EVALUATION OF THE Q SMART ANALYSER (GRIFOLS) FOR ROUTINE USE AND FOR INITIAL INVESTIGATION OF PATIENTS WITH POSSIBLE BLEEDING DISORDERS

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Introduction

The Q Smart is a new automated coagulometer from Grifols Diagnostics

Coagulometers can affect the sensitivity and performance of coagulation reagents, particularly for Activated Partial Thromboplastin Time (APTT) when used for the detection of clotting factor deficiencies associated with haemorrhagic disorders.

The performance of a new analyser must be evaluated in combination with the reagents to be routinely used.

Background

- The APTT is widely used in the initial investigation of patients with suspected bleeding disorders and the sensitivity of APTT depends on both the reagent and the instrument used for analysis.
- CLSI recommends that the APTT reagent/instrument combination should detect abnormally prolonged results with plasmas that have less than 30 IU/dL of FVIII, FIX or FXI

Objectives

To evaluate the Q Smart analyser in respect of:

- Assessment of relationship between APTT and single factor deficiency of FVIII, FIX, or FXI
- Comparability to the Grifols Q Hemostasis Analyzer for routine tests of haemostasis when combined with reagents from Diagnostic Grifols
- Assessment of suitability for routine use

Analyser

The Q Smart coagulometer from Grifols:

- is a recently launched photo-optical autoanalyser
- is capable of testing haemostasis parameters using clotting, chromogenic and immuno-turbidimetric methods
- has barcode reading for samples and reagents with tilted reagent positions for reduction of dead-volume
- is suitable for low to medium volume laboratories

Routine Tests/Reagents

Prothrombin Time (PT)	DG-PT (Grifols)
Activated Partial Thromboplastin Time (APTT)	DG-APTT Synth (Grifols)
Clauss Fibrinogen (Fbg)	DG-FIB L Human (Grifols)
Thrombin Time (TT)	DG-TT L Human (Grifols)

Methods

- Normal ranges for all the tests were determined from healthy normal subjects on the Q Smart and Q Hemostasis Analyzer.
- APTTs were determined on samples from patients with isolated single clotting factor deficiency of FVIII, FIX, FXI or FXII.
- Routine coagulation tests were determined using samples from patients with specific clinical disorders affecting haemostasis on the Q Smart and Q Hemostasis Analyzer.
- All samples were:

-collected into BD Vacutainer Plus citrate tubes

-centrifuged at 1700g for 15 minutes

-stored deep frozen at -70°C prior to analysis

Samples

Q Smart and Q patient groups (N=)	
Normals	30
Liver disease	12
Critical Care	13
Dysfibrinogenaemia	9
Lupus Anticoagulant	17
Q Smart single factor deficiency (N=)	
Factor VIII	15
Factor IX	10
Factor XI	14
Factor XII	10

Results

Normal Ranges for Routine Coagulation Tests (mean +/- 2 SD)

	Q	Q Smart
PT (sec)	11.8 – 14.9	11.5 – 14.8
APTT (sec)	20.3 – 29.8	19.9 – 30.6
Fbg (mg/dL)	225 – 432	233 – 468
TT (sec)	17.2 – 20.2	17.7 – 20.7

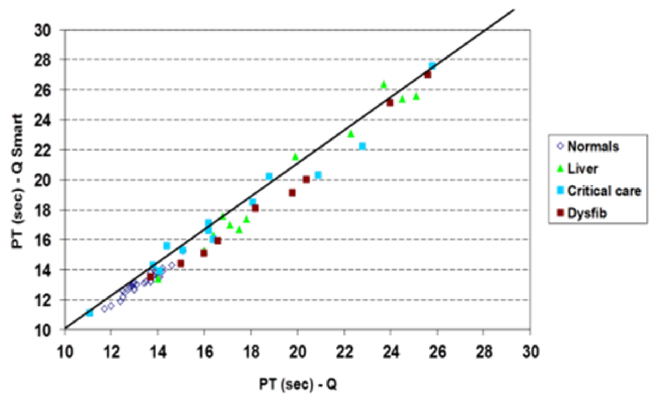
Q Smart and Q - mean of all results

Test	Reagent	n	Q	Q Smart	r	
PT	DG-PT	72	15.9 s	15.9 s	0.98	ns
APTT	DG-APTT Synth	89	29.9 s	29.7s	0.99	ns
TT	DG-TT L Human	72	21.4 s	21.7 s	0.99	P<0.01
Fbg	DG-Fib L Human	56	350 mg/dL	378 mg/dL	0.99	P<0.0001

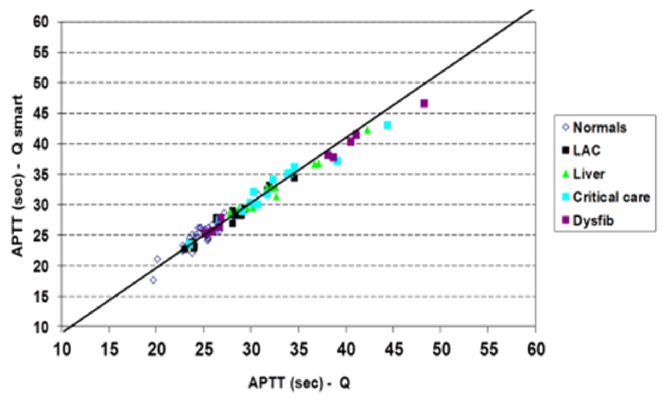
Q Smart and Q - Patient Group means

Patient Group	PT (sec)		APTT (sec)		Fbg (mg/dL)		TT (sec)	
	Q	QS	Q	QS	Q	QS	Q	QS
Normals	13.3	13.2	25.0	25.2	329	351	18.8	19.2
Liver Dis	19.3	19.6	32.7	32.8	318	351	23.4	23.7
Critical	17.2	17.6	32.3	32.7	516	559	21.6	22.3
LAC	-	-	27.4	27.5	-	-	18.9	19.9
Dysfbg	18.8	18.7	34.6	34.4	146	147	35.0	33.0

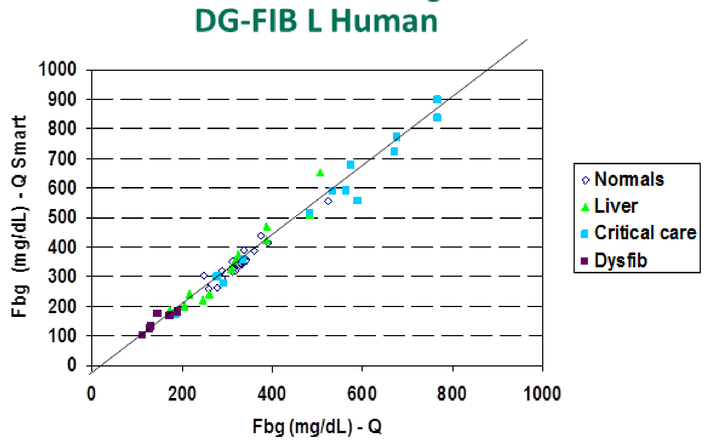
Q and Q smart - PTs with DG-PT



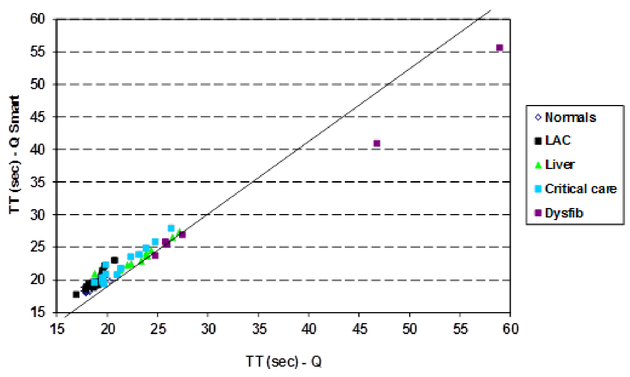
Q and Q smart - APTTs with DG-APTT Synth



Q and Q smart – Fibrinogen with DG-FIB L Human



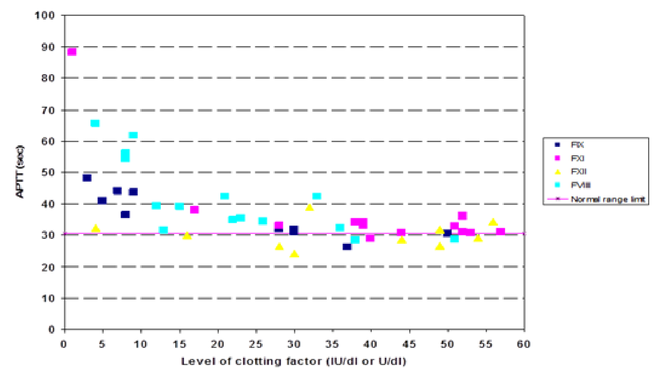
Q and Q smart – Thrombin Times with DG-TT L Human



Prolonged APTTs in presence of factor deficiency on Q Smart

Factor	Lower limit normal range	Range in test samples	Normal APTTs	
			n	Level
FVIII	52 IU/dl	4-51 IU/dl	2/15	38, 51
FIX	69 IU/dl	3- 50 IU/dl	2/10	37, 50
FXI	67 IU/dl	1-57 IU/dl	1/14	40
FXII	64 U/dl	4-56 U/dl	6/10	16,28,30 44,49,54

APTTs with Q Smart/DG-APTT Synth in deficient subjects



Summary

- APTTs on the Q Smart were prolonged in presence of FVIII, FIX or FXI deficiency in 34/39 samples.
- APTTs on the Q Smart were normal in presence of FXII deficiency in 6/10 samples.
- Q Smart and Q Hemostasis Analyzer were comparable for normal ranges for all routine coagulation tests.
- The Q Smart coagulometer is a reliable and simple to use analyser with software that allows operator to switch easily to use the Q Hemostasis Analyzer.

Conclusion

The Q Smart with DG-APTT Synth was suitable for initial investigation of possible bleeding disorders since all subjects with FVIII, FIX or FXI below 30 IU/dL had prolonged APTTs.

The high percentage of normal APTTs in the presence of mild FXII deficiency is an advantage since it avoids unnecessary further investigation which might have been performed if the APTT were prolonged.

The Q Smart analyser with Grifols Diagnostic reagents is suitable for routine use in a mid to low volume laboratory and is totally interchangeable for routine coagulation tests with the Q Hemostasis Analyzer which is suitable for a mid to higher volume laboratory.

Acknowledgments

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