +41 61 487 1212
Fax: +41 61 487 1234
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INTENDED USE

The BÜHLMANN ACE kinetic Control Kit is intended for use with the BÜHLMANN ACE kinetic, for quality control, in the determination of angiotensin converting enzyme (ACE) activity in serum samples.

For laboratory use only.

CONTROL VALUE

The BÜHLMANN ACE kinetic controls should be assayed measured daily before running serum samples to validate the calibration curve. The control measurements must be within the value ranges, indicated in the QC-data sheet, to obtain valid results for serum samples.

REAGENTS SUPPLIED

Reagents	Quantity	Code	Preparation
Controls Normal and High[1]	1 x 2 vials	B-ACK-CONSET	Add 2 mL of deionized water

Table 1

[1] Lyophilized ACE Normal and High Controls in a protein serum matrix with lot specific activity. Reconstitute for 15 minutes at 18-28 °C and mix well before use.

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 6 months at 2-8 °C.

Table 2

MATERIALS REQUIRED BUT NOT PROVIDED

- The reagents described below are not delivered with the kit and must be ordered separately:

Reagents	Quantity of substrate[1]	Code
BÜHLMANN ACE kinetic Including substrate, calibrator and controls	26 mL	KK-ACK
	2x 13 mL	KK-ACK2
	4x 26 mL	KK-ACK4
	3x 100 mL	KK-ACKX

Table 3

[1] Refer to the BÜHLMANN ACE kinetic IFU for exact kit composition.

- General laboratory equipment
- Clinical chemistry analyzer with 340 nm filter

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 controls, calibrators and samples as described in the application note.
- Do not mix controls of different lots or switch caps between reagents.
- Avoid evaporation of the controls.

ASSAY PROCEDURE

Application notes/ assay installation

The assay procedure for the BÜHLMANN ACE kinetic 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 ACE kinetic Control kit must be measured daily before running patient samples. This is to validate the calibration curve established with the calibrator provided in the BÜHLMANN ACE kinetic 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 serum samples.

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.

CHANGELOG

Date / Version	Change
2025-07-09 / A2	Addition of Clinical Laboratory Improvement Amendments (CLIA) complexity (only for US customers) on front page Revision of chapter *Materials required but not provided* Update of chapter *Reagents supplied*