Point of Care Testing in Coagulation

Dr Steve Kitchen

Scientific Director ,UK NEQAS Blood Coagulation

Head Scientist Coagulation Laboratory, Royal Hallamshire Hospital
Sheffield UK

POCT in Haemostasis

- Patient self testing – INR Vitamin K antagonist therapy
- Primary care - INR, DDimer for VTE exclusion
- Secondary care – INR, DDimer, TEG/ROTEM, ACT, Platelet function (PFA, Multiplate, Verifynow etc)

Frequently Asked Questions

- Is there an equivalent lab method?
  If so how do results compare?
- IQC?
- EQA?
- Documentation?

Issues related to INRs done by different methods

Differences between any 2 INR systems

- Systematic
  - Error in lab method, POC method or both
- Specific situations
  - Over anticoagulated patients
- Individual cases
  - Presence of Lupus anticoagulant

Sources of inaccurate INRs

- Blood collection system
- ISI determination
- MNPT
- Coagulometers

Effect of citrate on INR

- Assign ISI with 0.109M and apply to samples in 0.129M - INRs would be too high

- An INR of 4.5 could be out by up to 20% in study of Chantarangkul (1998)
- Does not affect POC/NPT INRS

Samples to laboratory

Points to consider

- Storage of sample until testing
- How long between sample taken and testing
- Transport of samples
- Quality of sample (haemolysed, under-filled)

POC v Laboratory Results where INR is higher than therapeutic Range

POC	Lab
6.1	6.1
5.0	4.6
5.5	4.6
6.5	4.8
5.6	6.9
5.5	5.4
6.7	5.7
5.5	5.4
7.8	6.4

Causes of POC/Lab INR discrepancy
Case report - LAC

Lab method (not stated)	POC (CUC)
4.2	4.9
3.5	4.2
2.7	3.6
3.1	4.7

Carrasco et al BJH 2004

INR discrepancy

Lab method 1	Lab method 2
2.0 (baseline)	1.1
7.0	1.6
9.3	2.1
13.9	2.6

Sheffield case

Lupus anticoagulant

- DRVVT ratio 2.2 (NR 0.9- 1.16)
- Correction with washed platelets 1.1

- ACA IgG >120 units (NR <10
- ACA IgM >100 units (NR <5)
- Anti beta-2 GP1 >100 units(NR < 5)

LAC can be transient

date	Lab method 1	Lab method 2
baseline	2.0	1.1
1 month	5.5	1.8
13 month	4.1	2.7
15 month	3.1	2.4
16 month (pre op)	1.2	1.1
17 month	1.5	1.4

Checking raised INRs
Patient self testing guideline
(Fitzmaurice et al 2005)

- Any INR results between 4 and 8
  - Repeat with POC device
  - Results should be within 0.5

- INRs >8.0 – venous samples to lab

Checking INRs
Health care professionals
(Perry et al 2010)

- Any INR results between 4 and 8
  - Repeat with POC device

- INRs >8.0 venous sample to lab

- Stable patients should be within 0.5
- Even in therapeutic range INR deviations of +/- 10% acceptable for clinical purposes

UK NEQAS POC INR programme

- Scheme introduced in 1996
- First survey had 30 users
- Separate survey for different devices
- Currently have 3800+ users
- 4 Surveys a year with 2 samples per survey

UK NEQAS POC Samples

- Postal service
- 17 days to complete test
- Return results by post, FAX or website
- Reports within 2 weeks

Fluid 1 to reconstitute

Fluid 2 to recalcify

Current programmes available

- POC INR testing XS series devices
- POC INR testing hemochron cuvette devices
- POC INR testing i-STAT devices
- POC ACT for hemochron cuvette devices
- Pilot programmes for Rotem, TEG,
- Pilot programmes for POC D-dimer testing

CoaguChek XS series

CUC XS for self-testers

CUC XS Plus for professional users

CUC Pro – barcode scanner , extended memory store, better connectivity

One centres persistent problems

Within consensus for 9 previous surveys

	Sample 1	Sample 2	Test strip lot number
Oct 2012 Target range	2.8-3.8	3.7-4.9	multiple
Local results	4.6	5.5	424
Repeat samples	4.1	5.0	153
Repeats from an earlier survey	3.8 (target 2.9-3.9)	6.1 (target 3.5-4.7)	153

Advice and outcome

- Advised to report to the manufacturer and to consider stopping patient testing
- Manufacturer provided loan device
- Manufacturer investigated - device had electrical corrosion
- Device replaced
- Following survey - results within consensus

EQA-Patients Guideline Recommendations- Option 1

- Compare self testing machine with a clinic based Point of Care machine which is itself in an accredited EQA programme
- INR results should be within 0.5

Patient's machine and test strips

Clinic machine and test strips

UK NEQAS

EQA-Patients Guideline Recommendations- Option 2

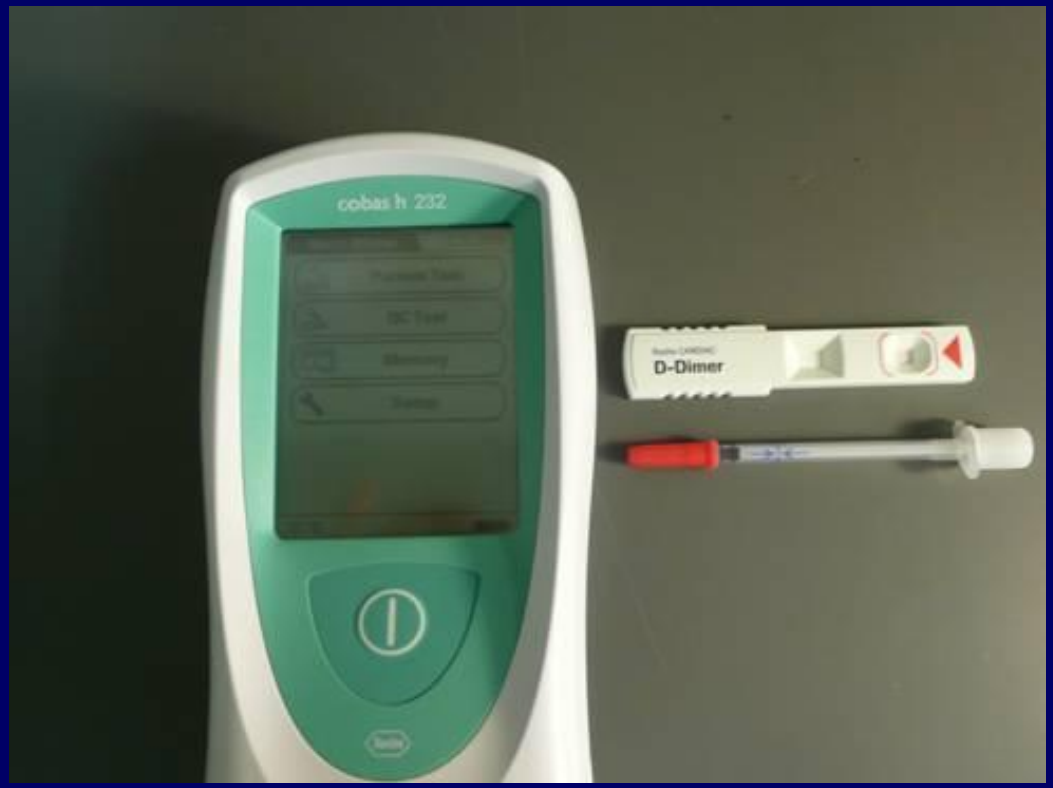
- Compare self testing machine with venous blood sample sent to laboratory
- INR results should be within 0.5

Patient's machine and test strips

Venous blood sample to laboratory

UK NEQAS

Cobas h232



- Cuvettes + calibrated syringe for applying sample
- Takes approx 12 minutes
- Requires 150µl venous heparinised whole blood
- Result given in µg/ml FEU with a stated cut off of 0.5 µg/ml

Results Cobas h232 (cut off 0.5)

Sample	1/11	2/11	3/11	4/11	1/12	2/12	3/12	4/12	1/13	2/13
n	6	7	33	33	30	31	32	32	52	53
Median µg/ml FEU	0.7	1.2	0.15	0.45	1.2	0.19	0.24	0.65	0.56	0.21
Interpretation	1 Ex 5 NE	1 Ex 6 NE	28 Ex	23 Ex 5 NE	27 NE	28 Ex	29 Ex 1NE	30 NE	10 Ex 41 NE	51 Ex

CV ranged from 14-25%

Only 5 out of a possible 10 samples had complete agreement on interpretations

Clearview SimpliFy

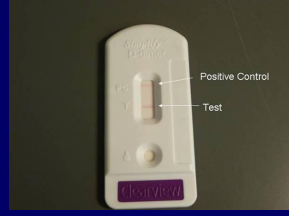
- Positive or Negative result
- Citrated ,EDTA or heparinised venous whole blood or plasma or non anticoagulated capillary whole blood

- One drop of sample is added plus 2 drops of the provided buffer

- Test is read visually after 10 minutes

Volume of sample required is 35µl for capillary or venous blood and 20µl plasma

Clearview SimpliFy results



Sample	1/12	3/12	1/13
n	27	25	29
Positive results	26	24	23
Negative results	1	1	6
Lab Programme Median µg/ml FEU	1.65	0.7	0.99
Interpretation	1 Ex 25 NE	2 Ex 21 NE	7 EX 18 NE

Triage

- Cuvettes + calibrated pipette for applying sample
- Takes approx 15 minutes
- Requires 250µl venous EDTA whole blood or plasma
- Result given in ng/ml FEU with a stated cut off of 400ng/ml

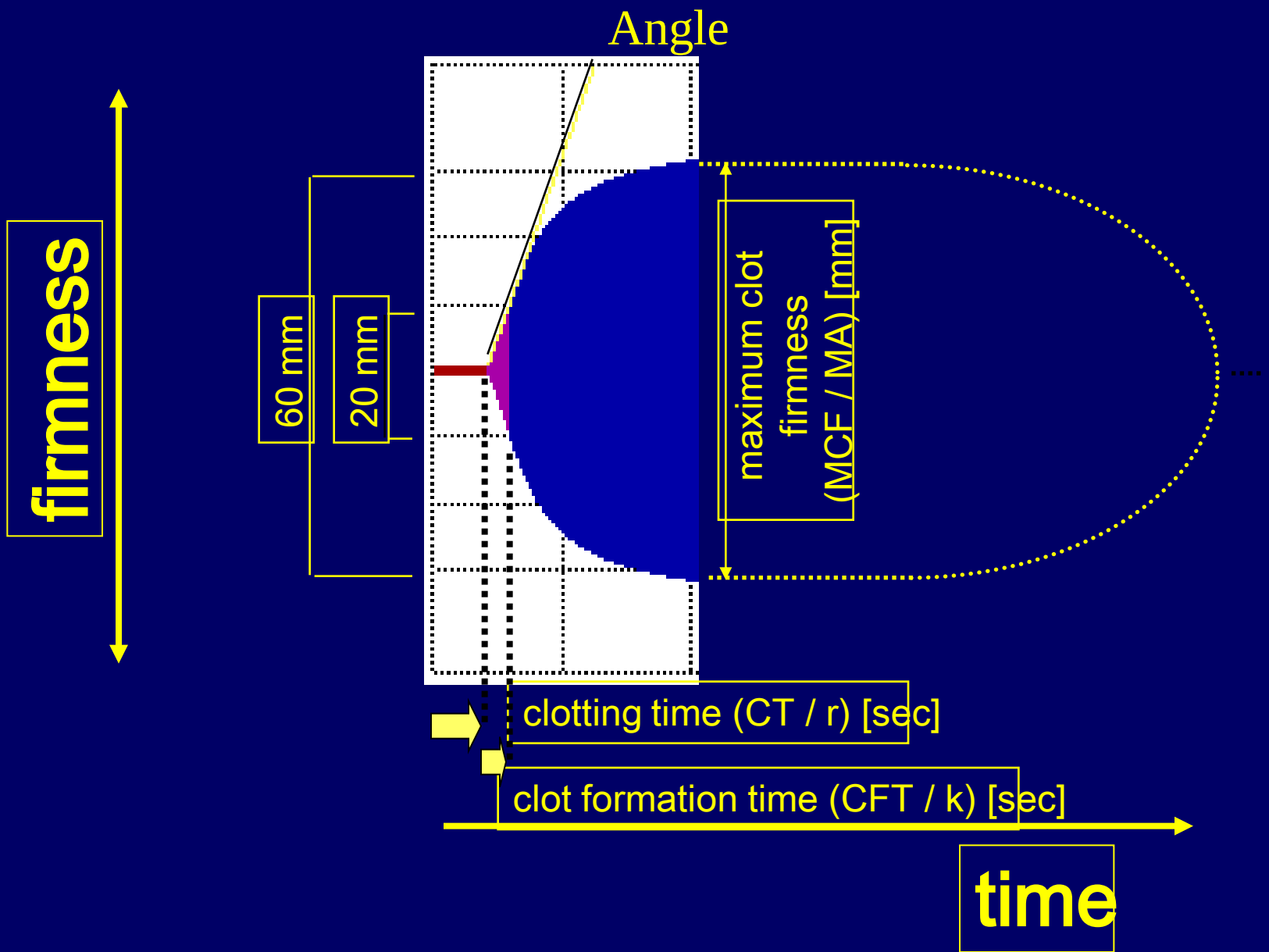
TEG® Analyser

Cup rotates pin is stationary

ROTEM ® Device

Pin rotates Cup is stationary

ROTEM / TEG analysis



TEG (40 centres)
Normal plasma in UK NEQAS

	Median	CV (%)	range
R time (min)	6.3	27	5.2-14.1
Angle (degrees)	76.2	9	55-80
K time min	0.9	52	0.8-3.8
Ma at 20 min	42	11	39-62```

ROTEM - INTEM (16 centres)
Normal plasma in UK NEQAS

	Median	CV (%)	range
CT (sec)	149	13	135-196
Angle (degrees)	84	1	81-85
CFT (sec)	28	16	24-43
MCF (mm)	38.5	9	30-46

UK NEQAS Blood Coagulation

POC lead scientist

Dianne Kitchen

dianne.kitchen@coageqa.org.uk