Emicizumab Controls Level 1 and Level 2

ASSAYED EMICIZUMAB CONTROLS
FOR RESEARCH USE ONLY (RUO)
DO NOT USE IN DIAGNOSTIC PROCEDURES

INTENDED USE

Emicizumab Controls Level 1 and Level 2 are assayed controls intended for quality control 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.

These controls are for research use only and should not be used for patient diagnosis, treatment or monitoring.

PRINCIPLE OF THE PROCEDURE

Emicizumab Controls Level 1 and Level 2 can be used in all testing in the same manner as any citrated plasma sample. **Emicizumab Controls** can be used to monitor testing variables in laboratory QC systems (e.g. instrumentation, reagents and technique) for the one-stage FVIII activity assay for determination of active emicizumab concentration.

REAGENTS

FOR RESEARCH USE ONLY
Catalog No: 152-401-RUO
Contents: 5 x 1.0 mL vials Level 1, 5 x 1.0 mL vials Level 2

Ingredients: **Emicizumab Controls Level 1 and Level 2** are prepared from FVIII immunodepleted citrated human plasma spiked with 25ug/mL and 75ug/mL emicizumab respectively. The plasma controls contain buffer and stabilizers and are lyophilized. **Emicizumab Controls** do not contain any preservatives.

Preparation for Use: **Emicizumab Controls** 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 Controls** are 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 8 hours at room temperature (23-25ºC).

WARNING

Standard precautions should always be taken, including wearing personal protective equipment with handling potentially biohazardous human sourced material such as citrated plasma.
Emicizumab Control 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 Controls** should be disposed of according to current local, state and federal regulations.

TRACEABILITY

Emicizumab Controls Level 1 and Level 2 values are assigned using **Emicizumab Calibrator** that has been assigned using an r^2 Diagnostics master calibrator lot.

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.

Controls should be run according to applicable local, state and federal regulation and accreditation requirements. If any of the controls are outside the reference ranges established by the laboratory, then the assay should be considered invalid, no patient results should be reported, and the assay and controls investigated to determine and correct the source of the problem(s).

EXPECTED VALUES

Emicizumab is spiked into FVIII deficient plasma at 25ug/mL (Level 1) and 75ug/mL (Level 2) and the actual active emicizumab concentration is assigned using **Emicizumab Calibrator**. The exact concentration of emicizumab in each control vial is indicated on the flier provided in each kit. Control ranges for each level are established over multiple days, runs and calibrations and expressed as mean +/-2.5SD.

Laboratories should establish the mean values and expected control ranges for their particular laboratory's instrument-reagent system for each new lot of control, upon instrument service, or a change in test procedure.

LIMITATIONS

Ranges provided with **Emicizumab Controls** are intended only as guidelines and laboratories should determine the ranges based on their own test system and tolerance limits.

If the controls fall outside their established ranges, the assay results should be invalidated and the samples re-assayed. Trouble shooting activities should be performed according to individual laboratory policies before the samples are re-tested.

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.

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