



Introducing ...

A new source of Quality Certified Blood Coagulation Products

The affordable alternative in Hemostasis

Manufacturing Site: 94 Wentworth Road, Windsor, Nova Scotia, CANADA, B0N 2T0

Registrations: US FDA - cGMP Inspected and Registered facility.
ISO 13485 certified quality system for Medical Devices manufacturing.
Health Canada certified Medical Devices Establishment.
US FDA 510K registered products.

Product Listing: **QuikCoag™ PT with Calcium** – A high-sensitivity reagent for Prothrombin Time testing. Optimized for sensitive monitoring of coumadinized patients and the screening of extrinsic factor deficiencies. Typical ISI rating of 1.0 – 1.3.

QuikCoag™ APTT – A liquid stable ellagic acid-activated reagent for Partial Thromboplastin Time testing. Optimized for sensitive monitoring of heparinized patients and the screening of intrinsic factor deficiencies.

QuikCoag™ Fibrinogen – Standardized thrombin reagent, controls and imidazole buffer for accurate determination of fibrinogen deficiencies.

QuikCoag™ Control Level 1 – Normal Coagulation Plasma Control.

QuikCoag™ Control Level 2 – Low Abnormal Coagulation Plasma.

QuikCoag™ Control Level 3 – High Abnormal Coagulation Plasma.

Distribution Offerings:

- 1. QuikCoag™ Label:** Complete kits under BioMedica's FDA-registered **QuikCoag™** labeling, ready for immediate distribution in selected new markets.
- 2. OEM / Private Label:** Complete kits manufactured and labeled under the client's selected label, for exclusive global distribution. Assistance for labeling, art-work and EU registration is available.
- 3. Bulk Packed Product:** Bulk unlabeled product, in economical 500 vial units for private labeling on site. Assistance for set-up of labeling infrastructure is available.

*Realize up to 75% in residual margins
Competitive pricing designed for small- to medium-sized markets*



Contact Us:

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www.biomedicadiagnostics.com



QuikCoag™

Coagulation Reagents & Controls

ORDERING INFORMATION:

PT with Calcium (ISI: 1.0 - 1.3)

Cat. No. HEM-10100	10 vials x 2mL (box)
Cat. No. HEM-10101	10 vials x 4mL (box)
Cat. No. HEM-10111	10 vials x 10mL (box)
Cat. No. HEM-10100-BLK	500 vials x 2mL (unlabeled)
Cat. No. HEM-10101-BLK	500 vials x 4mL (unlabeled)
Cat. No. HEM-10111-BLK	500 vials x 4mL (unlabeled)

APTT Reagent (Ellagic Acid)

Cat. No. HEM-10201	10 vials x 4mL (box)
Cat. No. HEM-10211	10 vials x 10mL (box)
Cat. No. HEM-10201-BLK	500 vials x 2mL (unlabeled)
Cat. No. HEM-10211-BLK	500 vials x 10mL (unlabeled)
Cat. No. HEM-10200-4LTR	4 Litres (bulk)

Calcium Chloride 0.02M

Cat. No. HEM-10401	10 vials x 4mL (box)
Cat. No. HEM-10411	10 vials x 10mL (box)
Cat. No. HEM-10401-BLK	500 vials x 4mL (unlabeled)
Cat. No. HEM-10411-BLK	500 vials x 10mL (unlabeled)

Control Plasma 1 (Normal Coagulation Time)

Cat. No. HEM-20101	10 vials x 1mL (box)
Cat. No. HEM-20101-BLK	500 vials x 1mL (unlabeled)

Control Plasma 2 (Low Abnormal Coagulation Time)

Cat. No. HEM-20101	10 vials x 1mL (box)
Cat. No. HEM-20201-BLK	500 vials x 1mL (unlabeled)

Control Plasma 3 (High Abnormal Coagulation Time)

Cat. No. HEM-20301	10 vials x 1mL (box)
Cat. No. HEM-20301-BLK	500 vials x 1mL (unlabeled)

Fibrinogen

Cat. No. HEM-30300	1 Kit (box)
Cat. No. HEM-30300-BLK	500 vials x 2mL (unlabeled)

Fibrinogen Normal Control

Cat. No. HEM-30301	10 vials x 1mL (box)
Cat. No. HEM-30300-BLK	500 vials x 1mL (unlabeled)

Fibrinogen Low Control

Cat. No. HEM-30302	10 vials x 1mL (box)
Cat. No. HEM-30300-BLK	500 vials x 1mL (unlabeled)



ORDERS & GENERAL INQUIRIES

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Website: www.biomedicadiagnostics.com



ISO 13485:2003
FM 72266



QuikCoag™

Blood Coagulation Reagents

Product Performance Characteristics:

PT with Calcium – High-Sensitivity Prothrombin Time (PT-HS) Reagent
APTT – Activated Partial Thromboplastin Time Reagent
Human Coagulation Control Plasmas, Levels 1, 2 and 3

Laboratory Technical Note:

The validation data provided in this dossier are for the purpose of general assessment on the performance of **QuikCoag™** coagulation reagents.

All values are specific to laboratory testing conditions at the manufacturing site and should be used for guideline purposes only.

Values derived using coagulation testing reagents may vary according to instruments, techniques, lot number, shipping conditions, water quality and ancillary materials used at each testing site.

Each laboratory must conduct specific evaluations to establish reference values appropriate for local testing conditions. Establishment of local normal working ranges and ISI calibration is recommended.

Recommended evaluation protocols can be obtained via e-mail at:
info@biomedicadiagnostics.com



A Technical Comparison of **QuikCoag™** PT-HS Reagent Versus Two Highly Sensitive Reagents

Testing Conditions	
Instrument (Auto-optical):	MLA™ Electra 900C Coagulometer
High Sensitivity Test PT:	BioMedica QuikCoag™ PT-HS (Test PT-HS)
High Sensitivity Reference PT-1:	Hemoliance IL PT-Fibrinogen HS-PLUS (Ref. PT-HS-1)
High Sensitivity Reference PT-2:	Teco Teclot PT-S (Ref. PT-HS-2)

Reference Comparative Data			
Prothrombin Time (in seconds)			
	Test PT-HS	Ref. PT-HS-1	Ref. PT-HS-2
Plasma Control Level 1 (Normal)	13.7	14.4	13.1
Plasma Control Level 2 (Low Abnormal)	34.3	27.6	32.1
Plasma Control Level 3 (High Abnormal)	52.6	49.4	50.0
Determined Mean Normal PT (_d MNP)	13.3	15.3	13.1
MNP Calculated by the Manchester Method (_c MNP)	13.5	N/A	N/A
ISI value	1.02	1.18	1.23

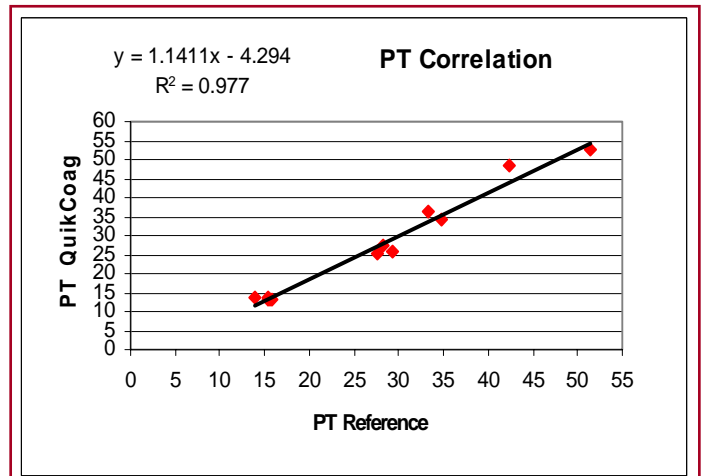
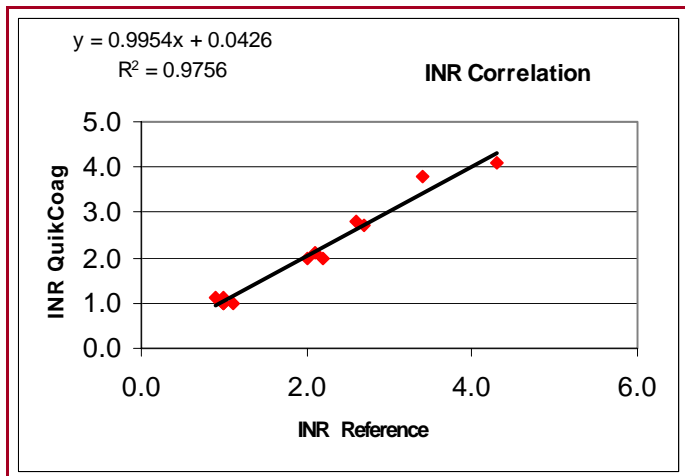
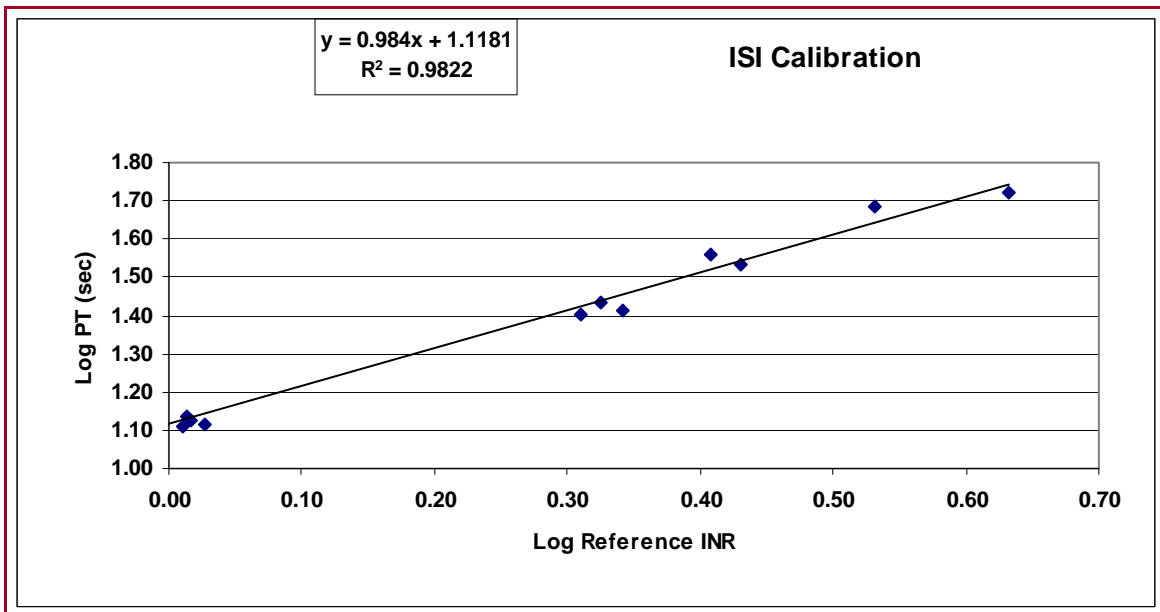
Factor Sensitivity Comparative Testing												
Prothrombin Time (in seconds)												
% Factor	Factor II			Factor V			Factor VII			Factor X		
	Test PT-HS	Ref. PT-HS-1	Ref. PT-HS-2	Test PT-HS	Ref. PT-HS-1	Ref. PT-HS-2	Test PT-HS	Ref. PT-HS-1	Ref. PT-HS-2	Test PT-HS	Ref. PT-HS-1	Ref. PT-HS-2
100%	13.1	15.7	13.0	13.1	15.7	13.0	13.1	15.7	13.0	13.1	15.7	13.0
60%	13.3	15.8	13.9	13.8	16.5	14.3	13.8	16.2	14.0	13.4	15.8	13.8
30%	14.2	16.4	14.6	15.1	17.9	16.5	15.4	17.8	15.0	14.7	17.2	16.0
10%	16.5	19.1	18.1	18.4	19.5	20.7	19.2	19.4	18.9	18.9	23.4	21.2

Precision Studies	
QuikCoag™ PT-HS / within-run precision	CV=0.27%
QuikCoag™ PT-HS / vial-to-vial precision	CV=0.51%
QuikCoag™ PT-HS / day-to-day precision	CV=2.50%
QuikCoag™ PT-HS / lot-to-lot precision	CV=3.43%

Storage Stability	
8 days at 2-8 °C (reconstituted)	<1.5% change
48 hours at 24 °C (reconstituted)	<1.8% change
32 hours at 37 °C (reconstituted)	<1.0% change
Lyophilized shelf life at 2-8°C	2 Years

QuikCoag™ PT-HS / ISI Verification and INR Correlation Data

Reference PT ISI value :				1.18	Test PT :		BioMedica QuikCoag™ PT-HS
Reference Normal Reading :				15.0	Reference PT :		Hemoliance IL PT-Fib HS Plus
Plasma	Average Test PT	Log Test PT	Ref. PT	Log Ref. INR	Ref. PT INR	Test PT INR	
1	13.7	1.136721	13.9	-0.039030	0.9	1.1	
2	34.2	1.534026	34.7	0.429801	2.7	2.7	
3	52.6	1.720986	51.5	0.632145	4.3	4.1	
4	13.3	1.123852	15.5	0.016804	1.0	1.0	
5	12.9	1.110590	15.3	0.010148	1.0	1.0	
6	13.7	1.136721	15.4	0.013487	1.0	1.1	
7	13.1	1.117271	15.8	0.026628	1.1	1.0	
8	25.9	1.413300	29.2	0.341364	2.2	2.0	
9	25.3	1.403121	27.5	0.310625	2.0	2.0	
10	36.4	1.561101	33.3	0.408697	2.6	2.8	
11	27.2	1.434569	28.3	0.325320	2.1	2.1	
12	48.4	1.684845	42.3	0.531294	3.4	3.8	
Correlation:		0.991		ISI Test PT:		1.02	
Slope:		0.984		MNP Test PT:		13.1	
Intercept:		1.118					



BioMedica QuikCoag™ APTT Reagent
Typical Performance Characteristics versus a Commercial APTT Reagent

Reference Comparative Data		
	QuikCoag™ APTT	Fisher Diagnostics
Plasma Control Level 1	28.4 sec	28.6 sec
Plasma Control Level 2	46.1 sec	46.0 sec
Plasma Control Level 3	55.2 sec	58.3 sec
Normal Range	19.1 – 33.9 sec	22.0 – 34.4 sec

Heparin Sensitivity Comparative Data		
Heparin Concentration	QuikCoag™ APTT	Fisher Diagnostics
Plasma without Heparin	24.1 sec	24.9 sec
Plasma with 0.10 U/mL Heparin	31.8 sec	31.1 sec
Plasma with 0.20 U/mL Heparin	42.3 sec	39.8 sec
Plasma with 0.30 U/mL Heparin	57.4 sec	51.1 sec
Plasma with 0.40 U/mL Heparin	73.8 sec	63.0 sec
Plasma with 0.50 U/mL Heparin	106.4 sec	92.3 sec

Factor Sensitivity Comparative Data								
% Factor	Factor VIII		Factor IX		Factor XI		Factor XII	
	QuikCoag APTT	Fisher Diagnostics	QuikCoag APTT	Fisher Diagnostics	QuikCoag APTT	Fisher Diagnostics	QuikCoag APTT	Fisher Diagnostics
100%	25.4 sec	24.9 sec	25.7 sec	25.2 sec	25.8 sec	24.5 sec	25.9 sec	25.0 sec
40%	29.6 sec	29.0 sec	30.7 sec	27.4 sec	32.0 sec	31.7 sec	33.2 sec	27.9 sec
20%	35.0 sec	32.8 sec	32.9 sec	30.7 sec	36.5 sec	37.9 sec	38.7 sec	30.9 sec
10%	41.4 sec	37.0 sec	36.7 sec	33.8 sec	42.4 sec	43.4 sec	45.7 sec	36.7 sec

Sensitivity to Lipemic Samples				
Triglyceride Level (mg/dL)	QuikCoag™ APTT		Fisher Diagnostics APTT-LS	
	Clotting Time (Average ± %CV)	% of Control	Clotting Time (Average ± %CV)	% of Control
0 (control)	23.2 ± 1.2	---	25.0 ± 2.3	---
1,500	25.0 ± 3.1	107.8 %	26.0 ± 4.1	104.0
2,400	25.6 ± 2.2	110.3 %	26.2 ± 3.9	104.8
3,000	26.5 ± 4.8	114.2 %	26.8 ± 5.0	107.2

Sensitivity to Hemolytic Samples:				
Hemoglobin Level (mg/dL)	QuikCoag™ APTT		Fisher APTT (Reference)	
	Clotting Time (Average ± %CV, n=4)	% of Control	Clotting Time (Average ± %CV, n=4)	% of Control
0 (control)	23.2 ± 0.93	---	25.2 ± 2.7	---
500	23.6 ± 0.53	101.7 %	23.8 ± 1.9	94.4 %

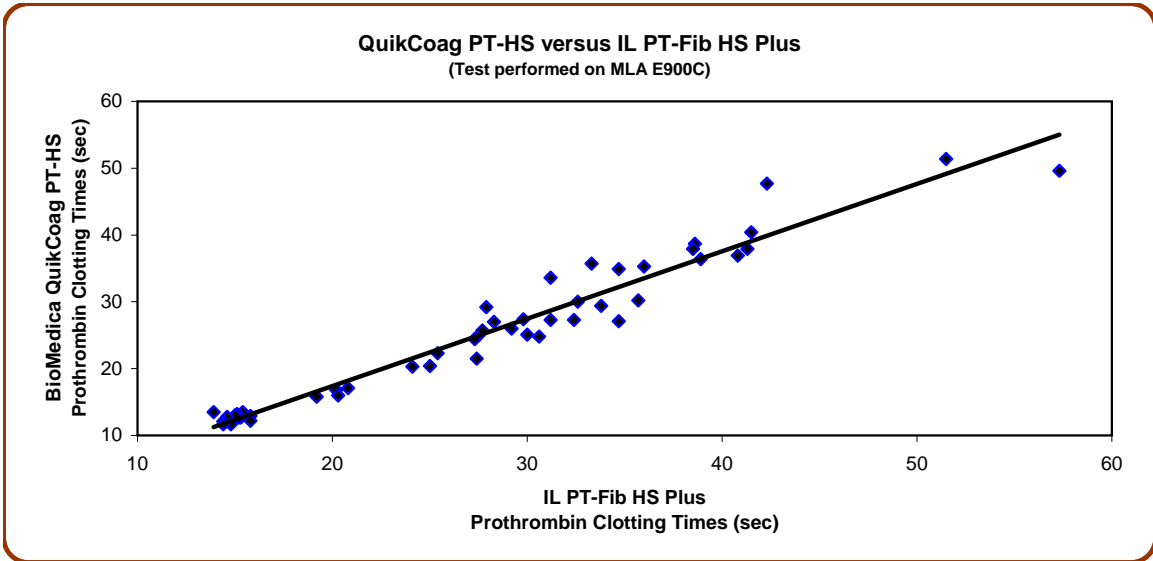
Sensitivity to Icteric Samples				
Bilirubin Level (mg/dL)	QuikCoag™ APTT		Fisher APTT (Reference)	
	Clotting Time (Average ± %CV, n=4)	% of Control	Clotting Time (Average ± %CV, n=4)	% of Control
0 (control)	27.0 ± 1.1	---	26.5 ± 2.2	---
20	26.3 ± 1.8	97.4 %	26.8 ± 2.2	101.1 %

Precision Studies	
QuikCoag™ APTT / within-run precision	CV=3.2%
QuikCoag™ APTT / vial-to-vial precision	CV=2.9%
QuikCoag™ APTT / day-to-day precision	CV=3.6%
QuikCoag™ APTT / lot-to-lot precision	CV=2.2%

Storage Stability	
45 days at 2-8 °C (opened vial)	<1.5% change
6 weeks at 24 °C (opened vial)	<3.0% change
6 weeks at 37 °C (opened vial)	<4.0% change
Sealed vial shelf life at 2-8°C	2 years

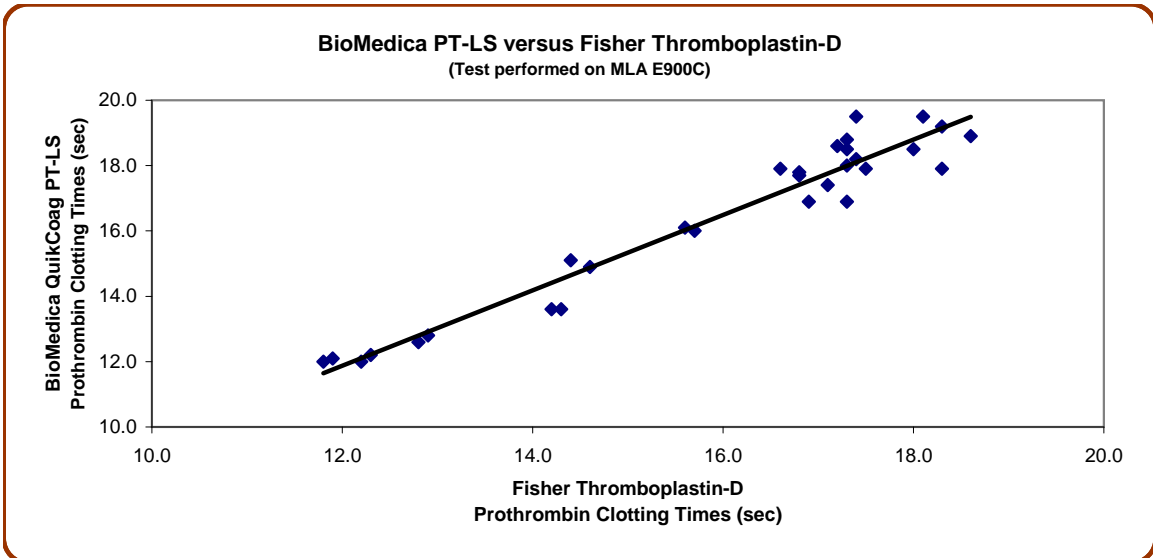
QuikCoag PT-HS Correlation Study on Patient Plasmas

Correlation	Slope	Intercept
0.97567	1.00839	-2.77304



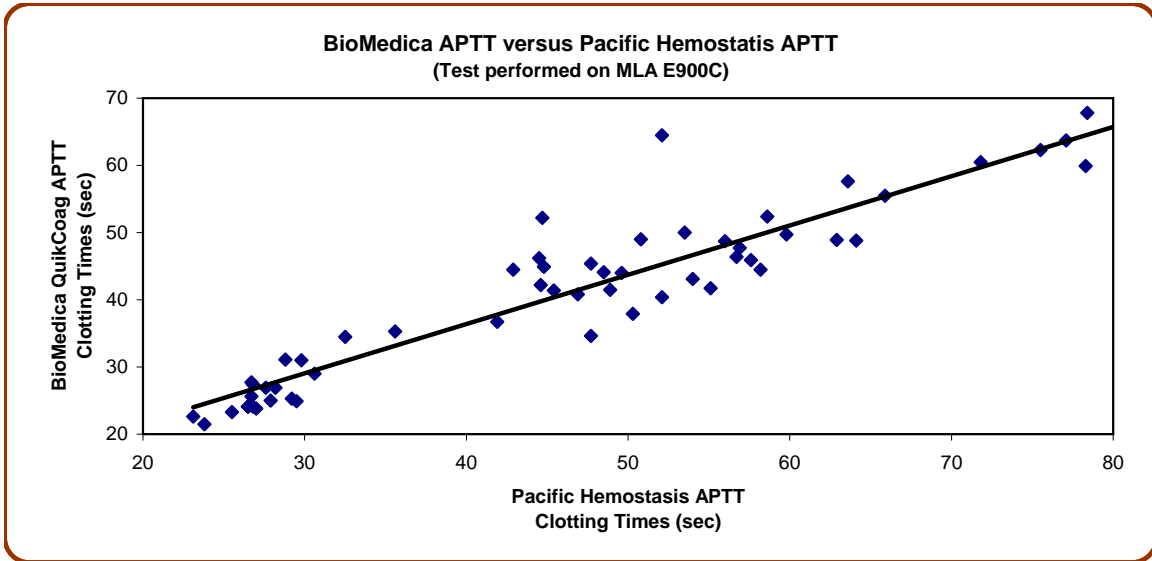
QuikCoag PT-LS Correlation Study on Patient Plasmas

Correlation	Slope	Intercept
0.97274	1.15401	-1.97495



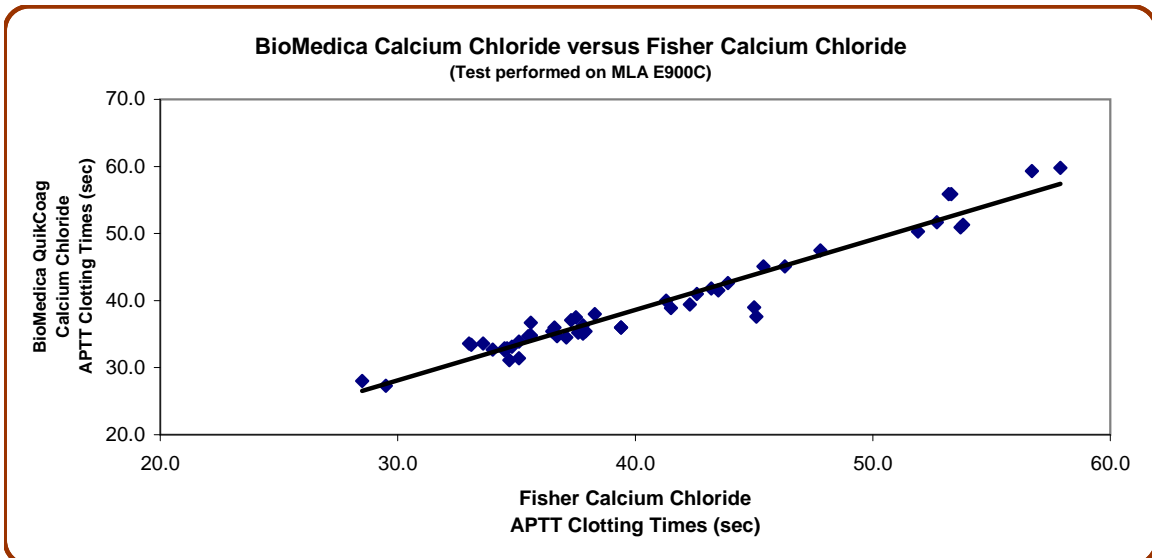
QuikCoag APTT Correlation Study on Patient Plasmas

Correlation	Slope	Intercept
0.94183	0.73290	7.06912



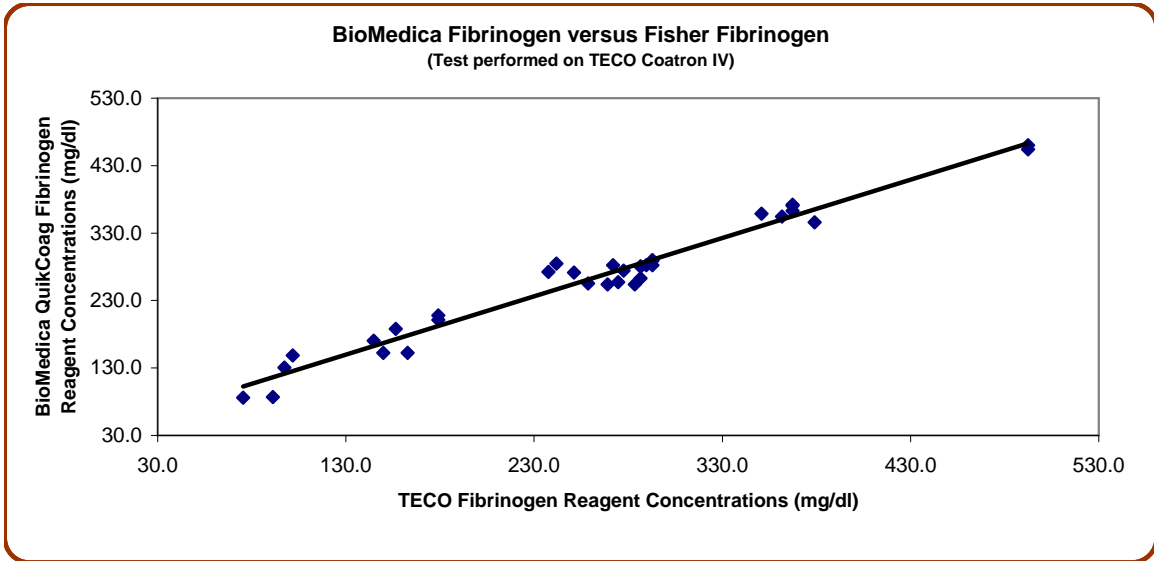
QuikCoag Calcium Chloride Correlation Study on Patient Plasmas

Correlation	Slope	Intercept
0.97199	1.05017	-3.41537



QuikCoag Fibrinogen Correlation Study on Patient Plasmas

Correlation	Slope	Intercept
0.98172	0.86254	38.03304





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info@biomedicadiagnostics.com
www.biomedicadiagnostics.com

**Manufacturer's Declaration of Conformity and essential device particulars
per USFDA, USDA, Canada CMDCAS and European (98/79/EC) IVD Directives:**

Establishment Name: BioMedica Diagnostics Inc.

Manufacturing Site: 94 Wentworth Road
PO Box 1030
Windsor, Nova Scotia
B0N 2T0 – CANADA.

Phone: (902) 798-5105
Fax: (902) 798-1025
E-mail: info@biomedicadiagnostics.com

Government Registrations: US FDA Establishment Registration Number: **3003691680**
Health Canada, Medical Devices Establishment License: **1730**

Quality System Registration Record:

Sep. 2000	KPMG Registration to: ISO 9002:1994
Sep. 2001	KPMG Registration to: ISO 9001:1994
Dec. 2002	BSI Registration to: ISO 13485:1996/cmdcas
Aug. 2003	BSI Registration to: ISO 13485:1996/cmdcas confirmation
Dec. 2003	USFDA external audit to certify compliance to (QS/GMP)
Dec. 2004	BSI Registration to: ISO 13485:1996/cmdcas confirmation
Dec. 2005	BSI Registration to: ISO 13485:2003/cmdcas registration
Oct. 2006	BSI Registration to: ISO 13485:2003/cmdcas confirmation

Quality Scope: Design, manufacture, and distribution of clinical chemistry analyzers, Hematology instruments, Laboratory equipment and reagents.

Device Names:

1. PT-HS with calcium. Also trade named as: QuikCoag and Vital PT.
Common name: Prothrombin Time Test
Classification name: Prothrombin Time Test, 21 CFR Section 864.7750 (GJS)
2. APTT (Ellagic Acid) Also trade named as: QuikCoag & Vital APTT
Common name: Activated Partial Thromboplastin Time (APTT)
Classification name: Class II Activated Partial Thromboplastin, 21 CFR 864.7925 (GFO)
3. Plasma Controls Level 1, 2 and 3. Also trade named as: QuikCoag & Vital Plasma Controls.
Common name: Coagulation Control Plasmas.
Classification name: Class II - Coagulation Controls Plasma, 21 CFR 864.5425, (GGN)

US FDA 510K Registration Numbers:

QuikCoag PT-HS with calcium KO20840
QuikCoag APTT and Calcium Chloride KO22021
QuikCoag Plasma Controls KO22046

HTS Classification code: 3800.00.5090 – Duty free.

Tariff Classification Blanket Control #: CLA-2-38:RR:NC:2:238 R01498

International Licences:

Conformity under IVD Directive 98/79/EC (IVDD) - Annex III
The Drugs Controller of India, Import Licence under the Drugs Act: NCD-43/06

USDA Health and Safety Declarations:

The following critical components of animal origin are used in the formulation of these products:

- 1. Bovine Serum Albumin: Imported from USA.
- 2. Normal Human Plasma: Imported from USA
- 3. Rabbit Brain Powder: Imported from USA
- 4. Other Chemical Additives Imported from USA

- All critical components are purchased from qualified FDA inspected facilities
- Components are derived from disease free species not exposed to any livestock or poultry disease agents exotic to the United States.
- Components do not originate from facilities where work with exotic disease agents affecting livestock and avian species is conducted.
- Human plasma has been tested with FDA approved methods and declared to be free of viruses causing HIV, Hepatitis A, B, and C.
- Potential biohazard warnings are indicated for users on device labelling and inserts.

Declaration of Conformity:

BioMedica Diagnostics Inc. Declares that the products listed above are manufactured and distributed in conformity with the essential requirements of USFDA medical devices regulations, European IVD Directives (98/79/EC, EN ISO 9001, IS EN 46001, ISO 13485, ISO 14971, IS EN 375, ISO 11014-1, and IS EN 45014), and under a Health Canada Certified ISO 13485 CMDCAS Quality Management System for Medical Devices Establishments.

BioMedica's manufacturing facility is cGMP certified under HFC-130 FDA Inspection program and has been declared in full compliance under 7382.845(b) and the OSIT quality inspection program.

Place: BioMedica Diagnostics Inc. Windsor, Nova Scotia, Canada.
Date: 31st October 2006
Name: Dr. A. Kirumira
Position: C.E.O.

Signature:

