

Viscoelastic Haemostasis EQA

INTENDED USE

Weqas Viscoelastic Haemostasis EQA samples are for in-vitro diagnostic use as an external quality assessment material for testing of coagulation status by Thromboelastometry or Thromboelastography.

SUMMARY

External Quality Assessment (EQA) or Proficiency Testing (PT) is an essential part of providing quality laboratory diagnostic services, and participation in EQA is required for laboratory accreditation to ISO 15189 and ISO 17025. EQA is the inter laboratory comparison and performance evaluation that extends throughout all phases of the healthcare diagnostic testing cycle.

PRODUCT DESCRIPTION

Viscoelastic Haemostasis EQA samples are supplied as 3.0mL vials of lyophilised citrate plasma.

STORAGE AND STABILITY

Un-reconstituted lyophilised plasma should be stored at 2-8°C. Reconstituted plasma should be kept at ambient temperature (18-30°C) after reconstitution and used within 1 hour of reconstitution.

! CAUTION !

Human source material. Treat as potentially infectious. Each unit of whole blood used in the manufacture of this product has been tested by CE marked IVD methods and found to be non-reactive for the presence of HBsAg and antibody to HIV-1/2, HCV and HIV-1 Ag. While these methods are highly accurate, they do not guarantee that all infected units will be detected.

Because no known test method can offer complete assurance that the hepatitis B virus, hepatitis C virus, human immunodeficiency virus (HIV) or other infectious agents are absent, all products containing human source material should be considered potentially infectious and handled with the same precautions used with patient specimens.

Although every effort is made to ensure that the material is free from any known infectious agent, the samples should be handled as for clinical specimens. Always wear gloves to avoid contamination.

LIMITATIONS OF PROCEDURE

The Viscoelastic Haemostasis EQA samples require storage as described in STORAGE AND STABILITY and handling as described in PROCEDURE.

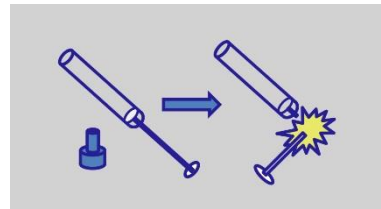
Accurate and reproducible results are dependent upon properly functioning instruments and reagents, and the use of correct procedures.

The Viscoelastic Haemostasis EQA samples should be analysed according to the instructions within this document.

PROCEDURE

For correct reconstitution both vials must reach ambient temperature (18-30°C) before use.

- Please add the vial labelled as diluent to the vial of lyophilised material.
- Leave vial for 5 minutes.
- Swirl vial gently.
- Leave for a further 15 minutes to complete reconstitution.
- Swirl vial gently.
- De-cap the neutral sample tube (supplied with samples) and set the cap aside for use later. There should be one neutral tube per sample level.
- Draw plunger out and break off.

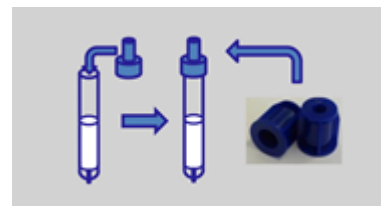


- Transfer the contents of the reconstituted vial to the neutral tube. Ensure all liquid is transferred from the vial.
- Reseal tube carefully with its original cap. Invert gently to mix.

For ROTEM Delta & TEG devices, samples are now ready for assay. Follow the manufacturers' instructions on loading sample on device. Record results on the return sheet provided.

For ROTEM Sigma:

Apply the blue cartridge adaptor over the cap (adaptor supplied with samples).



The samples are now ready for assay.

Test as patient sample, NOT AS ROTROL. Record results on the return sheet provided

ROTEM	
Channel	Analyte
Extem	CT
	A5
	A10
	MCF
	ML
Intem	CT
	A5
	A10
	MCF
	ML
Fibtem	CT
	A5
	A10
	MCF
	ML
Heptem	CT
	A5
	A10
	MCF
	ML
Aptem	CT
	A5
	A10
	MCF
	ML

TEG	
Channel	Analyte
CK	R
	K
	MA
CRT	TEG-ACT
	R
	K
	LY30
CKH	MA
	R
	K
CFF	A10
	MA