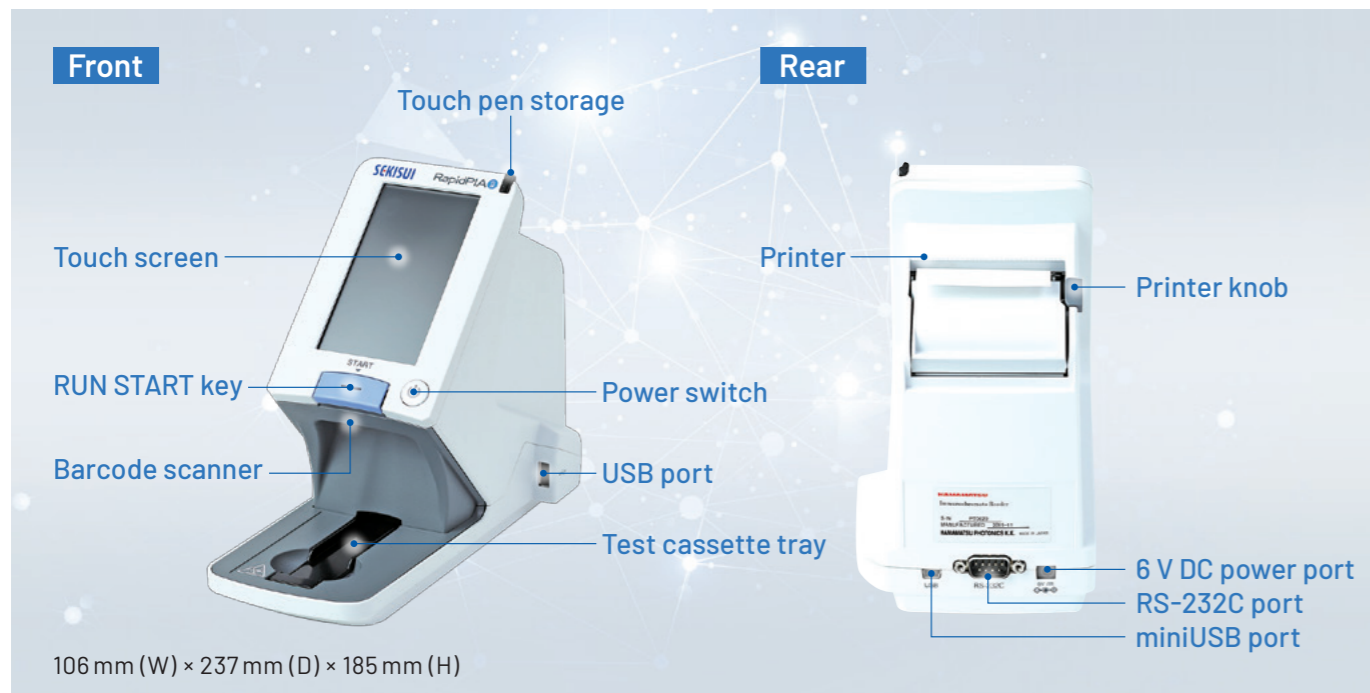


Rapidpia II(*) Analyzer Overview

RapidPIA II

SEKISUI



Japanese Registration Information
Generic name: Protein Analyzer Marketing notification number: 13B2X00163303001

Specifications	
Item	Description
External dimensions	106 mm (W) × 237 mm (D) × 185 mm (H)
Weight	Main unit
	AC adapter
Power supply input	Main unit
	AC adapter
Current consumption	Main unit
	AC adapter
Output current	AC adapter
External interfaces	miniUSB cable: miniUSB 2.0 RS-232C cable USB memory: USB 2.0/3.0
Screen display	4.3-inch color TFT LCD Touch Screen
Operating temperature range	15°C to 30°C
Operating relative humidity	70% or less (without condensation)
Storage / transport temperature range	-10°C to 45°C
Storage / transport relative humidity	70% or less (without condensation)
Installation category	II
Pollution level	2
Operation guarantee altitude	2,000 m or less
Location of use	Indoor
Compatible standard	Safety standards
	Electromagnetic interference

Specifications	
Item	Description
Data storage capacity	Patient data
	QC sample data
	QC device data
	Self-check result
	Measuring item
	Reagent lot data
Operator ID	10

Included Accessories	Quantity
AC adapter (length: approximately. 330 cm)	1
Touch pen	1
Printer paper	2
Instruction manual	1
Package insert	1
Quick guide	1
Warranty Certificate	1

Optional Accessories (Sold Separately)	
Product name	Quantity/Remarks
QC device for Rapidpia series	1 (with dedicated case)
miniUSB cable for Rapidpia II	1 (length: approximately. 150 cm)
RS-232C cable for Rapidpia series	1 (length: approximately. 150 cm)
Mobile battery connection cable for Rapidpia II	1 (length: approximately. 30 cm)
Printer paper for Rapidpia II	10 rolls/box

Features

- ### 1 Direct Analysis of Untreated Whole Blood or Plasma

The type of blood collection tube that must be used varies with the test. For fFN detection, cervicovaginal secretions must be used.
- ### 2 Reaction Time of Approximately. 10-15 minutes

Approximately. 10 minutes Approximately. 15 minutes

D-dimer	H-FABP	PCT	fFN
cTnI	BNP		
- ### 3 Monotest System Means No Reagent Loss

Each device contains exactly enough reagent for one test.
- ### 4 Color Touch Screen

Operating instructions are displayed on the screen
- ### 5 Built-in Barcode Scanner
- ### 6 Battery-Powered Option

In addition to operation with the AC adapter power supply, the analyzer can be powered using batteries. A mobile battery connection cable is available as an optional accessory.

For more information contact:
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Hamamatsu Photonics K.K.

SEKISUI MEDICAL CO., LTD.

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Preparation

1 Analyzer Quality Control

Simply place the QC device (sold separately) in the analyzer and confirm the result is within the required range. Please replace it once it has expired.

2 Test Device Lot Registration

Register the lot data by having the CAL code (included in the test cassette kit) read by the built-in barcode scanner. Once registered, the test cassette lot information is saved even after the analyzer is turned off.

3 Select and Save a Variety of Patient & Sample Data

- Patient ID
- Measurement item
- Specimen type

Analysis



Place the test cassette in the analyzer. After selection of "RUN MODE" ("ROUTINE" or "DILUTE") and "SPECIMEN TYPE" ("BLOOD" [=whole blood] or "PLASMA"), add 120 μ L of the sample.

Press the blue RUN START key.

The analyzer displays the remaining time.

Results are displayed automatically once they are ready.

Press the "PRINT" to print the result from the built-in printer. Press the "SEND" to send the test result to the USB memory stick or the PC to which the miniUSB cable or RS-232C cable is connected.

Brain Natriuretic Peptide Kit **Rapidchip BNP**

For in vitro diagnostic use only

Japanese Certification No.: 221ADAMX00004000 Product code: 465345

Sample type	Whole blood (EDTA-2Na, EDTA-2K) or plasma (EDTA-2K, EDTA-2Na) 120 μ L
Reaction time	Approximately. 15 minutes
Measurement range	10 to 800 pg/mL If the analyzer displays "> 800 pg/mL", dilute the sample with BNP dilution buffer for remeasurement.
Reference range	\leq 18.4 pg/mL ¹⁾
Package contents	20 test cassettes (Includes a CAL code for Rapidpia II and a CAL card for Rapidpia)
Storage and shelf life	2°C to 10°C, 12 months from the date of manufacture

Sold separately (Not for in vitro diagnostic use in Japan)

Product name	Package contents	Storage and shelf life
Rapidchip BNP Dilution Buffer	1 mL \times 10	2°C to 10°C, 12 months from the date of manufacture
Rapidchip BNP Control	1 vial \times 2 concentration for 0.5 mL	

1) Yasue H., Yoshimura M. et al.: Clinical Endocrinology, 40, 397, 1993

Troponin Kit **Rapidchip cTnI**

For in vitro diagnostic use only

Japanese Certification No.: 231ADEZX00008000 Product code: 536861

Sample type	Whole blood (EDTA-2Na, EDTA-2K, heparin Li, and heparin Na) or plasma (EDTA-2Na, EDTA-2K, heparin Li, and heparin Na) 120 μ L
Reaction time	Approximately. 15 minutes
Measurement range	30.0 to 1,500 pg/mL
Reference range	The cTnI concentration in the plasma of 109 healthy subjects was measured, and the 99th percentile value was 36.1 pg/mL. Since the reference range may vary, it is recommended to set the reference range at your own institution. ⁵⁾⁶⁾⁷⁾
Package contents	20 test cassettes (Includes a CAL code for Rapidpia II and a CAL card for Rapidpia)
Storage and shelf life	2°C to 10°C, 12 months from the date of manufacture

Sold separately (Not for in vitro diagnostic use in Japan)

Product name	Package contents	Storage and shelf life
Rapidchip cTnI Control	1 vial \times 2 concentration for 0.5 mL	2°C to 8°C, 12 months from the date of manufacture

5) Dongchon Kang: Nihon Naika Gakkai Zasshi 102, 3088-2095, 2013
6) Yader Sandoval, Fred S. Apple: Clinical Chemistry 60, 3, 2014
7) SEKISUI MEDICAL In-house Data

Fibrin Degradation Product Kit **Rapidchip D-dimer**

For in vitro diagnostic use only

Japanese Certification No.: 225ADAMX00125000 Product code: 499579

Sample type	Whole blood (sodium citrate, heparin Li, and heparin Na) or plasma (sodium citrate, heparin Li, and heparin Na) 120 μ L
Reaction time	Approximately. 10 minutes
Measurement range	0.2 to 15 μ g/mL If the analyzer displays "> 15 μ g/mL", dilute the sample with saline for remeasurement (Citratated whole blood only)
Reference range	\leq 1.0 μ g/mL (DDU) ²⁾
Package contents	20 test cassettes (Includes a CAL code for Rapidpia II and a CAL card for Rapidpia)
Storage and shelf life	2°C to 10°C, 12 months from the date of manufacture

Sold separately (Not for in vitro diagnostic use in Japan)

Product name	Package contents	Storage and shelf life
Rapidchip D-dimer Control	1 vial \times 2 concentration for 0.5 mL	2°C to 10°C, 12 months from the date of manufacture

2) Wakui M. et al.: Laboratory Test Guide 2020, p561, 2020

Heart-type Fatty Acid-binding Protein Kit **Rapidchip H-FABP**

For in vitro diagnostic use only

Japanese Certification No.: 226ADAMX00211000 Product code: 507410

Sample type	Whole blood (EDTA-2Na, EDTA-2K, heparin Li, and heparin Na) or plasma (EDTA-2Na, EDTA-2K, heparin Li, and heparin Na) 120 μ L
Reaction time	Approximately. 10 minutes
Measurement range	2.0 to 160 ng/mL
Reference range	\leq 6.2 ng/mL ⁸⁾⁹⁾
Package contents	20 test cassettes (Includes a CAL code for Rapidpia II and a CAL card for Rapidpia)
Storage and shelf life	2°C to 10°C, 12 months from the date of manufacture

Sold separately (Not for in vitro diagnostic use in Japan)

Product name	Package contents	Storage and shelf life
Rapidchip H-FABP Control	1 vial \times 2 concentration for 0.5 mL	2°C to 10°C, 12 months from the date of manufacture

8) Tanaka T. et al.: Japanese Journal of Medicine and Pharmaceutical Science, 37, 1367, 1997
9) Kurabayashi M. et al.: Laboratory Test Guide 2020, p.461, 2020

Procalcitonin Kit **Rapidchip PCT**

For in vitro diagnostic use only

Japanese Marketing Approval No.: 22900EZXX00003000 Product code: 522840

Sample type	Whole blood (EDTA-2Na, EDTA-2K, heparin Li, and heparin Na) or plasma (EDTA-2Na, EDTA-2K, heparin Li, and heparin Na) 120 μ L
Reaction time	Approximately. 10 minutes
Measurement range	0.2 to 10 μ g/mL
Reference range	Cut-off value for the differential diagnosis of bacterial sepsis: 0.5 μ g/mL Cut-off value for the evaluation of the severity of bacterial sepsis: 2.0 μ g/mL ³⁾⁴⁾
Package contents	20 test cassettes (Includes a CAL code for Rapidpia II and a CAL card for Rapidpia)
Storage and shelf life	2°C to 10°C, 12 months from the date of manufacture

Sold separately (Not for in vitro diagnostic use in Japan)

Product name	Package contents	Storage and shelf life
Rapidchip PCT Control	1 vial \times 2 concentration for 0.5 mL	2°C to 10°C, 12 months from the date of manufacture

3) American College of Chest Physicians/Society of Critical Care Medicine Consensus Conference: Definitions for sepsis and organ failure and guidelines for the use of innovative therapies in sepsis: Crit. Care Med, 20, 864, 1992

4) The Sepsis Registry Committee of JSICM: Chapter III. Diagnosis and Treatment of Infection, The Japanese Guidelines for the Management of Sepsis, The Journal of JSICM 20, 124, 2013

Fibronectin Kit **Rapidchip fFN**

Package Contents: Test cassettes \times 20

(Included accessories: CAL code for Rapidpia II \times 1 and CAL card for Rapidpia \times 1)

Storage and shelf life: 2°C to 10°C, 12 months from the date of manufacture

For in vitro diagnostic use only

Japanese Certification No.: 228ADEZX00006000 Product code: 513077

Sample type	Cervicovaginal secretions (For sample collection, please use the dedicated swabs included with the Rapidchip fFN Extraction Buffer (i). A sample of 120 μ L prepared according to the package insert is used for detection.)
Reaction time	Approximately. 10 minutes
Criteria	When the concentration of fetal fibronectin is less than 50.0 ng/mL, the test is negative. When the concentration is 50.0 ng/mL or more, the test is positive. ¹⁰⁾

Rapidchip fFN Extraction Buffer (i)

Package: 24 test cassettes

Storage and shelf life: 2°C to 30°C, 12 months from the date of manufacture

Sold separately (Not for in vitro diagnostic use in Japan)

Product name	Package contents	Storage and shelf life
Rapidchip fFN Control	1 vial \times 2 concentration \times 1.0 mL	2°C to 10°C, 24 months from the date of manufacture

10) Kanayama N.: Obstetrics and Gynecology, 8, 1173-1177, 1995