

Emicizumab Calibrator

EMICIZUMAB PLASMA CALIBRATOR FOR RESEARCH USE ONLY (RUO) DO NOT USE IN DIAGNOSTIC PROCEDURES

INTENDED USE

Emicizumab Calibrator is a calibrator plasma intended for use in the calibration of a modified one-stage FVIII activity assay for determination of active emicizumab concentration from a clot time measurement performed on an automated coagulation analyzer.

This calibrator is for research use only and should not be used for patient diagnosis, treatment or monitoring.

PRINCIPLE OF THE PROCEDURE

Emicizumab Calibrator enables the quantification, of the degree of correction of the APTT based one-stage assay by emicizumab present in the patient's sample using a coagulation instrument. The calibrator is diluted to generate a series of concentration levels and each level is combined with FVIII deficient plasma, APTT reagent and incubated. The reaction is initiated by addition of CaCl₂ and the clot time is measured. The degree of correction of the APTT is related to the emicizumab activity and is converted into ug/mL using the calibration curve.

REAGENTS

FOR RESEARCH USE ONLY

Catalog No: 151-201-RUO

Contents: 5 x 1.0 mL vials

Ingredients: **Emicizumab Calibrator** is prepared from FVIII immunodepleted citrated human plasma spiked with 100ug/mL emicizumab. The plasma calibrator contains buffer and stabilizers and is lyophilized.

Emicizumab Calibrator does not contain any preservatives.

Preparation for Use: **Emicizumab Calibrator** should be reconstituted with 1mL of deionized or distilled water. Allow to hydrate for 20 minutes at room temperature without disturbing and then swirl gently before using.

Storage and Stability: Unopened **Emicizumab Calibrator** is stable until the expiration date shown on the label when stored at 2-8°C. Reconstituted control material is stable (e.g., less than a 10% shift in the baseline values) for 8 hours when stored capped at 2-8°C or 4 hours at room temperature (23-25°C).

WARNINGS

Standard precautions should always be taken, including wearing personal protective equipment, when handling potentially biohazardous human sourced material such as citrated plasma.

Emicizumab Calibrator material is prepared with plasma collected from donors screened for CJD and which was tested at source and found negative for HBsAG, syphilis and antibodies to HIV and HCV and nonreactive for HIV-1 RNA and HCV RNA by FDA approved tests.

All biohazardous material including **Emicizumab Calibrator** should be disposed of according to current local, state and federal regulations.

TRACEABILITY

Emicizumab Calibrator lots are assigned using an r² Diagnostics master calibrator lot that has been assigned based on the manufacturer's potency assignment for the drug.

PROCEDURE

Testing is performed on a coagulation analyzer using mechanical or optical based clot detection. Individual system procedural details (e.g. reagents, volume, dilutions, incubation times) may be found in the instrument specific application sheets.

EXPECTED VALUES

Emicizumab is spiked into FVIII deficient plasma at 100ug/mL and the actual active emicizumab concentration is assigned versus a master calibrator lot. The exact concentration of emicizumab in each calibrator vial is indicated on the vial label and the box's outer label in each kit.

LIMITATIONS

Performance of **Emicizumab Calibrator** should be verified under individual laboratory conditions using **Emicizumab Controls Level 1 and Level 2**.

A new calibration curve should be run at minimum when a new batch of APTT reagent or FVIII reagent is obtained, after instrument maintenance and when quality control materials fall outside the range.

The results obtained should be used for research use only and must not be used for patient diagnosis or treatment.

REFERENCES

1. Kitazawa T, et al, (2012). "A Bispecific Antibody to Factors IXa and X Restores Factor VIII Hemostatic Activity in a Hemophilia A Model". Nature Medicine 18: 1570-1574.

