

Technofluor ADAMTS13 Activity 0 CAL - English

INTENDED USE

Calibration of the Technofluor ADAMTS13 activity assay, for use in research activities on Ceveron s100 in combination with Coagulation Reference.

SUMMARY

Von Willebrand factor (VWF) promotes clot formation by tethering platelets at the site of vessel injury and can also contribute to platelet aggregation. It is comprised of subunits of differing sizes, termed multimers, whose adhesiveness increases with size. The enzyme ADAMTS13 (a disintegrin-like and metalloproteinase with thrombospondin type 1 motif 13) acts as a gatekeeper against generation of highly thrombogenic ultra large multimers by regulating multimer size via a specific cleavage site, thereby breaking down large multimers into smaller, less reactive forms. Ultra large multimers can achieve millimeters in length if unregulated. In ADAMTS13 deficiency states, unusually large hyperfunctional VWF multimers can accumulate, leading to microvascular thrombosis and organ damage/failure due to VWF-platelet aggregates. In turn, a microangiopathic haemolytic anaemia can ensue, red blood cells being sheared as they travel past and through the microthrombi. ADAMTS13 deficiency can be hereditary or acquired, the latter commonly due to ADAMTS13 autoantibodies, and is termed thrombotic thrombocytopenic purpura.

In the Technofluor assay, ADAMTS13 from the plasma sample cleaves a VWF73 based substrate, thereby releasing the dark quencher. Consequently, the energy transfer that quenches fluorescence from an adjacent emitter does not occur, allowing emission of fluorescence. The fluorescent signal is proportional to the ADAMTS13 activity in the sample.

REAGENTS

The Technofluor ADAMTS13 Activity 0 CAL contains:

	Reagent / Content	Description
2 x 1 mL	0 calibrator (CAL)	Lyophilized human plasma with no ADAMTS13 activity

Material required (not supplied with the kit)

- Distilled water
- Precision pipettes
- Test systems
- REF 5800100 Technofluor ADAMTS13 Activity Calibration Plasma* 25 tests
- REF 5220110 Coagulation Reference 5 x 1 mL
- Laboratory timer
- * or any other package sizes.

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 must be applied.
- All human blood or plasma products as well as test 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 tested HbsAg, HIV 1/2 Ab and HCV-Ab-negative. 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 / Content	Ceveron s100 (open vial)	2...8 °C (closed vial)	< -20 °C (closed vial)
0 calibrator (CAL)	8 hours	-	2 months

Calibrator should only be frozen once. Thawing must be performed rapidly in a water bath kept at 37 °C.

TEST PROCEDURE

Preparation of reagents

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

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

- *Calibrator*: Dissolve each bottle of lyophilized calibrator in 1.0 mL distilled water and swirl gently. Allow the reconstituted material to stand for 10 minutes at room temperature before use. For standardizing tests, a reconstitution time of 30 minutes is recommended. Swirl to mix before use.

Performance of the test

The Technofluor ADAMTS13 Activity is performed on Ceveron s100 with the respective application.

Calibration is performed using a serial dilution of Coagulation Reference in Technofluor ADAMTS13 Activity 0 CAL. Normal and abnormal controls are recommended for a complete quality control program. Coagulation Control N and Coagulation Control A are designed for this program. Each laboratory should establish its own mean and standard deviation for a quality control program in order to monitor laboratory testing. Controls should be analyzed before validating sample results in accordance with good laboratory practice.

STANDARDISATION

Technofluor ADAMTS13 Activity 0 CAL and Coagulation Reference (Calibrator) are calibrated using Technofluor ADAMTS13 Activity and traceable to the WHO International Standard for ADAMTS13 Activity. Consult the respective batch table for each material.

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.



Biological



Distilled water



Manufacturing date / Herstellungsdatum



Dilute or dissolve in



Global Trade Item Number

Technoclone Herstellung von Diagnostika und Arzneimitteln GmbH, Brunner Str. 67 - 1230 Vienna, Austria
Ceveron is a registered trademark of Technoclone



Manufacturer



lot



Storage



Research use only



Expiry date



Catalogue



Consult instructions



Calibrator