

Ceveron TGA CAL - English

INTENDED USE

Ceveron TGA CAL is used for establishing a thrombin calibration curve on Ceveron alpha TGA and instruments of the Ceveron 100 series with fluorogenic channels, to be used with Ceveron TGA RB, Ceveron TGA RC Low and Ceveron TGA RC High.

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 contains:

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

Material required (not supplied with the kit)

- Distilled water
- Precision pipettes
- Variable pipette
- Laboratory timer
- **REF** 5006011 Ceveron TGA RB
- **REF** 5006013 Ceveron TGA RC Low
- **REF** 5006015 Ceveron TGA RC High

Warning and precautions

- RUO for research use only.
- This kit is intended for use by personnel trained in laboratory procedures and universal precautions for the use of chemicals and potentially biohazardous substances.
- All human blood or plasma products as well as samples must be considered as potentially infectious. They have to be handled with appropriate care and in strict observance of safety regulations. The rules pertaining to disposal are the same as applied to disposing hospital waste.
- Calibrators and control plasmas are made from human blood and any individual plasma involved in the procedure is HbsAg, HIV 1/2 Ab and HCV-Ab-negative as tested by FDA approved or CE marked methods. However, all human blood products should be handled as potentially infectious material.
- Get a Material Safety Data Sheet for this product 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 opened/ in use:

Reagent	Ceveron alpha TGA / Ceveron 100 series (open vial)
Ceveron TGA CAL	4 hours
Ceveron TGA CAL BUF	4hours

Avoid contamination by microorganisms.

TEST PROCEDURE

Preparation of reagents

Before starting the test, all the required components must be brought to room temperature.

Avoid foam formation when reconstituting plasmas and mixing reagents or buffers.

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.

- *Ceveron TGA CAL*: Dissolve each bottle of lyophilized TGA CAL in 0.5 mL distilled water and swirl gently. Allow the reconstituted material to stand for 30 minutes at room temperature before use.
- *Ceveron TGA CAL BUF*: Dissolve each bottle of lyophilized buffer in 3.0 mL distilled water and swirl gently. Allow the reconstituted material to stand for 20 minutes at room temperature before use.

Performance of the test

To establish a calibration curve on Ceveron alpha TGA or the instruments of the Ceveron 100 series use the Ceveron TGA CAL and the reagents from one of the Ceveron TGA kits.

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

After calibration, the validity of the calibration curve has to be checked by determination of controls.

STANDARDISATION

The thrombin calibrator is calibrated against the Thrombin Reference Preparation of the WHO. Consult the batch table.

LITERATURE

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

EDITORIAL NOTE

This document is available in several languages. The translations have been done using the master document in English. In the event of doubts or discrepancies, the wording in the master document in English shall take precedence.



Storage temperature



Expiry date



Consult instructions for use



Biological risk



Control



Determinations

Technoclone Herstellung von Diagnostika und Arzneimitteln GmbH, Brunner Str. 67 - 1230 Vienna, Austria
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Lot



Catalogue number



Global Trade Item Number



Buffer



Substrate



Manufacturer



Research use only