Samsung Smart Blood Analyzer

IMMUNOASSAY ANALYZER

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CT-LABGEO IB10 4.5-151125-EN

Thermo Fisher Scientific is the global collaboration partner of Samsung for commercialization and co-development of innovative solutions in the POC testing market. Together we provide excellent expertise in clinical diagnostics to fulfill customer needs and improve patient management.



HEMATOLOGY ANALYZER







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SAMSUNG

SAVE TIME, FAST DIAGNOSIS. SMART SOLUTION PROVIDER

Samsung LABGEO IB10

High Performance Portable Immunoassay Analyzer



The Samsung LABGEO ^{IB10} is a portable, reliable and easy-to-use immunoassay analyzer for in-vitro determinations and provides medical professionals with rapid and accurate test results in emergency care settings where near patient testing is critical.



Fast Easy Accurate





FAST

Fast & Fully Automated

راسة Rapid test results in 20 minutes Fully automated centrifugation inside the analyzer

Whole Blood Use

Ą٥ No sample pretreatment required for plasma separation

Multiple Analytes Tested in a Single Run

周 No additional time required to test multiple analytes Up to three analytes tested in a single run - One run, Three test results in 20 minutes

Accurate | 04 – – Samsung LABGEO



% Excellent Precision and Correlation

Excellent assay performance assists medical professionals in the diagnosis and treatment of critically ill patients

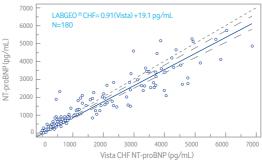
		Troponin I	CK-MB	Myoglobin	NT-proBNP	D-Dimer	beta-hCG	TSH	РСТ
Measuring Range		0.05 - 30 ng/mL	2 - 60 ng/mL	30 - 500 ng/mL	30 - 5000 pg/mL	100 - 4000 ng/mL (FEU)	4 - 400 mIU/mL	0.11~ 120 mIU/L	0.08 - 10 μg/L
Upper Ref (URL)	ference Limit	0.10 ng/mL (99 %ile)	8.58 ng/mL	99.84 ng/mL	< 75yrs = 125 pg/mL ≥ 75yrs = 450 pg/mL	446.8 ng/mL (FEU)	5.42 mlU/mL	0.25~3.85 mIU/L (euthyroid reference interval)	0.11 µg/L
Precision	Within-run CV	9.4 - 12.6%	9 - 11.2%	10.8 - 12.7%	8.5 - 10.2%	6.7 - 8.6%	12.4 - 13.4%	5.8 - 11.2%	11.2 - 14.3%
	Total CV				9 - 10.9%				11.9 - 14.6%

A Method Comparisons Show High Correlation with Central Laboratory Systems

Correlation coefficients above 0.90 and method comparison slopes near unity compared to central laboratory systems

Figure 1. Method Comparison – LABGEO ^{IB} NT-proBNP and Ortho VISTA[®] NT-proBNP

LABGEO IB CHF(plasma) vs Ortho Vista CHF(plasm



The Samsung LABGEO IB10 Analyzer produced rapid and accurate measurement of both Troponin I and NT-proBNP in whole blood and plasma and showed high correlation with the central laboratory system, the Siemens Dimension Vista™ platform

Table 3. Method Comparison - LABGEO ^{IB} Tnl and Siemens	
Dimension Vista™ cTnl*	

Comparison	N	Intercept (ng/mL)	Slope	Spearman rank correlation
LABGEO ^{IB} WB vs. VISTA plasma	36	-0.070	0.868	0.911
LABGEO ^{IB} plasma vs. VISTA plasma	36	-0.084	0.787	0.915
LABGEO ^{IB} WB vs. LABGEO ^{IB} plasma	36	0.006	0.993	0.964

* A study was performed by Dr. Steven Kazmierczak at Oregon Health and Science Universit OHSU (Portland, Oregon) AACC 2013 poster Kazmierczak, S. (suppl.) pg S2-S310 - B221

EASY

Simple & Easy-to-Use

Simple, LCD touch screen interface with clear, step-by-step instructions Multiple language support

Convenient & User Friendly

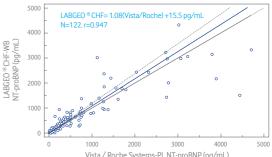
 \bigwedge^{\dagger} One step convenient testing method Test Discs stable at room temperature for 30-days Built-in thermal printer Multiple external devices available

Portable

Easy to move (Compact size, Lightweight) Optional battery operation Accurate testing when and where it's needed * It is recommended that each laboratory should establish a reference range that represents the patient population that is to be evaluated

Figure 2. Method Comparison – LABGEO ^{IB} CHF NT-proBNP and Ortho VISTA[®]/Roche NT-proBNP





Vista / Roche Systems-PL NT-proBNP (pg/mL)

Table 4. Method Comparison - LABGEO^{IB} NT-proBNP and Siemens Dimension Vista™ NT-proBNP*

Comparison	N	Intercept (pg/mL)	Slope	Spearman rank correlation
LABGEO ^{IB} WB vs. VISTA plasma	47	-6.6	1.028	0.938
LABGEO ^{IB} plasma vs. VISTA plasma	47	19.1	0.881	0.926
LABGEO ^{IB} WB vs. LABGEO ^{IB} plasma	47	-9.5	1.062	0.978

AVAILABLE TEST MENU

Product Name		Model #
Samsung LABGEO ^{IB} Troponin I Test	Troponin I	IVR-IB05
Samsung LABGEO ^{IB} CHF Test	NT-proBNP	IVR-IB06
Samsung LABGEO ^{IB} CHF Plus Test	Troponin I / NT-proBNP	IVR-IB07
Samsung LABGEO ^{IB} Cardiac 3-in-1 Panel Test	Troponin I / CK-MB / Myoglobin	IVR-IB08
Samsung LABGEO ^{IB} D-Dimer Test	D-Dimer	IVR-IB09
Samsung LABGEO ^{IB} SOB Cardiac 3 Panel Test	Troponin I / NT-proBNP / D-Dimer	IVR-IB11
Samsung LABGEO ^{IB} beta-hCG Test	beta-hCG	IVR-IB12
Samsung LABGEO ^{IB} TSH Test	Thyroid-stimulating hormone (TSH)	IVR-IB15
Samsung IB B·R·A·H·M·S PCT	Procalcitonin (PCT)	IVR-IB18

INTENDED USE OF TEST MENU

Troponin I Test Troponin I	The Samsung LABGEO ^{IB} Troponin I Test is for the quantitative determination of Troponin I (cTnl) in lithium heparin human whole blood and plasma. cTnl determinations aid in the diagnosis of myocardial infarction (MI) and patients with non-ST-segment elevation (NSTEMI) acute coronary syndromes (ACS).
CHF Test NT-proBNP	The Samsung LABGEO ^{IB} CHF Test is for the quantitative determination of N-terminal pro- brain natriuretic peptide (NT-proBNP) in EDTA and lithium heparin human whole blood and plasma. NT-proBNP determinations aid in the diagnosis and management of Congestive Heart Failure (CHF).
CHF Plus Test Troponin I / NT-proBNP	The Samsung LABGEO ^{IB} CHF Plus Test is for the quantitative determination of Troponin I (cTnI) and N-terminal pro-brain natriuretic peptide (NT-proBNP) in lithium heparin human whole blood and plasma.
Cardiac 3-in-1 Panel Test Troponin I / CK-MB / Myoglobin	Samsung LABGEO ^{IB} Cardiac 3-in-1 Panel Test is for the quantitative determination of Tro- ponin I (cTnI), Creatine Kinase isoform MB (CK-MB), Myoglobin in lithium heparin human whole blood and plasma.
D-Dimer Test D-Dimer	The Samsung LABGEO ^{IB} D-Dimer Test is for the quantitative determination of D-Dimer in lithium heparin and citrated human whole blood and plasma. D-Dimer determinations aid in the quantitative assessment and evaluation of patients presenting with clinical symptoms of Venous Thromboembolism (VTE) including severely evolving disseminated intravascular coagulation (DIC), pulmonary embolism (PE) and deep vein thrombosis (DVT).
SOB Cardiac 3 Panel Test Troponin I / NT-proBNP / D-Dimer	The Samsung LABGEO ^{IB} SOB Cardiac 3 Panel Test is for the quantitative determination of Troponin I (cTnI), NT-proBNP and D-Dimer in lithium heparin human whole blood and plasma. The SOB (Shortness of Breath) test panel is intended as an aid in the differential diagnosis and prognostic assessment of patients with symptoms of chest pain, typically accompanied by respiratory distress.
<mark>beta-hCG Test</mark> beta-hCG	The Samsung LABGEO ^{IB} beta-hCG Test is for the quantitative determination of human chori- onic gonadotropin in lithium heparin human blood and plasma.
TSH Test Thyroid-stimulating hormone (TSH)	The Samsung LABGEO ^{IB} TSH Test is for the quantitative determination of Thyorid-stimulating hormone in lithium heparin human whole blood and plasma.
<mark>B·R·A·H·M·S PCT</mark> Procalcitonin (PCT)	The Samsung IB B·R·A·H·M·S PCT is for the quantitative determination of Procalcitonin in EDTA whole blood or plasma to aid in the early detection and differential diagnosis of clinically relevant bacterial infections to assess the degree of severity and to prognosticate the outcome of systemic bacterial infection, sepsis, severe sepsis, and septic shock. Also, this test aids in the monitoring of antibiotic treatment within the measuring range and in the assessment of successful antibiotic treatment within the measuring range.

*Please refer to the insert of each test menu for the complete intended use statement.

SIMPLE ONE STEP PROCEDURE



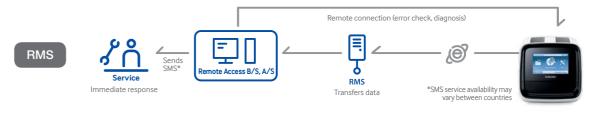
KEY FEATURES

Analyzer (Size / Weight)	177(W) x 330(D) x 177(H) mm /
Sample Volume	500µl Whole Blood or Plasma
Display	4.3-inch TFT LCD
Memory	5,000 reports for regular tests
Printer	Built-in Thermal Printer
Options	Battery, EQC Disc
Proactive Service	RMS (Remote Management Syste
IT Solution	Samsung LABGEO Data Manager

SMART HEALTHCARE

Proactive Customer Service

RMS (Remote Management System) provides real-time service through equipment status checks and immediate response to errors from a service team



IT Solution

Connects to HIS (Hospital Information System), PC, and Mobile phone / device for efficient database management



Automatically update software, store, show, print and backup the results.



Support Multiple Devices

Multiple external devices available (WIFI USB Dongle, USB, Barcode Scanner, and LAN Connectivity)



′ 2.4 kg

tem) er, Samsung IVD Mobile Application



Transfers test results to build a database



Deliver test results via text message using Smartphone

Mobile Application

Notify analysis completion, error and critical result occurrence, browse patient result, and LABGEO ¹⁸¹⁰ information.

HIS (LIS/EMR System) Support HIS standard protocol (HL7, ASTM, POCT1-A): HIS sends an order to LABGEO ^{(B10} and the device backs up the results to HIS

