

Ceveron® TGA CAL Set - English

INTENDED USE

Ceveron® TGA CAL Set is used for establishing a thrombin calibration curve on Ceveron® alpha TGA to be used with Ceveron® TGA RB Kit, Ceveron® TGA RC Low Kit and Ceveron® TGA RC High Kit.

SUMMARY

Ceveron® TGA is based on monitoring the fluorescence generated by the cleavage of a fluorogenic substrate by thrombin over time, upon activation of the coagulation cascade in plasma by a trigger reagent composed of tissue factor and negatively charged phospholipids. From the changes in fluorescence over time, the concentration of thrombin (nM) in the sample can be calculated using the thrombin calibration curve. The increase in thrombin concentration over time allows the calculation of the thrombin generation curve and to calculate thrombin generation parameters.

REAGENTS

The Ceveron® TGA CAL Set contains:

mL	Reagent	Description
1 x 0.5	Ceveron® TGA CAL	~1.000 nM thrombin in buffer with BSA, lyophilized.
1 x 3	Ceveron® TGA CAL BUF	Hepes-NaCl-buffer containing BSA, lyophilized.

Material required (not supplied with the kit)

- Pipettes
- Distilled water
- Reagent kits

REF 5006011 Ceveron® TGA RB Kit

REF 5006013 Ceveron® TGA RC Low Kit

REF 5006015 Ceveron® TGA RC High Kit

Warning and precautions

RUO – for research use only.

A Material Safety Data Sheet for this product is available from www.technoclone.com

Stability and storage

The expiry date printed on the labels is only applicable to storage of the unopened containers at 2...8°C. Stability after reconstitution:

Reagent	Ceveron® alpha TGA
Ceveron® TGA CAL	4 hours
Ceveron® TGA CAL BUF	4 hours

TEST PROCEDURE

Preparation of reagents

The Ceveron® TGA CAL Set is always used in combination with a Ceveron® TGA reagent kit.

All lyophilized reagents of the Ceveron® TGA CAL Set and the Ceveron® TGA reagent kit must be dissolved in the volume of distilled water indicated on the vials. Reconstitution time is 20 minutes for the reagents and controls and 30 minutes for the calibrator.

Vials with lyophilized reagents and distilled water used for reconstitution need to reach room temperature (18...25°C) before reconstitution.

Vials have to be mixed thoroughly to ensure that the whole material is resuspended. Mixing is performed best by careful upside-down movements of the vial. Vortex must be avoided as it would cause air bubbles in the reagent and these would disturb fluorescence measurement.

Special care has to be taken on substrate reconstitution. The lyophilized material is clear and can adhere to the wall of the vial. Make sure that the whole material is dissolved!

Before using the reagents, the vials need to be mixed again thoroughly by careful upside-down movements. Vortex must be avoided.

After a minimum of 30 min of reconstitution time and thorough mixing by careful upside-down movements the calibrator is ready to use.

Thrombin Calibration curve

To establish a calibration curve on Ceveron® alpha TGA use the Ceveron® TGA CAL Set and the reagents from one of the Ceveron® TGA kits. Follow the instructions from kit insert and application sheet for Ceveron® TGA calibration.

One calibration is made once per lot of substrate and can be used for testing with all the Ceveron® TGA kits.

Technoclone provides application sheets for Ceveron® TGA kits. The application sheets contain analyser/assay specific handling and performance information. Please consult also the instruction manual of the Ceveron® alpha.

After calibration, the validity of the calibration curve is checked by determination of controls.

Please consult the lot specific batch table included in the kit for the reference ranges.

STANDARDISATION

The thrombin calibrator is calibrated against the Thrombin Reference Preparation of the WHO (see batch table).

LITERATURE

Please contact Technoclone www.technoclone.com or your local distributor.



manufacturer

RUO

Research use only



storage temperature

LOT

lot



expiry date

REF

catalogue number



consult instructions for use

GTIN

Global Trade Item Number



Biological risk

BUF

Buffer