Scarborough, Hull and York Pathology Service

Procedure for the Use of TEG-6s

Document Author/Reviewer	Jane Mason/Rachel Lampard
Document Owner	Rachel Lampard
Approved By	Jane Mason
Review Interval	2 years

Changes from last version of this document

General review

Table of Contents

1 Purpose and Principle

Thromboelastography (TEG) provides a rapid real time assessment of the blood's ability to form a clot. Interpretation of the result can aid clinicians in determining whether a patient needs to receive blood component therapy in order to allow them to clot properly and will guide clinicians in delivering the correct blood components. This should enable patients with a clotting problem to receive faster, more accurate treatment.

TEG reports 3 common domains assessing real time clotting function. The time it takes to start forming a clot (Rate, or R time in mins), the maximal strength of the clot formed (Maximal amplitude, or MA in mm) and the breakdown rate of the clot (Lysis, or LY30 in %, meaning the percentage of clot breakdown from MA at 30mins).

The TEG 6s system provides these and other measures relevant to clotting function, delivered through a Global Haemostatic Assay (GH) cartridge. A separate platelet Mapping® (PLM) assay cartridge is also available for use, to assess the impact of antiplatelet therapy on clotting function in clinically urgent situations.

2 Patient Preparation & Sample Requirements

Global Haemostatic (GH) cartridges require initial patient blood sampling in a sodium citrate blue topped peadiatric tube.

Platelet mapping (PLM) cartridges require initial patient blood sampling in a separate lithium Heparin green topped paediatric tube.

3 Tasks, Responsibilities and Authorisations

Tasks	Responsible	Authorised By
Patient testing	Clinical staff who have received training	Trained member of POCT staff or certified POCT link trainer
Maintenance tasks	Clinical staff who have received training	Trained member of POCT staff or certified POCT link trainer

4 Equipment

The Thrombelastograph (TEG) analyser is a non-invasive diagnostic instrument designed to monitor and analyse the coagulation state of a blood sample in order to assist in the assessment of patient clinical hemostasis conditions. The analyser is supplied by

Haemonetics Ltd

5 Hercules Way

Leavesden Park

Watford

WD 25 7GS

The analyser is operated and maintained by the ODP staff. The service contract is held by the Theatres, Anaesthetics and Critical Care. Surgery Care Group.

5 Chemicals and Reagents

Biological QC Level 1 Ref 07-650 QC should be stored between 4-8 C

Biological QC Level 2 Ref 07-651 QC should be stored between 4-8 C

GH assay cartridges stored between 4-8 C

PLM assay cartridges stored between 4-8 C

All consumables can be obtained from

Haemonetics Ltd
5 Hercules Way
Leavesden Park
Watford
WD 25 7GS

At Haemonetics the health and safety of our customers is of paramount importance. We have consulted with an external SDS authoring source and our internal Environmental Health and Safety experts about providing SDS documents for TEG 6s cartridges. We have determined that an SDS is not required because the total reagent weight does not exceed 0.1% of the total product weight. The TEG 6s cartridges contain very small amounts of reagent that do not meet or exceed this threshold. All reagents are encapsulated within the cartridge, and customers cannot be exposed to the reagents at any point in time. This means that TEG 6s cartridges do not require SDS sheets.

Hemonetics alert August 2016

6 Risk Assessment (Environmental and Safety Controls)

Full risk assessment can be found in PC/RA/YS-15 on Q-pulse

Staff carrying out this procedure should have read and understood the Local Rules or Health and Safety Manual applicable to their site which should be always followed during the procedure.

- All human samples must be treated as potentially BIO-HAZARDOUS.
- Approved Personal Protective Equipment (PPE) including laboratory coats, disposable gloves must be worn. Eye protection should also be considered and must be worn when directed within the procedure.
- Include reference to table in ‘chemicals and reagents’ section for specific COSHH assessment.
- Include reference to the process risk assessment which shall identify potential risks to patient care as well as staff safety. Ensure this document is up to date and has considered any non-conformities raised against the process.

This SOP and the associated risk assessment(s) have considered all hazards and necessary precautions required to control any risks identified. Where appropriate this is detailed in the COSHH assessment and Risk Assessment. Any risk is mitigated as far as possible and or monitored with health surveillance to ensure health and safety for all those affected by this procedure.

7 Calibration

The TEG6s analyser is manufacturer calibrated and does not require any manual calibration

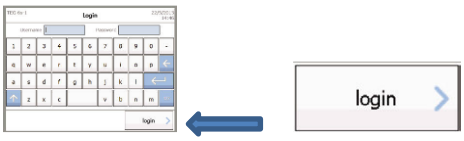
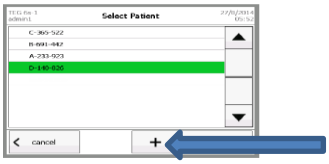
8 Quality Control

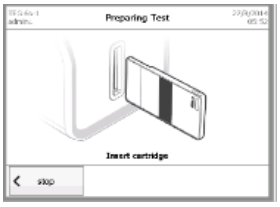
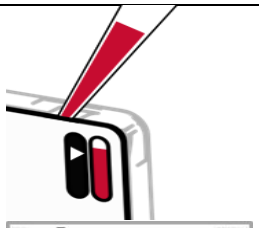
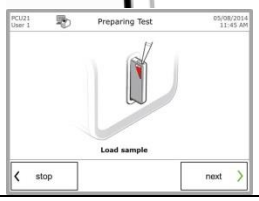
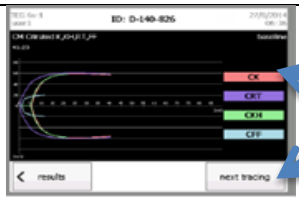
Liquid quality control is carried out weekly using 2 levels of QC. Haemonetics TEG6s QC level 1 and level 2

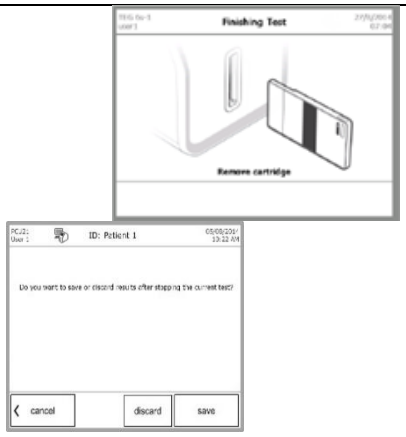
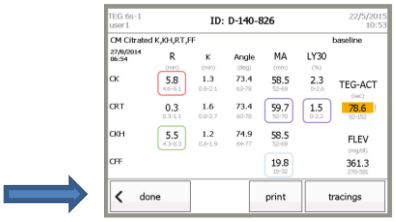
9 External Quality Assurance (EQA)

UKNEQAS sample received quarterly

10 Procedural Steps

	Instruction	Photograph / Diagram
1.	**Touch screen** to start. (Device should be left switched on. Power switch on rear panel.)	
2.	Enter **Username**, touch Password box and enter **password**. Then touch **login.**	
3.	Select **new test.** There may be a slight delay. If the button has turned grey, do not press again.	
4.	Select patient ID from list or + for a new patient.	

5.	**Enter patient unit number** or NHS number. Press **ok**. The device will jump back to the previous screen to confirm the ID. Press **Next** The analyser will then try to retrieve patient data. A screen will be displayed with either the patient details or 'No patient data available'. Select **continue.**	
6.	Remove a cartridge and pipette from the fridge. Remove the cartridge from the pouch and insert it into the cartridge slot with the barcode on the left side with the sample inlet left sticking out of the device.	
7.	**Confirm** that you have the correct **cartridge and sample type** by pressing **next**.	
8.	Type optional test information as required or scan from the list next to the device. Then touch **next**.	
9.	Add blood sample. Take one full paediatric tube from the patient and invert to mix thoroughly. Use the pipette to load enough sample into the sample inlet on the cartridge to cover the indicator arrow. Steady the pipette tip with your hand to ensure the sample goes into the cartridge without spilling into the cartridge slot or onto the device. Press **next**. The test should then start.	 
10.	Viewing Results. Results will replace dashed lines as they are finalised. Interim results are displayed with an asterix. Results can be viewed graphically by touching **Tracings**.	
11.	Touch the legend or **next tracing** to go to the individual tracing. Touch **results** to go back.	

12.	Test completion. Test stops automatically when all parameters are finalised. (Approximately 20 minutes.) Remove cartridge when prompted. (The cartridge port LED will flash.) Alternatively, to stop the test at any time touch **results** to return to the numerical display and then touch **stop**.	
13.	Touch **done** to return to home screen. Dispose of the used cartridge in the yellow sharps bin.	

11 Reporting of Results

Results are available on the analyser and also stored and accessible through TEG Manager either via the short cut on various PC's or using Login (yha.com)

12 Reference Intervals

CK Reference ranges

Citrated Blood Parameter	Range
R (min)	4.6-9.1
K (min)	0.8-2.1
ANGLE (deg)	63-78
MA (mm)	52-69
LY30 (%)	0.0-2.6

CRT Reference ranges

Citrated Blood Parameter	Range
TEG-ACT (sec)	82-152
R (min)	0.3-1.1
K (min)	0.8-2.7
ANGLE (deg)	60-78
A10 (mm)	44-67
MA (mm)	52-70
LY30 (%)	0.0-2.2

CKH Reference range

Citrated Blood Parameter	Range
R (min)	4.3-8.3
K (min)	0.8-1.9
ANGLE (deg)	64-77
MA (mm)	52-69

CFF Reference range

Citrated Blood Parameter	Range
A10 (mm)	15-30
MA (mm)	15-32

13 Performance Characteristics

Precision

The precision of the Kaolin test was evaluated according to CLSI EP5-A2. Testing was performed for within-run (using 3 donors), Within-device (20-day tests using QC levels 1 and 2, between lots (using three different cartridge lots) and between operators (Using five operators) Also multi-site reproducibility across three sites, three lots, three operators and three analysers.

CV% for the Kaolin Assay<10% for all parameters.

CV% for Rapid TEG <13% for the TEG-ACT and <10 for the K, Angle and MA parameters

CK Sensitivity and specificity

The Kaolin reagent is often used in conjunction with tests performed on blood samples from patients with Heparin, with the goal of determining heparin effect (titration of dose) or determining full reversal (post-protamine) of heparin administered. Five different heparin spiked samples were examined across the therapeutic ranges (0.2-6.0, five non-heparin spiked samples were also examined.

Kaolin's sensitivity to Heparin was 100%, with the R parameter elongated. Specificity was also 100%, with all non-spiked samples having R parameters within normal range.

Known Limitations

Include, as appropriate:

- Clearly indicate how the assay is used clinically and interpretation information. Check with the Consultants if necessary.
- Any known or suspected interferences and methods of detecting and eliminating such interferences (e.g., lipaemia, haemolysis, icterus, and drugs) and cross reactions.

14 Known Limitations

TEG6s analyser results should always be considered within the clinical context of the individual patient's case. In the event of inconsistencies with the patients' clinical status, samples should repeated or supplemented with additional clinical information.

Interfering factors

CK assay only Haemplysis and Haemodilution level >20% were found to be interfering factors

CRT assay haemodilution >30%, EACA (Epsilon aminocaproic acid), absence of a discard tube, were found to be interfering factors.

CKH assay Protamine at concentrations >0.062 mg/mL.

CFF assay Heparin was found to be an interfering factor for functional Fibrinogen above concentrations of 1IU/mL and haemodulition at levels >40%

15 Related Forms/Templates and Documents

TEG6 Operator Guide: PC/ED/YS-8

16 References

TEG6 Operator Guide: PC/ED/YS-8